NHS
West Norfolk
Clinical Commissioning Group

WEST NORFOLK CLINICAL COMMISSIONING GROUP

Serious Incidents (SIs) & Never Events (NEs) Requiring Investigation Policy

Document Control Sheet

Name of Document:	Serious Incidents (SIs) & Never Events (NEs) Requiring Investigation Policy
Version:	V2.1
Date Of This Version:	July 2018
Produced By:	Head of Quality (Reviewed by Quality Assurance Nurse Manager)
What is it for? *(Intro)*	This policy establishes a clear procedure to be adhered to following a SI/NE for any services commissioned by WNCCG or for WNCCG's own staff raising a SI/NE. The policy adheres to the national policy therefore ensuring a consistent approach and clarifying the responsibilities of WNCCG.
Who is it aimed at and which settings? *(Scope)*	This policy applies to NHS Trusts, Foundation Trusts, CCG providers, independent health care provider organisations, Independent practitioners (including general practitioners), community pharmacists, community optometrists, general dental practitioners, prison healthcare services and integrated services and Care Trusts. This policy is also aimed at any staff member working in NHS West Norfolk Clinical Commissioning Group.
Evidence Base:	This policy is based on: • National Framework for Reporting & Learning from Serious Incidents Requiring Investigation • Serious Incident Framework – Supporting learning to prevent recurrence 2015 • East of England Strategic Health Authority Serious Incident Policy • National Patient Safety Agency guidance • Care Quality Commissions Regulation Requirements
Reviewed by	Patient Safety and Clinical Quality Committee
Equality Impact Assessment *(completed)*	Yes
Consultation *(Staff, Trade Unions, Lay Members)*	N/a
Approved By *(as per scheme of Delegation 38)*	Accountable Officer
Date Approved:	27/07/2018
Signature:	
Dissemination	WNCCG Staff
Date Due For Review:	July 2019

Evaluation	West Norfolk CCG will monitor the implementation and effectiveness of this policy to ensure all SIs are reported, appropriately investigated acted upon and learning is widely shared.

Revision History

Revision Date	Summary of changes	Author(s)	Version Number
May 2016	Reviewed and updated	Deputy Head of Clinical Quality and Patient Safety	2.0
July 2018	Reviewed and agreed to extend by 12 months and then we can use the new SI framework to revise a new policy.	Quality Assurance Nurse Manager	2.1

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1. INTRODUCTION

1.1 Organisations providing NHS-funded care in England are required to demonstrate accountability for effective governance and learning following a serious incident or never events. The NHS has a responsibility to ensure that when a serious incident does happen, there are systematic measures in place for:

- safeguarding people, property, the service's resources and its reputation
- understanding why the event occurred
- ensuring that steps are taken to reduce the chance of a similar incident happening again
- reporting to other bodies where necessary and sharing the learning

1.2 Providers are expected to follow the national "serious incidents requiring investigation policy" published March 2010 by the National Patient Safety Agency, the updated Serious Incident Framework published in 2015 by the NHS Patient Safety Domain and supplemented by the DOH The Never Events Policy Framework 2012. If in doubt, err on the side of caution and report. Serious Incidents can be declared void when more information is known. Advice can be obtained from West Norfolk Clinical Commissioning Group (WNCCG) Head of Clinical Quality and Patient Safety on 01553 666900

1.3 West Norfolk Clinical Commissioning Group is committed to the principles of "being open", that healthcare staff should use when communicating with patients, their families and carers following a patient safety incident in which the patient was harmed. Being Open supports a culture of openness, honesty and transparency, and includes apologising and explaining what happened. There are ten principles: Acknowledgement; Truthfulness, Timeliness and clarity of communication; Apology; Recognising patient and carer expectations; Professional support; Risk management and systems improvement; Multidisciplinary responsibility; Clinical governance; Confidentiality and Continuity of care.

2. DEFINITION

2.1 A serious incident requiring investigation is defined as an incident that occurred in relation to:-

2.2 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
  - Maternal death

- 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 Safeguarding Children 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.

- 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:
  - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues.
  - Property damage.
  - Security breach/concern
  - Incidents in population-wide healthcare activities like screening 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); or
  - Activation of Major Incident Plan (by provider, commissioner or relevant agency)

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

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death.

2.3 One of the core set of 'Never Events' as updated on an annual basis and currently for 2015/16 including:

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-operation
4. Mis-selection maladministration of a strong potassium-containing solution
5. Wrong route administration of medication
6. overdose of insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis-selection of high strength midazolam during conscious sedation
9. Failure to install functional collapsible shower or curtain rails
10. Falls from poorly restricted windows
11. Chest or neck entrapment in bedrails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso- or oro-gastric tubes
14. scalding of patients

2.4 The definition of a serious incident requiring investigation extends beyond those which affect patients directly and includes incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare. Serious incidents are often triggered by events

staff and/or the organisation involved. They may be identified through various routes including, but not limited to, the following:

- Incidents identified during the provision of healthcare by a provider e.g. patient safety incidents or serious /distressing/catastrophic outcomes for those involved.
- Allegations made against or concerns expressed about a provider by a patient or third party.
- Initiation of other investigations for example: Serious Case Review's (SCR), Serious Adult Reviews (SAR), Safeguarding Adult Enquiries (Section 42 Care Act), Domestic Homicide Reviews (DHR) and Death in Custody investigations (led by the Prison Probation Ombudsman) NB: whilst such circumstances may identify serious incidents in the provision of healthcare this is not always the case and SIs should only be declared where the definition above is fulfilled
- Information shared at Quality Surveillance Group meetings
- Complaints
- Whistle Blowing
- Prevention of Future Death Reports issued by the Coroner.
- Child protection issues which are mismanaged or unreported

2.5 If an incident is identified by an organisation that is not involved in the delivery of care in which the incident occurred, then that organisation must take action to ensure that the relevant provider and commissioner are informed to ensure the incident is reported, investigated and learned from to prevent future risk of reoccurrence.

3. REPORTING THE SI

3.1 SIs must be reported on the NHS serious incident management system, STEIS within **2 working days** of the incident being identified. The serious incident report must not contain any patient or staff identifiable information and the description of the incident should be clear and concise. If the SI has very significant implications for the NHS in terms of clinical, managerial or media issues, West Norfolk CCG must be contacted directly by telephone. **(WNCCG 01553 666900)**

3.2 Organisations without the facility to report via the STEIS system must report using the serious incident reporting template detailed in the Serious Incident Framework, 2015. Reports must be sent to **NELCSU.SUI@nhs.net** within **2 working days** of the incident being identified.

3.3 On receipt of the SI, NELCSU will forward the SI report form to the WNCCG Serious Incident mailbox **(WESTNORFOLKCCGSeriousIncidents@nhs.net)** which is managed by the WNCCG Quality Team.

3.4 The WNCCG Head of Clinical Quality notifies the Accountable Officer, Chair of the Governing Body, Chief Operating Officer, Head of Corporate Services and the communication team within NELCSU. In addition, SIs may be notified to appropriate experts within NELCSU and WNCCG, for example, Infection Control lead, Safeguarding leads or the Prescribing team. The SI is entered on to the WNCCG SI database and monitored by the NELCSU Serious Incident Management team. If more than one provider is involved in the SI, WNCCG will take a lead role negotiating between providers and determine who should carry out the investigation.

4. PROCESS FOLLOWING IDENTIFICATION OF THE SI

4.1 Providers will be required to undertake an initial review of the serious incident within 3 working days of the incident being identified. The aim of this review is to:-

- Identify and provide assurance to WNCCG that any immediate actions to ensure the safety of staff, patients and the public are in place.
- Assess the information in more detail which will also help confirm the incident does meet the serious incident criteria and enables the provider to propose the appropriate level of investigation.

4.2 This report will be submitted to WNCCG via the STEIS system.

4.3 **Agreeing the level/type of investigation**
The nature, severity and complexity of serious incidents vary on a case-by-case basis therefore the level of investigation should be proportionate to the circumstances of each specific incident. Following the initial review the provider will propose the appropriate level of investigation. There are 3 recognised levels of systems based investigation (root cause analysis investigation), these are:-

- Level 1 - Concise internal investigation
- Level 2 - Comprehensive internal investigation
- Level 3 - Independent investigation

4.4 Level 1 and Level 2 investigations must be completed and reported to WNCCG within 60 working days of the incident being reported. Level 3 investigations should be reported to the CCG within 6 months from the date the investigation is commissioned.

5. REPORTING REQUIREMENTS

5.1 Serious incident reports and action plans should be submitted to WNCCG within 60 working days of the incident being reported. In certain circumstances WNCCG may agree an alternative timeframe for submission of the final report. This will be recorded within the serious incident management system.

5.2 Lead Commissioner and Registered Clinical Commissioning Group
Where lead commissioning arrangements exist as a shared responsibility around an individual provider, e.g. Queen Elizabeth Hospital King's Lynn or the Norfolk and Norwich University Hospital, NELCSU will share the SI reporting with both the lead commissioning CCG and the CCG with who the patient is registered. It remains the responsibility of the registering CCG to sign off the action plan from the Provider.

6. QUALITY ASSURANCE AND CLOSURE OF THE INVESTIGATION

6.1 Providers will submit the final investigation report and action plan to NELCSU who will forward to WNCCG for review. These will then be reviewed and quality assured jointly with providers at RCA review meetings.

6.2 RCA reports will be reviewed to determine whether all aspects of the incident have been adequately investigated and whether there is a clear action point to address each root cause and evidence of implementation of actions to improve safety provision. WNCCG will apply the NPSA investigation checklist to RCA reports, and triangulate with other evidence collected through contract and clinical quality monitoring. If the provider does not meet the SI reporting timescales,

escalation is via the contract performance meetings. The escalation route for specific quality issues is the Clinical Quality Review meetings. If a negative response is received, escalation will be at Director level and Accountable Officer. NELCSU monitors SIs according to their status, i.e. open,(where the case may be awaiting reports from Provider or being reviewed by WNCCG or where WNCCG have requested further information) or closed, (which may also be subject to completion of outstanding actions). Risks are highlighted on risk registers.

6.3 The responsibility for quality assurance and signing off the SI report remains with WNCCG by the Head of Clinical Quality or their deputy. WNCCG will give feedback to the provider organisation within **20 working days** of receipt of action plan. If further development is required, timescales will be specified. As part of the quality assurance process, WNCCG will ensure that the principles of the NHS Being Open guidance have been applied with regard to the incident.

6.4 It may be necessary to involve other commissioning organisations in the quality assurance and sign off process depending on the nature and circumstance of the incident.

7. DISSEMINATING LEARNING

7.1 SI reports are provided for the Governing Body, the Management Executive and the Clinical Quality and Patient Safety Committee.

7.2 WNCCG is responsible for ensuring that learning from a single incident or aggregation of incidents is shared in their areas, for example, through newsletters. Learning is also shared through annual quality reporting. Learning from serious case reviews is taken forward by the local Safeguarding Adult Board and the Norfolk Safeguarding Children Board Learning and Improvement Procedure.

8. COMMUNICATIONS

8.1 Provider organisations are required to work closely with the Communications team at NELCSU to agree appropriate media handling strategies. Initial media handling must be indicated on the SI reporting form.

8.2 NELCSU communications team is responsible for liaising with NHSE Communications team who have responsibility for briefing the Department of Health Ministerial Briefing Unit or Media Centre.

9. SPECIAL CIRCUMSTANCES

9.1 Some SIs require further attention in respect of the process applied as follows:

9.1.1 **Death in custody**
Where a death in custody occurs appropriate guidance should be followed. Any relevant investigations are the responsibility of the Independent Police Complaints Commission. The Prison and Probation Ombudsman (PPO) has clear expectations in relation to health involvement in PPO investigations in to death in custody and guidance published by the PPO must be followed by those involved in the delivery and commissioning of NHS care within settings covered by the PPO. In addition, if the death is unexpected, a root cause analysis review should be conducted by the Provider as per SI policy.

9.1.2 **Fraud**

For incidents of suspected fraud, refer to the West Norfolk CCG Counter Fraud and Corruption Policy. West Norfolk CCG internal incidents must be reported to the Director of Finance or Local Counter Fraud Specialist For incidents reported by a provider, West Norfolk CCG will check that the provider has reported these within their own organisation to the appropriate person.

9.1.3 **Information governance (IG) /breaches of confidentiality SIs**

An IG SI is defined as an instance which will typically breach one of the principles of the Data Protection Act and/or the Common Law Duty of Confidentiality. This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.

West Norfolk CCG manages IG SIRIs in accordance with the *Health & Social Care information Centre Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation. (2015)* all level 2 IG SIRIs or above are reported using the IG Toolkit Incident Reporting Tool which reports level 2 IG SIRIs to the DH, ICO and other regulators. Incidents classified at a IG SIRI severity level 2 are those that are classed as a personal data breach (as defined in the Data protection Act) or high risk of reputational damage, reportable to the Department of Health and the Information Commissioner's Office. These incidents are detailed individually in the CCGs annual report.

9.1.4 **IG Cyber SIs**

The CCG reports Cyber SIs as part of its overall incident reporting. A Cyber-related incident is defined as: "A Cyber related incident is anything that could (or has) compromised information assets within Cyberspace. "Cyberspace is an interactive domain made up of digital networks that is used to store, modify and communicate information. It includes the internet, but also the other information systems that support our businesses, infrastructure and services" Source: UK Cyber Security Strategy 2011

These types of incidents could include:

- Denial of Service attacks
- Phishing emails
- Social Media Disclosures
- Web site defacement
- Malicious Internal damage
- Spoof website
- Cyber Bullying

9.1.5 **Healthcare Associated Infections (HAI)**

HAIs should be reported to NELCSU via the normal SI reporting process. These include outbreaks, infected healthcare workers, breakdown of infection control procedures or serious decontamination failures with actual or potential for cross infection and, other high profile incidents. Note that for outbreaks, there is a local agreement that a SI is generated when an outbreak meeting is formed. Note that RCAs on individual MRSA Bacteraemia or C Diff deaths, C Diff colectomy or C Diff ITU admissions should NOT be sent via the SI reporting process but sent directly to Infection Control Norfolk County Council.

9.1.6 **Maternal deaths**

In addition to the SI, all maternal deaths must be reported to the Local Supervising Authority Midwifery Officer, (LSAMO), via the LSA Co-ordinator on 0113 8253184 or via

secure email joykirby@nhs.net. This is in compliance to the NMC Midwives Rules and Standards 2004. Although not all maternal deaths are classified as a SI the SI form should be utilised to notify.

9.1.7 **Mental Health Service Incidents, (including homicides involving service users):**
Where patients in receipt of mental health services commit a homicide, NHS England will consider and if appropriate commission an investigation. This process is overseen by NHS England's regional investigation teams. An Independent Investigation Review Group (IIRG) has been established by each of the regional investigation teams which reviews and considers cases requiring investigation.

9.1.8 **Rule 43s**
This rule gives Coroners the power to make reports to a person or an organisation where the Coroner believes action needs to be taken to prevent future deaths and where that person or organisation may have the power to act. The Corporate Governance Manager monitors Rule 43s.

9.1.9 **Serious Case Reviews, Safeguarding Children Board and Safeguarding Adult Reviews**
The Local Authority via the Local Safeguarding Children Board (LSCB) or Local Safeguarding Adult Board (LSAB) has a statutory duty to investigate certain types of safeguarding incidents/concerns. In circumstances set out in 'Working Together to Safeguard Children (2013), the LSCB will commission and in circumstances set out in guidance for adult safeguarding concerns, the LSAB will commission Safeguarding Adult Reviews. The Local Authority will also initiate Safeguarding Adult Enquiries if they suspect an adult is at risk of abuse or neglect. Where it is indicated that a serious incident within healthcare has occurred, the necessary declaration must be made.

A safeguarding Memorandum of Understanding is in place with partner CCGs to support partnership working. The performance management of SIs will be used to ensure that appropriate actions are taken by NHS organisations in response to findings of any serious case reviews.

9.1.10 **Screening Programme SIs**
Serious Incidents in NHS National Screening Programmes must be managed in line with the guidance 'Managing Safety Incidents in National Screening Programmes' (Interim guidance for managing screening incidents, 2013). An SI could be an actual or possible failure at any stage in the pathway of the screening service, which exposes the programme to unknown levels of risk that screening, and assessment or treatment people have been inadequate, and hence there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low, but because of the large numbers involved the corporate risk may be very high. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care, and inappropriate actions within one area, or communication failures between providers, can result in serious incidents.

9.1.11 **Theft**
Incidents of theft must be reported to the Local Management Security Specialist.

9.1.12 **Use of adult psychiatric wards for children aged 16 and under**
This is no longer permitted under the Mental Health Act. In accordance with the Department of Health Gateway letter 8390, where a child of 16 or under is placed on an adult ward a SI should be raised and include how the child will be moved to the appropriate accommodation and how in the interim period, the accommodation has been made appropriate to the needs of the child. NHS Norfolk expects that incidents involving 16 and 17 year olds placed on an adult ward to be reported and investigated.

9.1.12 **Domestic Homicide Reviews**
A Domestic Homicide is identified by the police usually in partnership with the Community Safety Partnership with whom the overall responsibility lies for establishing a review of the case. The Domestic Violence, Crime and Victims Act, 2004 sets out the statutory obligations and requirements of providers and commissioners in relation to domestic homicide reviews

9.1.13 **Services commissioned by NHS England Specialist Commissioning Group,**
Managers reporting a SI hours occurring in a service commissioned by NHS England Specialist Commissioning Group must report the SI to the SCG at England.reports-eaat@nhs.net who will lead the SI process, and advise West Norfolk CCG as appropriate.

9.1.14 **East of England Ambulance Services Trust, (EEAST) , SIs**
There is a lead commissioner arrangement in place for EEAST SIs, therefore, SIs from the EEAST must be reported to the lead commissioner who will inform West Norfolk CCG as appropriate. West Norfolk CCG will lead the SI process locally and update the lead commissioner who will update NHS England.

9.1.15 **IC 24 – Out of Hours and 111 service provider**
There is a lead commissioner arrangement in place for IC24 SIs, therefore, SIs from IC24 must be reported to the lead commissioner (NHS Norwich CCG) via the STEIS system who will inform West Norfolk CCG as appropriate. West Norfolk CCG will lead the SI process locally and update the lead commissioner who will update NHS England.

9.1.16 **Work related deaths:**
Work related deaths should follow the Work Related Death protocol, an agreed protocol between the Health and Safety Executive, the police, the Crown Prosecution Service and the British Transport Police.

10. OTHER RELEVANT APPROVED DOCUMENTS

- Incident Management Policy
- Health & Safety Policies
- Risk Management Policy
- Investigation Policy
- Counter Fraud Policy
- Independent contractor Incident/SI Policy
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20: Duty of Candour
- Safeguarding Children Policy
- Safeguarding Adult Policy

- East of England Specialist Commissioning Group SI reporting – additional guidance for Specialist Service Providers
- Managing SI in the English National Screening Programmes V4, Jun 10
- Health & Social Care information Centre Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation. (2015)
- Saying sorry when things go wrong – being open, Nov 09
- National Framework for Reporting & Learning from Serious Incidents
- Requiring Investigation, Mar 10, DH Gateway 13733
- Clinical Governance & Adult Safeguarding, Feb 10, DH Gateway 13549
- DOH The Never Events Policy Framework 2012
- Serious Incident Framework – Supporting learning to prevent recurrence 2015
- Working Together to Safeguard Children (2013)

11. TRAINING IMPLICATIONS

11.1 All staff must read and understand the policy and be able to report, investigate and prevent recurrence for any serious incident.

Appendix 1: Serious Incident Management Process