NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

70 YEARS OF THE NHS 1948 - 2018

[SERIOUS INCIDENTS REQUIRING INVESTIGATION POLICY

Shaping better health

Please complete the table below: *To be added by corporate team once policy approved and before placing on website*	
Policy ref no:	13
Responsible Executive Director:	Anne Morris, Director of Nursing and Quality
Author and Job Title:	Heidi Buck, Quality and Patient Safety Support Manager
Date Approved:	June/2018
Approved by:	*Governing Body*
Date of next review:	December/2019

	Yes/No/NA	**Supporting information**
Has an Equality Impact Assessment Screening been completed?	Yes	EIA Screening document
Has the review taken account of latest Guidance/Legislation?	Yes	National Serious Incident Framework, NHSE 2015 Never Events, NHSI 2015
Has legal advice been sought?	No	National Framework
Has HR been consulted?	No	National Framework
Have training issues been addressed?	Yes	
Are there other HR related issues that need to be considered?	No	National Framework
Has the policy been reviewed by JCC?	No	National Framework
Are there financial issues and have they been addressed?	No	National Framework
What engagement has there been with patients/members of the public in preparing this policy?	NA	National Framework
Are there linked policies and procedures?	No	Safeguarding Children Policy and Safeguarding Adults Policy Information Governance Policy
Has the lead Executive Director approved the policy?	Yes	
Which Committees have assured the policy?	Yes	Quality Committee Corporate Policy Group
Has an implementation plan been provided?	Yes	
How will the policy be shared with: • Staff? • Patients?	Yes	National Framework

• Public?		
Will an audit trail demonstrating receipt of policy by staff be required; how will this be done?	No	National Framework already in place. Due for revision this year. On revision audit trail will be required.

Contents

SERIOUS INCIDENTS REQUIRING INVESTIGATION POLICY

1. Introduction

1.1 In March 2015 NHSE published a revised Serious Incident Framework along with a Never Events Policy and Framework for commissioners and providers providing NHS funded care. This document supersedes all previous guidance published by NHS England and the National Patient Safety Agency (NPSA).

1.2 In March 2016 NHSE published the Serious Incident Framework – frequently asked questions which provide additional guidance to support implementation of the Serious Incident Framework (March 2015).

1.3 In January 2018 NHS Improvement (NHSI) published new guidance on the management of Never Events which now supersedes the published document in March 2015 by NHSE.

1.4 The organisation where the incident occurred has overall responsibility for the investigation, the immediate dissemination of learning and implementation of subsequent action plans.

1.5 BNSSG CCG Quality Team is responsible for monitoring the management of Serious Incidents reported within the boundaries of the BNSSG CCG areas including University Hospital Bristol (UHB), Weston Area Health NHS Trust (WAHT), North Bristol Trust (NBT), Avon and Wiltshire Mental Health Partnership Trust (AWP), Bristol Community Health (BCH), North Somerset Community Partnership (NSCP), Sirona Community Health Provider, and all providers commissioned to deliver NHS funded care. Where a Serious Incident relates to a patient who is undergoing treatment that is commissioned by the NHS Southwest Specialist Commissioning Group (SCG), the CCG must contact the SCG to notify them of the incident.

2. Purpose and scope

The purpose of this policy is to provide guidance to the BNSSG CCG on the required elements of reporting Serious Incidents Requiring Investigation (Serious Incident). It highlights the processes that should be followed on receipt of notification from NHS Commissioned service providers that a Serious Incident has taken place.

3. Executive Summary

3.1 This policy provides a detailed description of procedures and processes that should be followed by BNSSG CCG on the reporting and management of Serious Incidents.

3.2 The process will support the provision of a uniform approach to the reporting and management of Serious Incident reported whilst fulfilling the requirements of the NHS England (NHSE) Serious Incident Framework published in March 2015 and the NHS Improvement (NHSI) new Never Events Policy and Framework published in January 2018.

4. Responsibilities

Within BNSSG CCG:

4.1 The **Chief Executive Officer** has responsibility for ensuring that the CCG has the necessary processes and procedures in place to support the effective management of implementation of all risk management and governance policies and delegates the responsibility for the management of Serious Incidents to the BNSSG CCG Director of Nursing and Quality.

4.3 The **Director of Nursing and Quality** has executive responsibility for ensuring the necessary management systems are in place for the effective implementation of Serious Incident reporting for commissioned services and for ensuring that areas identified as high risk are transferred to the BNSSG CCG Risk Register or the Board Assurance Framework as necessary.

4.4 **BNSSG CCG commissioning leads** are responsible for ensuring that there are specific references to Serious Incident reporting in all contracts and the expectations of reporting.

4.4 **NHS England** is responsible for assuring itself that CCGs have effective systems for Serious Incident management and for supporting CCGs to hold their providers to account appropriately. They can also provide oversight including review of trends, quality analysis and early warning systems via Quality Surveillance Groups (QSGs). Where an incident is high profile or wide-ranging – for example, incidents which have extensive media interest, NHS England may take a lead in coordinating a response to the incident.

4.5 **NHS Improvement** is working in collaboration with NHSE and will going forward oversee and monitor the Serious Incident process. New guidance is expected in late 2018.

5. Serious Incident reporting and monitoring

5.1 Reporting Serious Incident Requiring Investigations

The following paragraphs are taken from the NHS England National Serious Incident Framework published in March 2015, which must be adopted by Providers.

5.1.1 In broad terms, Serious Incident Requiring Investigation 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.

5.1.2 The occurrence of a Serious Incident Requiring Investigation demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious Incident Requiring Investigation 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 Incident Requiring Investigation can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

5.1.3 There is no definitive list of events/incidents that constitute a Serious Incident Requiring Investigation 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. 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 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.
- 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; 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

5.1.5 All Serious Incident Requiring Investigations, must be reported in 2 working days of the Provider being aware of the incident onto the Strategic Executive Information System (STEIS) and then produce a preliminary report within three working days of identification to BNSSG CCG that includes the following:

- STEIS identification number
- The principal facts/description of the incident (including date, description, location, background and consequences)
- Initials, gender and date of birth of the client, where appropriate;
- Level of investigation to be undertaken and whether it is a Never Event;
- Details of the initial investigations undertaken including the scope, methodology and the individuals involved (including relatives/carers);
- Immediate action taken
- Initial recommendations; and proposals for the full investigation (including scope, methodology and details of the review team with clear timeline and accountability)
- Duty of Candour has been initially undertaken.

5.1.6 All Investigation reports for level 1 and 2 investigations must be completed within 60 working days of the Serious Incident Requiring Investigation being reported. The Provider must submit an approved Root Cause Analysis (RCA) and action plan to BNSSG CCG for commissioner review. Level 3 Independent Investigation time line is 6 months from reporting the Serious Incident Requiring Investigation onto the STEIS system.

Levels of Investigations for Serious Incident Requiring Investigations are as follows:

Level 1
Concise internal investigation
Suited to less complex incidents which can be managed by individuals or a small group at a local level

Level 2
Comprehensive internal investigation
Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved

Level 1 & 2 Timeline - Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner

All internal investigation should be supported by a clear investigation management plan

Level 3
Independent investigation

Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved

Level 3 Timeline - 6 months from the date the investigation is commissioned

5.1.7 Some Serious Incident Requiring Investigations are classed as Never Events and should be reported in the same way as a Serious Incident Requiring Investigation. Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare Providers. The aim of the Department of Health is to drive the incidence of Never Events to zero. A new Never Events policy has been published by NHS Improvement in January 2018 that should be read in conjunction with the Serious Incident policy guidance published by NHS England in May 2015.

5.1.8 A key component of the Never Events framework is its inclusion in the NHS Standard Contract, which ensures that never events are discussed as part of the contract negotiation process. This also ensures that each provider is contractually required to respond to Never Events in a nationally consistent manner, as set out in the relevant guidance.

5.1.9 The framework also states that failure to learn the lessons of a single Never Event or a prevented Never Event could be perceived as organisational failure on grounds of patient safety for which Board leaders, particularly the Chief Executive and Medical and Nurse Directors are accountable.

5.1.10 Some Serious Incident Requiring Investigations relate to vulnerable adults and children. Alignment of processes is required to ensure that patient's safety is maximised and the leaning that is gained can be disseminated across the wider arena (refer to the CCG Safeguarding Children Policy and Safeguarding Adults Policy).
If abuse or neglect is suspected, an incident form must be completed and discussed with the line manager and reported as an alert to the relevant safeguarding team.

There are four key questions to help determine whether the incident is abuse or neglect.

- Are there concerns that all reasonable steps have NOT been taken to prevent the incident?
  Care given should be assessed against available local and national guidelines. A second opinion should be sought if necessary – advice available from relevant Specialist.
- Is the person a Vulnerable Adult?
  i.e. is aged over 18 and is or may be in need of community care or support services by reason of mental or other disabilities, age or illness and who is unable or may be unable to take care of him / herself or unable to protect him / herself against significant harm or exploitation.

- Is the person a vulnerable child or young person at risk of harm?
  i.e. is aged under 18 who may be at risk of significant harm from parents, carers or others with a duty of care towards the child
- Is there evidence of neglect?
  Neglect is the deliberate withholding OR unintentional failure to provide appropriate and adequate care and support such as; Lack of Appropriate equipment, Manual handling, Risk Assessment (e.g. Nutritional Assessments and falls assessments), Development of care plans following risk assessments, , Staff awareness of related development and care. Consider the person's capacity and concordance to planned treatment.

5.1.11 BNSSG CCG has a clear structure in place for giving advice and support to Provider staff through their Named Professional / Designated Nurses for Safeguarding Children and Adults. The Named Professional / Designated Nurses meet frequently to confirm that all are aware that progress is being made on on-going incidents.

5.1.12 All Information Governance (IG) SERIOUS INCIDENTs are to be handled in accordance with the guidance developed by the Department of Health "Checklist for reporting Managing and Investigating information Governance Serious Untoward Incidents". This guidance includes details on assessing the severity of the incident and reporting requirements via the Information Governance (IG) Toolkit.

5.1.13 All members of BNSSG CCG staff should report any IG incidents to the Information Governance Manager, who would then:

- Inform the Senior Risk Information Officer (SIRO) and Caldicott Guardian as appropriate
- Record the initial facts on the IG Toolkit reporting Tool
- Record any investigation and follow up on the IG Toolkit reporting Tool
- Reporting upwards and onwards using the data recorded on the Tool on the IG Toolkit reporting Tool.

5.1.14 All organisations have a responsibility to ensure that members of staff are treated fairly and with consistency.

5.1.15 Where the incident involves more than one organisation the investigation will involve representatives from those other agencies e.g. the ambulance service, primary or acute care with agreement, via the BNSSG CCG Director of Nursing and Quality, as to who will be the lead agency.

5.1.16 BNSSG CCG will report Serious Incidents Requiring Investigations on behalf of the Providers who do not have access to STEIS. This may include independent hospitals and health services commissioned by the Public Health Team in the Local Authority. In these situations BNSSG CCG will have to fulfil the responsibilities outlined within this policy for Providers. The responsibility for the investigation still lies within the organisation where the incident occurred. The Public Health Team will liaise with Public Health England as

required. NHSE and NHSI will monitor Serious Incidents Requiring Investigations relating to the business of BNSSG CCG.

5.2 Actions for BNSSG CCG

5.2.1 BNSSG CCG will need to undertake different levels of oversight depending on a range of local circumstances, including their confidence in the relevant Provider's ability. Closer monitoring involving more step-by-step information and assurance around the response to individual incidents may be required for smaller providers with lower capacity, for example, or those with a history of responding insufficiently or in a non-robust manner to Serious Incidents.

5.2.2 BNSSG CCG will only lead an investigation by exception or where the Serious Incidents sre deemed to be extremely complex. The decision as to whether BNSSG CCG will lead an investigation will only be taken by the BNSSG CCG Director of Nursing and Quality.

5.2.3 BNSSG CCG will maintain the Serious Incidents monitoring and Action Plan Monitoring Databases to provide the Director of Nursing and Quality with all available information when required as well as regular progress reporting to ensure deadlines are met.

5.2.4 Once a satisfactory final, executive signed off, Root Cause Analysis (RCA) report and time-bound action plan has been received it will be put forward for the next scheduled CCG Serious Incidents Review Panel to ensure it meets the requirement to be reviewed within 20 calendar days by the CCG (and following the completion of all relevant entries on STEIS by the Provider), the incident will be closed on STEIS following agreement at the CCG Review Panel. It is the responsibility of the Provider to provide assurance of completion of the action to BNSSG CCG Quality Leads on a monthly basis with any exceptions reported by the Provider to the relevant Quality Sub Group Meetings (QSG) with the potential to escalate to the Integrated Contract, Quality and Performance Management Group Meeting (ICQPMG).

5.2.5 Feedback from the Serious Incidents Panel will be communicated back to the Provider to ensure that sufficient assurance has been gained by the Provider in relation to the investigation, that there is clear identification of lessons learnt including recommendations and actions to be taken along with specific timelines for this to take place. A request to the Provider will be made if further assurance is required along with a timeline for the assurance to be provided. Once assurance has been received it will be returned to the CCG panel process until closure is agreed.

5.2.6 BNSSG CCG will provide regular reports to the appropriate CCG Quality Committee on a quarterly basis and as requested on the management of Serious Incidents. These will:

- Clearly communicate performance against targets at key stages within the process
- Identify where there are recurring delays/problems in the process

- Analyse the age of overdue Serious Incidents in order that long overdue cases may be identified and progress closely monitored.
- Use Serious Incidents trend analysis to identify areas requiring a more focused review by the CCG
- Include details of any actions taken, follow-ups and/or discussions that have taken place with Providers where the data suggests areas of concern or non-compliance.

5.2.7 The CCG will also monitor reports for compliance with the principles of Being Open and the contractual Duty of Candour and highlight breaches to be discussed at Quality Sub Group Monitoring Meetings.

6. Communicating with Patients, Carers and Families

6.1 The Government has reinforced the principles of Being Open by the requirement of a contractual 'Duty of Candour' which came into place on 1 April 2013. This is now included in all NHS contracts. A follow up to this was new guidance for all NHS bodies being published in November 2014 by the Care Quality Commission known as regulation 20 detailing out clear expectations for all providers that should be adhered to and information included in the RCA reports.

7. Equality Impact Assessment

7.1 This policy is an amalgamation of the Serious Incident policies that were in place across Bristol, North Somerset and South Gloucestershire CCG's and is based on the requirements of the National Serious Incidents that require Investigation 2015. An Equality Impact Assessment was undertaken for the merged policy.

7.2 An initial Equality Impact Screening Assessment has been undertaken on the revised policy which has identified that a full assessment is not required at this stage.

8. Dissemination of Learning

8.1 The NHS has a responsibility to ensure that when Serious Incidents or incident occurs, there are systematic measures in place for safeguarding people, property, NHS resources and reputation, for understanding why the event occurred and ultimately to ensure steps are taken to reduce the chance of a similar incident happening again.

8.2 Provider organisations will have systems in place to ensure that learning is disseminated within their organisation as detailed in the Action Plans attached to the RCA reports. Assurance is to be provided to the Commissioner of completed implementation of actions.

8.3 The CCG will ensure that it has processes in place to share learning more widely within the local area. These processes will include dissemination of learning via: - Reporting of themes

and trends and issues requiring prompt action, arising from analysis, through the CCG governance structure. The Public Health Team within the Local Authority will be responsible for dissemination as appropriate via their networks.

8.4 For Safeguarding Children dissemination of learning from Serious Incidents takes place through the local Safeguarding Children Board. Identified learning is disseminated as soon as it is recognised and the CCG publishes details of learning from Serious Incidents within their annual quality reporting arrangements. Quarterly reports on learning from Serious Incidents to ensure that trends are identified are also published.

9. Monitoring compliance and effectiveness

The policy will be evaluated on annual basis by BNSSG CCG. Occasionally more frequent evaluation may be required in response national direction or local identification of issues. A review of the national framework is underway and it is expected that a revised framework will be issued from NHS Improvement by the end of 2018.

10. Resources

NHS England Serious Incident Framework 2015. Available at :
http://www.england.nhs.uk/?s=serious+incident+policy

NHS England Serious Incident Framework – frequently asked questions (March 2016).
https://www.england.nhs.uk/patientsafety/serious-incident/.

NHS Improvement Never Events Policy and Framework January 2018.
https://improvement.nhs.uk/resources/never-events-policy-and-framework

Care Quality Commission (2010): Essential Standards of Quality and Safety. Available at:
www.cqc.org.uk

Care Quality Commission Regulation 20: Duty of Candour Nov 2014 Available at:
www.cqc.org.uk

National Patient Safety Agency (2004):. Seven Steps to Patient Safety. Available at:
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59787&q=0%c2%acseven+steps+to+patient+safety%c2%ac

National Patient Safety Agency (2009): Being Open: Communicating Patient Safety Incidents With Patients, Their Families and Carers. Available at: http://www.nrls.npsa.nhs.uk/resources

National Patient Safety Agency (2008): Three Levels of RCA Investigation - Guidance. Available at: www.npsa.nhs.uk/rca

National Patient Safety Agency (2008): Good Practice Guidance 'Independent Investigation of Serious Patient Safety Incidents in Mental Health Services'. Available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59836

NHS Connecting for Health (2010): Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents. Available at http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/links/suichecklist.pdf

NHS Commissioning Board's Framework for Collaborative Commissioning, Model agreement and FAQs. Available at http://www.commissioningboard.nhs.uk/resources/resources-for-ccgs/