NHS England

Serious Incident Framework

Supporting learning to prevent recurrence

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

Part One: Definitions and Thresholds

1. What is a Serious Incident?

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

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm[7] to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

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

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

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

[7] Serious harm:

- Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);
- Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or
- Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death[8] of one or more people. This includes
        - suicide/self-inflicted death; and
        - homicide by a person in receipt of mental health care within the recent past[9] (see Appendix 1);
    - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
    - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:—
        - the death of the service user; or
        - serious harm;
    - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
        - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring[10]; or
        - where abuse occurred during the provision of NHS-funded care.

      This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident (see Part One; sections 1.3 and 1.5 for further information).
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information;[11]
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

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

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

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

[11] Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at:
http://www.england.nhs.uk/ourwork/patientsafety/never-events/

- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 2 for further information);
- Property damage;
- Security breach/concern;[12]
- Incidents in population-wide healthcare activities like screening[13] and immunisation programmes where the potential for harm may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services[14]); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)[15]

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation[16].

1.1. Assessing whether an incident is a serious incident

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

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

Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care)

[12] This will include absence without authorised leave for patients who present a significant risk to themselves or the public.
[13] Updated guidance will be issued in 2015. Until that point the Interim Guidance for Managing Screening Incidents (2013) should be followed.
[14] It is recognised that in some cases ward closure may be the safest/ most responsible action to take but in order to identify problems in service/care delivery , contributing factors and fundamental issues which need to be resolved an investigation must be undertaken
[15] For further information relating to emergency preparedness, resilience and response, visit: http://www.england.nhs.uk/ourwork/eprr/
[16] As an outcome loss in confidence/ prolonged media coverage is hard to predict. Often serious incidents of this nature will be identified and reported retrospectively and this does not automatically signify a failure to report.

serious incident, it is better to err on the side of caution and treat the incident as a serious incident until evidence is available to demonstrate otherwise. Serious incident reports can be downgraded and relevant records amended at any stage in the investigation[37]. Any downgrading must be agreed with the relevant commissioner on a case by case basis. Incidents that are found to not meet the threshold of a serious incident must be managed in line with the organisation's risk management and patient safety policies if appropriate.

3. Reporting a Serious Incident

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

- Incidents which activate the NHS Trust or Commissioner Major Incident Plan:
- Incidents which will be of significant public concern:
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies:

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

Reporting a serious incident must be done by recording the incident on the NHS serious incident management system, STEIS,[38]or its successor system. The serious incident report must not contain any patient or staff names and the description should be clear and concise.

Other regulatory, statutory, advisory and professional bodies should be informed about serious incidents depending on the nature and circumstances of the incident. Serious incident reports must clearly state that relevant bodies have been informed. See Appendix 2 for a list of other organisations that must be considered. In some circumstances, where a serious incident or multiple serious incidents raise profound concerns about the quality of care being provided, organisations should consider calling a Risk Summit, which provides a mechanism for key stakeholders in the health economy to come together to collectively share and review information.[39]Most serious incidents will not warrant this level of response however.

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

[37] This may depend on local procedures and capacity to ensure de-logging of incidents is performed in a timely manner.

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

[39] Guidance available online at http://www.england.nhs.uk/ourwork/part-rel/nqb/