South Norfolk Clinical Commissioning Group

Serious Incidents (SI) & Never Events (NE) Requiring Investigation Policy

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Contact for Review: Karen Ward Quality and Safety Manager South Norfolk CCG				

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Version	Date issued	Brief summary of change	Owner's name
0.6	14/10/2013	Initial CCG version following extensive revamp of previous PCT/CSU policy	Toby Richmond
0.7	25/10/13	Duty of Candour section included Referencing format updated.	Karen Ward
0.8	25/10/13	Format updates	Toby Richmond
0.9	03.01.14	Changes to Information Governance	Amanda Brown

SOUTH NORFOLK CLINICAL COMMISSIONING GROUP
SERIOUS INCIDENTS (SI) & NEVER EVENTS (NE) REQUIRING INVESTIGATION POLICY

This policy establishes a clear procedure to be adhered to following an SI/NE for any services commissioned by South Norfolk Clinical Commissioning Group (CCG) or for South Norfolk CCG's own staff raising an SI/NE. The policy adheres to the Serious Incident Framework March 2013[1], an update to the 2010 National Framework for Reporting and Learning from Serious Incidents, NHS Commissioning Board[2], therefore ensuring a consistent approach and clarifying the responsibilities of South Norfolk CCG.

Scope

This policy applies to South Norfolk CCG staff, NHS Trusts, Foundation Trusts, CCG providers, independent healthcare 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 designed for any staff member working in NHS Anglia Commissioning Support Unit (NHSACSU).

Training implications

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

Monitoring and audit

South 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.

Authorised by

South Norfolk Clinical Commissioning Group Governing Body.

Date of issue: ……

[1] NHS Commissioning Board, 2013. *Serious incident Framework March 2013*. http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf
[2] NHS National Patient Safety Agency, 2010. *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation.* http://www.nrls.npsa.nhs.uk/resources/?entryid45=75173

SERIOUS INCIDENTS AND NEVER EVENTS REQUIRING INVESTIGATION POLICY

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 (SI) or Never Event (NE). 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 Serious Incident Framework March 2013, an update to the 2010 National Framework for Reporting and Learning from Serious Incidents, NHS Commissioning Board, supplemented by Department of Health (DH) The Never Events Policy Framework 2012[3] [4] [5]. If in doubt, report as an SI. An SI can always be voided when more information is available.

1.3. South Norfolk CCG is committed to the principles of Being Open, principles that healthcare staff should use when communicating with patients, their families and carers following a patient safety incident in which the patient was harmed or a near miss occurred. 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[6] .

2. DEFINITION

2.1. 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 including incidents graded under the National Patient Safety Agency (NPSA)[7] definition of severe harm. The NPSA definition of severe harm is "any patient safety incident that appears to have

[3] Department of Health, 2012. *The never events policy framework: An update to the never events policy.* http://www.idsc-uk.co.uk/docs-2012/never-events-policy-framework-update-to-policy.pdf
[4] NHS Commissioning Board, 2013. *Serious incident Framework March 2013*. http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf
[5] NHS National Patient Safety Agency, 2010. *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation.* http://www.nrls.npsa.nhs.uk/resources/?entryid45=75173
[6] NHS National Patient Safety Agency, 2009. *Saying Sorry When Things Go Wrong Being Open.* http://www.nrls.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=65172
[7] On 1 June 2012, the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) transferred to the NHS Commissioning Board.

resulted in permanent harm to one or more persons receiving NHS-funded care."[8].

- 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, or IT failure
- Allegations of abuse, or incidents of abuse
- Loss of confidence in the service, adverse media coverage or public concern about the organisation or the wider NHS
- One of the core set of Never Events as updated on an annual basis and currently including:

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-operation
4. Wrongly prepared high-risk injectable medication
5. Maladministration of potassium-containing solutions
6. Wrong route administration of chemotherapy
7. Wrong route administration of oral/enteral treatment
8. Intravenous administration of epidural medication
9. Maladministration of Insulin
10. Overdose of midazolam during conscious sedation
11. Opioid overdose of an opioid-naïve patient
12. Inappropriate administration of daily oral methotrexate
13. Suicide using non-collapsible rails
14. Escape of a transferred prisoner
15. Falls from unrestricted windows
16. Entrapment in bedrails
17. Transfusion of ABO-incompatible blood components
18. Transplantation of ABO-incompatible organs as a result of error
19. Misplaced naso- or oro-gastric tubes
20. Wrong gas administered
21. Failure to monitor and respond to oxygen saturation
22. Air embolism
23. Misidentification of patients
24. Severe scalding of patients
25. Maternal death due to post partum haemorrhage after elective Caesarean section

2.2. Never Events are detailed in the 2013/4 NHS Standard Contract[9] .

2.3. 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 on-going healthcare.

3. REPORTING THE INITIAL SI

3.1. SIs must be reported within 2 working days of the incident being identified using either the Strategic Executive Information System (STEIS) reporting system or, for those providers without access to STEIS, an electronic form* (appendix 1) is sent via secure email to the NHSACSU SI email account: **angliacsu.SUI@nhs.net**. If the SI has very significant implications for the NHS in terms of clinical, managerial or media

[8] NHS National Patient Safety Agency, 2013. *Guidance.* http://www.nrls.npsa.nhs.uk/resources/type/guidance/
[9] NHS Commissioning Board, 2013. *NHS Standard Contract 2013/14*. http://www.england.nhs.uk/nhs-standard-contract/

issues, South Norfolk CCG and NHSACSU must be contacted directly by telephone (contact details in appendix 2). In forensic/criminal cases, communication with media should be in partnership with the relevant agencies involved with the incident, led by the police.

3.2. When not submitting the information via STEIS, the SI code should be the organisation's own incident reference number. When submitting information, all parties should adhere to Caldicott principles. Do not use patient identifiable information unless absolutely necessary. Staff must ensure that description and action fields are anonymous. This applies to all patients, staff or visitors and includes names, date of birth, unique patient numbers, telephone numbers, addresses, postcodes, email addresses and place names. All providers must include details of the patient's GP to enable clarification of accountable CCG. Reporting an incident to South Norfolk CCG/ NHSACSU does not remove responsibility to comply with national guidance issued by the Department of Health, or other organisations such as NHS Commissioning Board and Care Quality Commission (CQC)[10] [11] [12] [13] [14] [15] [16].

4. ON COMPLETION OF SI

4.1. On receipt of an SI, NHSACSU will work with the provider and South Norfolk CCG to agree the SI grading for the purposes of determining the investigation and monitoring approach. The two possible grades are:

- **Grade 1 SI**: NHSACSU will monitor the SI and report findings, recommendations and associated action plans to the NHS England Area Team (AT). Examples include mental health deaths in the community, unexplained deaths, mental health attempted suicides as inpatients, ambulance service missing target for arrival resulting in death / severe harm to patient, data loss and information security (HSCIC Level 1), Grade 3 pressure ulcer develops, poor discharge planning causing harm to patient. Closure of Grade 1 Incidents can occur when South Norfolk CCG is satisfied with the investigation, recommendations and action plan and that provider monitoring arrangements are in place and working appropriately.

- **Grade 2 SI**: Examples include maternal deaths, inpatient suicides, safeguarding children, data loss and information security (HSCIC Level 2), Never Events, accusations of physical misconduct or harm and homicides. Agreement to close Grade 2 SI's should be made once the provider has given evidence that each element of the action plan has been implemented.

- On receipt of the SI, NHSACSU will acknowledge the provider, copying in the Director of Quality and Patient Safety South Norfolk CCG, indicating suggested grades and timescales. It will be for the Director of Quality and Patient Safety to agree the final grade of SI where there is any doubt.

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[10] Care Quality Commission, 2010. *Guidance about compliance Summary of Regulations, Outcomes and Judgement Framework.* http://www.cqc.org.uk/sites/default/files/media/documents/guidance_about_compliance_summary.pdf
[11] Department of Health, 2010. *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents* http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/links/suichecklist.pdf
[12] Legislation.gov.uk, 2013. *Search Results for Care Quality Commission Regulations.* http://www.legislation.gov.uk/all?title=care%20quality%20commission%20regulations
[13] NHS East of England, 2010. *Serious Incidents Requiring Investigation Policy.* http://www.suffolk.nhs.uk/LinkClick.aspx?fileticket=FRE1ssJeKxs%3D&tabid=3278&mid=6418
[14] NHS National Patient Safety Agency, 2004. *Seven Steps to Patient Safety* http://www.nrls.npsa.nhs.uk/sevensteps/
[15] NHS National Patient Safety Agency, 2013. *Guidance.* http://www.nrls.npsa.nhs.uk/resources/type/guidance/
[16] NHS National Patient Safety Agency. *Exploring Incidents, Improving Safety* https://report.npsa.nhs.uk/rcatoolkit/course/iindex.htm

4.2. A new SI received by NHSACSU will be communicated to South Norfolk CCG as soon as possible and at least within one working day via the SI/NE secure email address: SNCCG.Incidents@nhs.net. Although the investigation and processing of the SI is the responsibility of NHSACSU, they will at all times work in partnership with South Norfolk CCG who remain accountable for ensuring adequate actions arising from the incident are undertaken.

4.3. If the reported incident does not fall within the definitions of an SI/NE then, by agreement with South Norfolk CCG, NHSACSU will contact the NHS England Area Team to void the incident. This is done automatically through the STEIS system. The request to void the incident will be assessed and the incorrect incident removed from STEIS by the NHS England Area Team where appropriate. If despite being downgraded it continues to be a patient safety incident it should be reported by the provider via the Local Risk Management System (LRMS) and investigated appropriately.

4.4. South Norfolk CCG's Director of Quality and Patient Safety notifies the Accountable Officer, Chair of the Governing Body, Chief Operating Officer, Head of Corporate Affairs and the communication team within NHSACSU of any potentially highly sensitive SIs or SIs with media interest. In addition, SIs may be notified to appropriate experts within NHSACSU and South Norfolk CCG, for example, infection control lead, safeguarding leads or the prescribing team. The SI is entered onto an SI database by NHSACSU and monitored by the Risk and Safety Manager within the Corporate Services team. It is the responsibility of NHSACSU to notify the NHSCB LAT of the SI and the grading. If more than one provider is involved in the SI, South Norfolk CCG will take a lead role in collaboration with NHSACSU to negotiate between providers and determine who should carry out the investigation.

5. REPORTING REQUIREMENTS

5.1. 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), NHSACSU will share the SI reporting with the lead commissioning CCG, the CCG with whom the patient is registered and all other CCGs commissioning with the provider. It remains the responsibility of the registering CCG to sign off the action plan from the provider and agree closure of the SI/NE.The timescale for reporting requirements are determined according to the grade the SI has been allocated as follows:

- **Grade 1 SI:** Providers are expected to provide additional information relating to the event update within 3 working days from the date of the SI/NE being submitted and conduct a comprehensive investigation as defined by the NPSA within 45 working days.

- **Grade 2 SI:** Providers are expected to provide a further update at 3 working days from the date of the SI/NE being submitted. A comprehensive investigation as defined by the NPSA should be completed within 60 working days. For some Grade 2 SIs it may be necessary to carry out an independent investigation for which the timescale is 6 months.

6. MONITORING

6.1. The role of NHSACSU is to receive and review the content of the investigation report, before onward transmission to South Norfolk CCG for review at the Quality and Patient Safety Assurance Committee (QPSAC).

6.2. Appropriate advice can be obtained 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. South Norfolk CCG will ensure that NHSACSU will apply the NPSA investigation checklist to RCA reports, and triangulate with other evidence collected through contract and clinical quality monitoring. This is embedded within provider contracts. 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 and Accountable Officer level. NHSACSU monitors SIs according to their status - i.e. open (where the case may be awaiting reports from provider or being reviewed by South Norfolk CCG or where South Norfolk CCG have requested further information) or closed (which may also be subject to completion of outstanding actions). Risks are highlighted on risk registers.

6.3. Appendix 2 details the CSU/CCG operational SI sign off process. Queries raised by South Norfolk CCG following the 45/60 day report are forwarded to the provider by NHSACSU. If queries are not resolved, they are escalated to CQRM following agreement between South Norfolk CCG and NHSACSU. When queries have been resolved, NHSACSU completes a closure template and forwards it on to South Norfolk CCG for sign off. The responsibility for signing off the SI report remains with the Director of Quality and Patient Safety, South Norfolk CCG with delegated responsibility to a nominated individual. South Norfolk CCG 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.

7. DUTY OF CANDOUR

7.1. All healthcare service providers have a responsibility to patients/their families or carers to ensure they are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported through this process and in dealing with any consequences[17].

7.2. All NHS providers now have a contractual duty of candour. The contractual duty of candour applies to patient safety incidents that occur during care provided under the NHS Standard Contract that results in **moderate harm, severe harm or death** (using NPSA definitions)[18] below;

Moderate Harm incidents (short term harm, patient(s) required further treatment or procedure) (e.g. grade 3 pressure ulcers, some patient falls and medication errors)

Severe harm incidents (permanent or long term harm).

Death incidents (Any unexpected or unintended incident which caused the death of one or more persons).

7.3. South Norfolk CCG have a responsibility of observance of the duty in relation to SI's and NE's, to ensure that the patients/their families or carers have been informed of the patient safety incident affecting them and informed/supported as per 7.1.

8. DISSEMINATING LEARNING

[17] The Mid Staffordshire NHS Foundation Trust 2013. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry - Executive summary*
http://www.midstaffspublicinquiry.com/sites/default/files/report/Executive%20summary.pdf

[18] NHS National Patient Safety Agency, 2004. *Seven Steps to Patient Safety* http://www.nrls.npsa.nhs.uk/sevensteps/

8.1. SI reports are provided for the Governing Body, Quality and Patient Safety Assurance Committees, Commissioning Boards and joint CCG meetings. A monthly provider report discussing SIs is produced by NHSACSU.

8.2. South Norfolk CCG 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 Safeguarding Children Board.

9. COMMUNICATIONS

9.1. Provider organisations are required to work closely with the communications team at NHSACSU to agree appropriate media handling strategies. Initial media handling must be indicated on the SI reporting form. Any actual or likely media interest, whether local, national or political interest must be indicated by the provider whilst completing the initial SI form (appendix 1).

9.2. NHSACSU communications team is responsible for liaising with the NHS England AT Communications Team who have responsibility for briefing the DH Ministerial Briefing Unit or Media Centre.

10. SPECIAL CIRCUMSTANCES

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

- Death in custody

Where a death in custody occurs, appropriate guidance should be followed. An independent clinical review is carried out by NHSE on behalf of the Prison and Probation Ombudsman. In addition, if the death is unexpected, a root cause analysis review should be conducted by the provider as per SI policy. Deaths in custody are dealt with by the area team and not South Norfolk CCG. The current SI lead within the area team is John Morrison (john.morrison4@nhs.net).

- Fraud

From 31st March 2013, under the NHS Standard Contract for 2013/14[19], all organisations providing NHS services must put in place and maintain appropriate counter fraud and security management arrangements. Suspected cases of fraud must be reported in accordance with the terms of the NHS Standard Contract 2013/14 General Particulars section GC6.

Incidents of suspected fraud can also be reported via the NHS Business Services Authority online form at https://www.reportnhsfraud.nhs.uk/ or via the NHS Fraud and Corruption Reporting line on 0800 028 40 60.

- Information governance (IG) and breaches of confidentiality SIs

IG SIs are defined as “any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals” and include electronic media and paper records. NHSACSU manages IG SIs in accordance with Department of Health[20] [21] and Health and Social Care

[19] NHS Commissioning Board, 2013. *NHS Standard Contract 2013/14*. http://www.england.nhs.uk/nhs-standard-contract/
[20] Council of Europe, 2010. *European Convention on Human Rights* http://book.coe.int/sysmodules/RBS_fichier/admin/download.php?fileid=3502

Information Centre Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation v2 published 1 June 2013[22]. Providers are required to submit an Information Loss Briefing Form (appendix 4) in the first instance and in addition to the SI form. Risk ratings are regularly reviewed. Risk ratings of level 2 are reported to the Information Commissioner. IG SIs should also be included in the annual reports in accordance with Gateway letter 9912, 20th May 2008. Sign off and closure of these SIs remains the responsibility of South Norfolk CCG with advice from NHSACSU IG team[23] .

- Healthcare Associated Infections (HCAI)

HCAIs should be reported to NHSACSU 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 an SI is generated when an outbreak meeting is formed. 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 by South Norfolk CCG to Infection Control Norfolk County Council. The Infection Control team includes Rowan Slowther (rowan.slowther@norfolk.gov.uk) and Judy Ames (judy.ames@norfolk.gov.uk).

- Maternal deaths

In addition to the SI, all maternal deaths must be reported by the provider to the Local Supervising Authority Midwifery Officer, (LSAMO), via the LSA Co-ordinator on 01223 597568 or via secure email. The current contact for East of England is Joy Kirby (joykirby@nhs.net). Contact details for the LSAMO can be found online at: http://www.nmc-uk.org/Nurses-and-midwives/Midwifery-New/Contact-a-LSAMO1.

This is in compliance to the NMC Midwives Rules and Standards 2004. Although not all maternal deaths are classified as an SI, the SI form should be used to notify.

- Mental health service incidents (including homicides involving service users)

In June 2005, guidance was published regarding independent investigations. It is the responsibility of the patient's registered CCG to commission independent investigations. Considerations include when a homicide has been committed by a person who is, or has been, under the care of specialist mental health services in six months prior to the event; when it is necessary to comply with the state's obligations under Article 2 of the European Convention on Human Rights (2) – whenever a state agent is, or may be, responsible for a death or where the victim sustains life threatening injuries, or where a serious patient safety incident warrants an independent investigation. The process for independent investigations involves an initial service management review by the Trust (within 3 working days), an investigation by the Trust within 45 working days, and then an independent investigation.

- Schedule 5 coroner's enquiry

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

[21] Department of Health, 2008. *Gateway letter 9912* http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/igap/dnletter20may08.pdf

[22] HSCIC, 2013, Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation, http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/security/risk

where that person or organisation may have the power to act. South Norfolk CCG's Corporate Governance Manager has the responsibility for monitoring schedule 5s.

- Safeguarding children

All Serious Case Reviews and Multi Agency Management Reviews must be reported as a SI. 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.

- Safeguarding adults

Where a SI is reporting safeguarding concerns, a referral to the Multi-agency Safeguarding Hub (MASH) may also be appropriate. In these circumstances the MASH investigation will take precedent until the health organisation is advised by the MASH that a root cause analysis investigation can proceed. It remains the provider's responsibility to report all safeguarding incidents to the MASH team at Norfolk County Council who have the statutory responsibility to inform NHS colleagues[24].

- Screening programme SIs

Additional guidance is available for screening programme SIs[25]. 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 and may result in 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.

- Theft

Incidents of theft must be reported to the Local Management Security Specialist in accordance with the terms of the NHS Standard Contract 2013/14 General Particulars section GC6.

- Use of adult psychiatric wards for children aged 16 and under

The Mental Health Act 2007[26] introduced important changes in law for children and young people, including the provision of an appropriate environment for admission to hospital. When a child of 16 or under is placed on an adult ward, an 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. South Norfolk CCG expects that incidents involving 16 and 17 year olds placed on an adult ward to be reported and investigated.

- Services commissioned by East of England Specialist Commissioning Group (EoESCG)

All SIs occurring in a service commissioned by EoESCG are reported via STEIS by the provider. The AT is automatically notified of the SI via STEIS.

- East of England Ambulance Service NHS Trust (EEAST) SIs

[24] Department of Health, 2010. *Clinical Governance and Adult Safeguarding An Integrated Process.* http://www.nmc-uk.org/Documents/Safeguarding/England/1/Clinical%20governance%20and%20adult%20safeguarding.pdf
[25] NHS Screening Programmes, 2004. *Managing Serious Incidents in the English NHS National Screening Programmes Guidance on behalf of the UK National Screening Committee (UK NSC) Version: 4.0.* http://www.screening.nhs.uk/getdata.php?id=9902
[26] Legislation.gov.uk, 2007. *Mental Health Act 2007* http://www.legislation.gov.uk/ukpga/2007/12/contents

NHS Suffolk CCG is lead commissioner for EEAST SIs. All SIs are reported via STEIS and the CCG responsible is notified.

- 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[27].

[27] NHS National Liaison Committee for the Work-related Deaths Protocol (England and Wales), 2011. *Work-related deaths: A protocol for liaison (England and Wales)* http://www.hse.gov.uk/pubns/wrdp1.pdf

Appendix 1: Serious Incident Form

STRICTLY CONFIDENTIAL

SERIOUS INCIDENT INITIAL REPORT

REVISED FORM JANUARY 2013

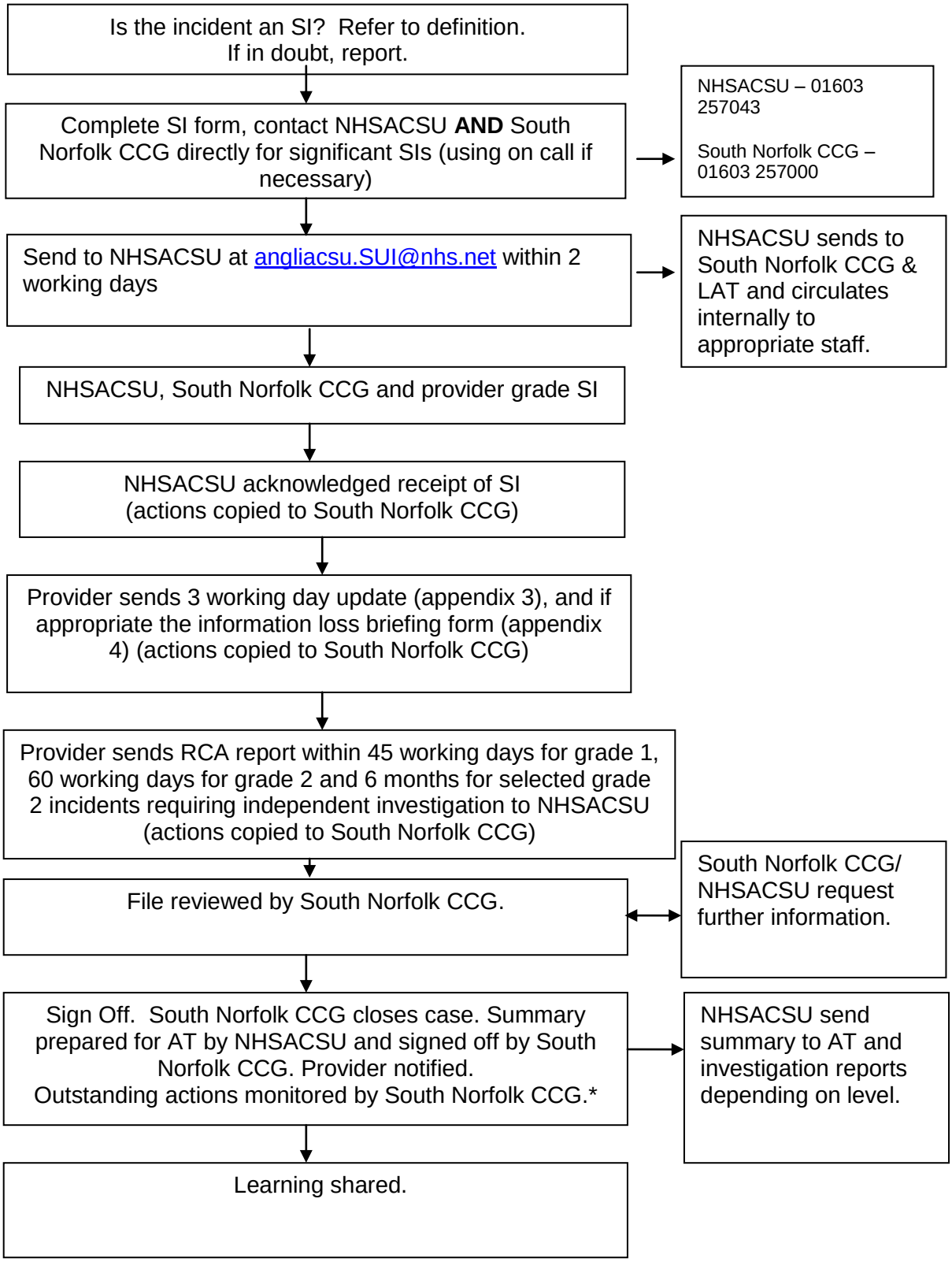
1.	Your Local Organisation SI Code		
2.	Date of this report		
3.	Name of Organisation		
3a.	Name of Commissioner		
4.	NPSA Category		
5.	Your Name and Contact details	Name	
		Job Title	
		Tel No	
		SecureEmail	
6.	Name and Contact details for Correspondence	Name	
		Job Title/role	
		Tel No	
		Secure Email	
7.	Date of Incident		(dd/mm/yyyy)
8.	Incident Category		

			Person 1.		Person 2.
9.	Details of Patient or other person(s) involved	Reference Code			
		Age (years)		Age (Months)	
		Gender			

10.	Outcome in terms of patient, other persons, staff or service failure		
		Other, please specify	
11.	Where did the incident occur? Eg. site, ward, in the home, etc	Location	
		Speciality	
12.	Staff Involved (designation only)		

13.	Summary details of incident/issue: give a factual account, incl. a description of any medical devices, equipment and/or any medicines involved, and time of day if relevant. If a data loss, incl. how many individuals are involved, if they have been notified, any safeguards in place around the data, DH level of severity. **PLEASE NOTE THIS FIELD IS LIMITED TO 1000 CHARACTERS OF TEXT.** If you have more information, please attach an additional Word document.		**Character count** 0
14.	Other information not in the public domain.		
15.	Immediate Action Taken		
16.	Legal Advice Taken?		
17.	Has, or will information on this incident be reported to any other agency/body (specify e.g. Police, Information Commissioner,etc)		
18.	Information about actual or likely media interest (local or national) and/or political interest or involvement (MP's, Ministers, etc)		
19.	Lines to take. (Include local and suggested national lines if applicable). *YOUR COMMUNICATIONS MANAGER should complete this section or provide you advice.*		

Appendix 2: South Norfolk Clinical Commissioning Group (SI) Process



- Incident grade dictates whether an action plan must only be submitted or must actually be implemented before incident closure

Appendix 3: 3 Working Day Update

Organisation	
SI / local reference number	
Date of incident	

Update
(brief update to include immediate actions taken, status of investigation etc)

Please return this form to NHSACSU **via the SI reporting address - angliacsu.SUI@nhs.net**

Appendix 4: Information Loss Briefing Form for Information Governance SIs

Organisation	
Date of incident	
Date of reporting	
Level of severity (DH levels)*	
Summary of incident	
Where information was held	
Safeguards in place, (including if encrypted)	
Number of individuals at risk	
Have patients been notified?	
Has the Information Commissioner been notified?	
Is the data loss in the public domain	
Action taken by organisation	

Please return this form to NHSACSU **via the SI reporting address - angliacsu.SUI@nhs.net**

***Categorising SIRIs**
The IG SIRI category is determined by the context, scale and sensitivity. Every incident can be categorised as level:

1. Confirmed IG SIRI but no need to report to ICO, DH and other central bodies.
2. Confirmed IG SIRI that must be reported to ICO, DH and other central bodies.

A further category of IG SIRI is also possible and should be used in incident closure where it is determined that it was a near miss or the incident is found to have been mistakenly reported:

0. Near miss/non-event

Where an IG SIRI has found not to have occurred or severity is reduced due to fortunate events which were not part of pre-planned controls this should be recorded as a “near miss” to enable lessons learned activities to take place and appropriate recording of the event.

The following process should be followed to categorise an IG SIRI

Step 1: Establish the scale of the incident. If this is not known it will be necessary to estimate the maximum potential scale point. **Baseline Scale**		
0	Information about less than 10 individuals	
1	Information about 11-50 individuals	

1	Information about 51-100 individuals	
2	Information about 101-300 individuals	
2	Information about 301 – 500 individuals	
2	Information about 501 – 1,000 individuals	
3	Information about 1,001 – 5,000 individuals	
3	Information about 5,001 – 10,000 individuals	
3	Information about 10,001 – 100,000 individuals	
3	Information about 100,001 + individuals	

Step 2: Identify which sensitivity characteristics may apply and the baseline scale point will adjust accordingly. Sensitivity Factors (SF) modify baseline scale	
Low: For each of the following factors reduce the baseline score by 1	
-1 for each	No clinical data at risk
	Limited demographic data at risk e.g. address not included, name not included
	Security controls/difficulty to access data partially mitigates risk
Medium: The following factors have no effect on baseline score	
0	Basic demographic data at risk e.g. equivalent to telephone directory
	Limited clinical information at risk e.g. clinic attendance, ward handover sheet
High: For each of the following factors increase the baseline score by 1	
+1 for each	Detailed clinical information at risk e.g. case notes
	Particularly sensitive information at risk e.g. HIV, STD, Mental Health, Children
	One or more previous incidents of a similar type in past 12 months
	Failure to securely encrypt mobile technology or other obvious security failing
	Celebrity involved or other newsworthy aspects or media interest
	A complaint has been made to the Information Commissioner
	Individuals affected are likely to suffer significant distress or embarrassment
	Individuals affected have been placed at risk of physical harm
	Individuals affected may suffer significant detriment e.g. financial loss
	Incident has incurred or risked incurring a clinical untoward incident

Step 3: Where adjusted scale indicates that the incident is level 2, the incident will be reported to the ICO and DH automatically via the IG Incident Reporting Tool.	
Final Score	Level of SIRI
1 or less	Level 1 IG SIRI (Not Reportable)
2 or more	Level 2 IG SIRI (Reportable)

An IG SIRI tool is available to staff in helping to determine the level of the IG incident and is available via the CCG Corporate Affairs team

HSCIC Checklist Guidance for Reportir

Appendix 5: Glossary

AT	NHS England Area Team
C. diff	Clostridium difficile
CCG	Clinical Commissioning Group
CQC	Care Quality Commission
EEAST	East of England Ambulance Service NHS Trust
EoESCG	East of England Specialist Commissioning Group
HCAI	Healthcare Associated Infection
IG	Information Governance
LRMS	Local Risk Management System
LSAMO	Local Supervising Authority Midwifery Officer
MASH	Multi-agency Safeguarding Hub
NE	Never Event
NHS England	The operating name of the NHS Commissioning Board
NHSACSU	NHS Anglia Commissioning Support Unit (CSU)
NHSCB	NHS Commissioning Board – the legal name of NHS England
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency - on 1 June 2012, the key functions and expertise for patient safety developed by the NPSA transferred to the NHS Commissioning Board
QPSAC	South Norfolk CCG Quality and Patient Safety Assurance Committee
SI	Serious Incident
STEIS	Strategic Executive Information System