NHS Nottingham North and East Clinical Commissioning Group

NHS Nottingham West Clinical Commissioning Group

NHS Rushcliffe Clinical Commissioning Group

Policy for the Reporting and Management of Serious Incidents

May 2013

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Name of Originator/ Authors:	Cheryl Crocker Director of Quality and Patient Safety
Name of Responsible Individual:	Cheryl Crocker Director of Quality and Patient Safety
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Target Audience	Provider Organisations Primary Care and Clinical Commissioning Groups

Contents

Essential Contact Numbers

In case of Serious Incident call:

IN HOURS	OUT OF HOURS
Clinical Quality Team **Tel: 0780 864 7120** Monday to Friday 09:00 – 17:00 Complete STEIS within one working day	Operational On-Call **Tel: 0300 456 4957** Outside of Office Hours 17:01 – 08:59 Complete STEIS on the first available working day The Operational On-Call Manager will automatically refer the call straight to the Director On-Call.

SECTION 1.0

Introduction

1.1 This policy is based on the National Serious Incident Framework (published NHS Commissioning Board March 2013). The NHS Commissioning Board (NHS England) has provided NHS Providers with a clear framework and their intention is that the framework can be locally embedded. This policy is designed to help NHS providers take appropriate steps in the best interest of their patients/clients/service user's, staff and the NHS as a whole. It contains the minimum reporting requirements expected in the region.

1.2 Making services safe for patients is fundamental to the provision of high-quality care and it is essential that providers of healthcare have good systems in place for staff to report when patients have, or could have been harmed. Open and honest reporting demonstrates a commitment to patients and their safety and is a mark of "high reliability". The focus on reporting should be on analysing the root cause of the incident because serious incidents yield important lessons about changing process to reduce risk. It is only through active learning and service improvement from serious incidents that the benefits of experience are actually realised.

1.3 It is an expectation that healthcare providers within their incident investigation processes adhere to the 'Being Open' principles and have their own internal 'Being Open' policy.

1.4 The Area Team (AT) of NHS England are able to provide its constituent organisations with specialist knowledge and objective advice on a range of issues. The Area Team is also required to manage the media appropriately and brief the Department of Health therefore requiring timely and accurate details.

1.5 Commissioners must assure themselves that there are robust systems for reporting and monitoring performance of commissioned services. There is an expectation that all serious incidents will be thoroughly investigated and associated action plans implemented. Providers will have a process of escalating those incidents of a serious nature to their Board and will publish details of their serious incidents, including never events, in their Quality Account.

1.6 Providers are required to investigate thoroughly all incidents that do not fall within the serious incident definition through their internal governance structures.

SECTION 2.0

Purpose

2.1 The purpose of this Policy is to make explicit the requirements for managing Serious Incidents (SIs). This Policy has been written in partnership with the Area Team and Clinical Commissioning Groups (CCGs) to define the role of the CCG in supporting their provider organisations to improve patient safety through the SI process and the AT's role in supporting Commissioners/CCGs to ensure they have the capacity and capability to perform.

2.2 The Clinical Commissioning Group expects all organisations commissioned to provide NHS funded healthcare within Nottinghamshire to incorporate the requirements of this policy into their contracting arrangements and own local policies. The provisions of this policy are a requirement within the NHS Standard Contract (Section C 7.3). This document outlines the approach for supporting learning and performance managing commissioned services.

2.3 The Clinical Commissioning Group, in consultation with Area Team will update this policy in keeping with any national or regional changes to the definition of SIs.

2.4 This policy should complement, not replace, the incident reporting systems already in place within NHS organisations. It does not replace the duty to inform the Police and other authorities, such as Social Care, where appropriate. National guidance governs certain types of incidents e.g. homicides and other serious incidents involving mentally ill people (HSG/94/27) and arrangements for dealing with major incidents (HSC/98/197). In certain specific instances organisations will need to inform other agencies in accordance with national guidance, such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the case of equipment failure, the Care Quality Commission (CQC), the Counter Fraud Operational Service in the case of fraud and the Health Protection Agency in cases of infection control. In such circumstances this SI policy should be followed in conjunction with the relevant national guidance.

SECTION 3.

Definitions

3.1 The term **'Commissioner'** is used throughout the document and is used to identify the Clinical Commissioning Groups (CCGs) who undertake the commissioning function.

3.2 A **Serious Incident** is defined as:
A Serious Incident is defined as an incident that occurred in relation to NHS-funded services and care resulting in unexpected or avoidable death, serious harm, a provider organisation's inability to continue to deliver healthcare services, allegations of abuse, adverse media coverage and/or one of the core set of Never Events.

NB: The CCG defines the term '*an incident that occurred in relation to NHS funded services*' as an incident that occurred in receipt of NHS funded services.

3.3 NB: Any media issue that is not related to a serious incident must not be reported through STEIS but through relevant communication teams.

3.4 All identified serious incidents must be notified to the relevant bodies without delay and within **two working days** of becoming aware of the incident occurring. If there is a delay in reporting the incident a rationale must be recorded on STEIS by the reporting organisation.

3.5 Supplementary terms

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

Permanent harm
Directly related to the incident and not related to the natural course of a patient's illness or underlying condition is defined as permanent lessening of bodily functions; including sensory, motor, physiological or intellectual.

Major harm
Hazard to life or function of an organ, requiring life saving intervention (surgical / medical) or will shorten life expectancy.

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

Abuse
A violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent.
Abuse can occur in any relationship and may result in significant harm, or exploitation, of the person subjected to it. As defined for adults by 'No Secrets' DH, 2000.

In *Working together to safeguard children (2006)* abuse is defined as follows: 'abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by 'inflicting harm' or by failing to act to prevent harm'.

3.6 Homicides by Mental Health Patients do we need this as we are not responsible

Department of Health has agreed that incidents of homicides committed by mental health patients will continue to be managed by the AT, even if the mental health trust involved is a foundation trust. This is because Are Teams are independent from both the provision and commissioning of services. Homicides will be managed in accordance with the Area Team Homicide Protocol which meets the requirements of HSG (94) 27 and subsequent amendments:
(http://www.eastmidlands.nhs.uk/about-us/publications/indinvmh/).

Not all homicides will meet the criteria for HSG (94) 27. All homicide investigation reports should be submitted to relevant Commissioners as per usual SI processes.

3.7 Criteria for independent investigations ***as above***

An independent investigation should be undertaken in the following circumstances:

- A homicide has been committed by a person who is or, has been under the care, i.e. subject to a regular or enhanced care programme approach, of specialist mental health services in the six months prior to the event.
- The Area Team determines that an adverse event warrants independent investigation, for example if there is concern that an event may represent significant systemic service failure, such as a cluster of suicides.
- The only time a homicide inquiry may not be commissioned is in the circumstances outlined in 3.9 and 3.10 below:

3.8 A homicide inquiry is not commissioned by the AT when the victim is a child and it is considered that the report by the Local Safeguarding Children Board fully covers the remit of an independent inquiry to fulfil the requirements in 3.8 above. If the victim is an older adolescent, i.e. under 18 years of age this also should be reported as a SI.
Once the commissioned report is completed, it is sent to the Trust/ CCG and the report and joint action plan is shared at the Trust/CCG and Area Team Boards.

3.9 A homicide inquiry may not be commissioned by the Area Team where there is a Domestic Homicide Review. Domestic Homicide Reviews (DHR) were established on a statutory basis under section 9 of the Domestic Violence, Crime and Victims Act (2004) on 13th April 2011 (http://www.homeoffice.gov.uk/crime/violence-against-women-girls/domestic-violence/domestic-homicide-reviews/).

Section 9(3) of the Domestic Violence, Crime and Victims Act (2004) act states that:
A "domestic homicide review" means a review of the circumstances in which the death of a person aged 16 or over has or appears to have, resulted from violence, abuse or neglect by –

a) A person to whom they were related or was/had an intimate relationship,
Or
b) A member of the same household.

The secretary of state may in a particular case direct a specified person or body within subsection (4) to establish, or to participate in a domestic homicide review.

The purpose of a domestic homicide review is to:

- Establish what lessons are to be learned regarding the way local professionals and organisations work individually and together to safeguard victims
- Identify any lessons and within what timescales they will be acted upon
- Apply lessons to service responses including changes to policies and procedures as appropriate
- DHRs are not inquiries into how the victim died or into who is culpable and are not specifically part of any disciplinary enquiry or process.

3.10 Suicides

Suspected suicide, actual suicide and attempted suicide of any person currently in receipt of NHS services on or off NHS premises must be reported as a SI. This includes:

- Patients currently in receipt of mental health services, or who have been discharged within the last 12 months.
- Patients of primary care practitioners where on review of chronology have identified care/service delivery problems.

Suicide is defined as death where:

- There is obvious evidence or strong suspicion of self-harm, or
- The above does not apply initially but emerges later from a clinical review or investigation of the case, or
- Where the Coroner's verdict is suicide, or where the narrative indicates that the individual took their own life

3.11 Safeguarding Children

Child deaths, significant harm and serious sexual abuse may or may not trigger a SI review; however all are reported to the Local Safeguarding Children's Board (LSCB). SI will be reported in accordance to the criteria below:

Expected Death (anticipated)

Where the death of a child was anticipated within a 24 hour period – No SI investigation is required but the case needs to be reported to the LSCB Child Death Overview Panel for review.

Unexpected Death

Where the death of the child was not anticipated within a 24 hour period, consider which of the following criteria applies:

*Where there are no suspicious concerns and no healthcare management issues identified t*he case needs to be reported to the LSCB Child Death Overview Panel only. However this does not require reporting as a SI.

Where there are no suspicious concerns, but healthcare management issues have been identified the case needs to be reported as a SI and to the LSCB Child Death Overview Panel. Once the SI investigation report is complete it must be submitted to the LSCB Child Death Overview Panel (CDOP) and Commissioners for review and closure.

Where there are possible suspicious circumstances or child protection concerns but no care management issues identified. The case needs to be reported to the LSCB for consideration as to whether or not a serious case review should take place and to the CDOP. If no care management issues are confirmed the case does not require reporting as a SI.

Where there are possible suspicious circumstances or child protection concerns and healthcare management issues. The case needs to be reported to the LSCB for consideration as to whether or not a serious case review (SCR) should take place and to the CDOP. The case also needs to be reported as a SI. It may take a little time to confirm whether or not a SCR is required, however this should not hamper the trusts internal investigation. The final SI report must be submitted to the LSCB in accordance to agreed timescales with the commissioners.

3.12 Where the death of a child by a mental health user and the local safeguarding board investigation would not cover the full requirements of HSG 94/27.

3.13 Child harm (significant)

When a child has been significantly harmed but not died the following criteria will be taken into consideration:

- Did the harm occur on NHS premises,
- Was the harm as a result of NHS funded care,
- Caused by the direct actions of healthcare staff.
- Receipt of healthcare within the last 12 months.

If so the case will need to be reported as an SI as well as to the LSCB.

Any child under the age of 18 admitted to an adult mental health ward qualifies as an SI.

Allegations of serious abuse (physical / mental / sexual) against healthcare staff who work with children must be reported as a SI and to the designated safeguarding person.

3.14 Safeguarding Adults (see Appendix 4 for Safeguarding Adults Incident flowchart)

A vulnerable adult is someone over the age of 18 years in need of services by reason of mental or other disability who is unable to take care of or protect themselves against harm or exploitation. All incidents of abuse including neglect to a vulnerable adult are notified through Safeguarding Adults procedures. In the following circumstances, the case needs to be reported as an SI as well as through Safeguarding Adults procedures:

- a vulnerable adult dies (including death by suicide) and abuse or neglect is known or suspected to be a factor in the vulnerable adult's death
- a vulnerable adult has sustained a potentially life threatening injury through abuse or neglect; serious sexual abuse; or sustained serious and permanent impairment of health or development through abuse or neglect

And/or where:

- the harm occurred on NHS premises
- as a result of NHS funded care
- caused by the direct actions of healthcare staff the case gives rise to concern about the way in which healthcare staff and services have worked together to safeguard vulnerable adults
- consideration where healthcare delivered within the last 12 months is implicated in the concern

Cases of death or significant harm, the case may also be investigated as a Serious Case Review under Safeguarding Adults procedures. The interagency decision to investigate as a SCR should not delay the investigation as an SI. The SI report will form the basis of any SCR individual management report.

3.15 Deaths and Serious Injuries in Custody

All deaths in custody (including those that appear to be natural causes) and near misses, such as serious self harm, attempted suicide, and serious failures within healthcare services must be reported as a Serious Incident and recorded on STEIS. In addition, deaths of offenders who were known to healthcare services and died after release of up to 3 months must also be reported and investigated. It is not suggested that these are subject to a commissioned clinical review but should be systematically investigated as part of the Providers SI policy to identify if any learning can be identified to prevent similar incidents.

The Area Team are responsible for ensuring that a death in custody incident is subjected to a clinical review by an independent investigator. This must be a clinician, with skills in Root Cause Analysis (RCA) techniques. This clinical review will contribute to the Prison and Probation Ombudsman (PPO) Investigation and should be completed in accordance to the PPO timescale of 10 weeks. The Area Team will need to review the clinical review to ensure it has been conducted in a robust manner and obtain assurances from the Prison healthcare staff that any recommendations outlined have been actioned and implemented. All other incidents reported as serious must be thoroughly investigated internally and in accordance with this policy.

3.16 Healthcare Associated Infections

MRSA
All identified cases of MRSA bacteraemia need to be reported as an SI.

PIR (Post Infection Review)

The approach called "zero tolerance" will involve a Post Infection Review (PIR) for all MRSA bloodstream infection cases from April 2013. The PIR must be undertaken on all MRSA bloodstream infection (MRSA BSI) cases using a toolkit within the NHS Commissioning Board Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections from April 2013 (embedded below) to identify any possible failings in care and to identify the organisation best placed to ensure improvements are made (Appendix 5). The toolkit will ensure consistency in approach and improve the quality of data provided. The PIR replaces the current requirement to undertake Root Cause Analysis (RCA). MRSA BSIs RCAs will still be required for other HCAIs (currently MSSA and *E. coli* BSIs and *Clostridium difficile* infections).


pir-guidance.pdf

Where an MRSA BSI has been identified, it is the responsibility of the organisation from which the sample originated to ensure that the full mandatory data set is recorded on the new national system DCS (for example, in the case of a GP, the CCG is the responsible organisation and will involve any other provider organisation as necessary)

The PIR will be conducted by a multidisciplinary clinical team that will review the bloodstream infection event and identify the factors that contributed to it.
The PIR process requires strong partnership working by all organisations involved in the patient's care pathway. This close collaboration will enable organisations to jointly identify and agree both the possible causes and any factors contributing to the patient's MRSA BSI.
Where an MRSA BSI is identified, the DCS will automatically and provisionally assign an organisation with the responsibility for leading the PIR process. This does not necessarily assume that the organisation was responsible for the BSI, but considers that they are best placed to lead and coordinate the PIR process.

If an MRSA BSI sample was taken from the patient on or after the third day of the admission to an acute trust, (where the day of admission is Day 1), the acute trust will be required to lead the PIR.
For all other MRSA BSI cases, the CCG responsible for the patient will be required to lead the PIR. *This will include in particular any patients not admitted at the time the specimen was taken, for example those in Accident and Emergency or outpatients.)*

Additionally:

The organisation with responsibility for conducting the PIR will automatically be notified as such by the new DCS.

If an acute trust is leading the PIR the CCG with responsibility for the patient will also be notified that a PIR has been initiated;

Similarly, if a CCG is leading a PIR for a case where the patient is an inpatient at the reporting trust the trust will also be notified.

Once the lead organisation has been notified by the DCS that they will be coordinating a PIR they will begin to call on the necessary multidisciplinary expertise. This will include, but is not limited to:

The staff who provided care	Any other organisation recently involved (e.g. in the last two weeks) in the care of the patient;
Local infection prevention and control (IPC) team	Director of Infection Prevention and Control (DIPC)
The CCG responsible for the patient;	Public Health England (PHE) *(in some circumstances)*

The organisation to which the case is initially assigned (either the acute trust or CCG) will be the lead organisation responsible for completing a PIR within one week of the date of assigning. The outcome of the PIR should establish the organisation to which the BSI should be finally assigned. The final assignment will identify the organisation best placed to ensure that any lessons learned are acted upon. The final assignment must be logged on the DCS within seven days of the initial assigning.

The head of the organisation (e.g. Chief Executive) or a designated nominee will need to record on the DCS the "outcome" of the PIR, that is the set of summary fields and the agreed organisation to which the MRSA BSI will be finally assigned for surveillance purposes.

If the duly assigned organisation is the same as the organisation leading the PIR this will end the process of recording the data on the DCS.

If the duly assigned organisation is different from the organisation leading the PIR, the system will notify the duly assigned organisation and they will need to indicate on the DCS that they agree with the outcome of the PIR.

In exceptional cases, where the acute trust or the CCG is unable to determine within one week which organisation should be assigned a case of MRSA BSI, the DPH of the local authority responsible for the CCG of the patient will be informed and is expected to then lead a review panel to assess the evidence presented in the PIR. The DPH can call on the assistance of CCGs, DIPC or equivalent, PHE and others as appropriate.

The outcome summary of the PIR will result in information recorded on the DCS by the local provider, DIPC/equivalent or the DPH, which can then be requested by CQC, CCGs, Monitor, NQB and PHE. If users wish to complete the whole PIR directly onto the DCS, they will be able to do so. Only the recording of the summary information on the DCS will be mandatory.

CCG led PIRs

The new investigation process has been introduced nationally giving CCG leads 7 days (including weekend) to complete a post infection review of the patient's journey prior to acquiring the MRSAb. This process will involve all clinicians recently involved with the patient and will include looking through patient records and attending a PIR meeting to establish an accurate timeline for the patient (similar to previous RCA investigations with a greatly reduced time frame for completion). The patient will be informed of the PIR process. The PIR process will be led by the CCG that the patient GP is linked to, in all cases classed as community acquired i.e. patient has MRSA positive blood culture

sample taken within 48 hours of admission to hospital –these cases will be attributed to the CCG that the patients GP is linked to. All MRSA positive blood cultures taken 48 hours after admission are classified as acute trust acquired and the PIR process will be led by the acute trust. These cases will be attributed to the acute trust objective

In all MRSAb cases a full case review will be required. Community patient information will be required to assist with this process and may be obtained by CCG PIR lead or Infection Control Matron Public Health this may include GP records, care home records and other records relating to community care to establish an accurate timeline for the patient prior to admission (as with the previous RCA process). During this time the GP practice may be requested to allow access to the patient record where this is not possible clinicians will have to be directly involved in the PIR process, clinical engagement will be required for all community acquired MRSAb cases. The outcome of the process is to help identify factors that may have contributed to an MRSAb, in order to prevent a similar occurrence, this includes non-optimal practice. Lessons learned are to be shared across healthcare providers to reduce the risks of re-occurrence.

This process involves all clinicians recently involved with the patient and will include looking through patient records and attending a PIR meeting to establish an accurate timeline for the patient (similar to previous RCA investigations with a greatly reduced time frame for completion). The patient will be informed of the PIR process. The PIR process will be led by the CCG that the patient GP is linked to, in all cases classed as community acquired i.e. patient has MRSA positive blood culture sample taken within 48 hours of admission to hospital –these cases will be attributed to the CCG that the patients GP is linked to. All MRSA positive blood cultures taken 48 hours after admission are classified as acute trust acquired and the PIR process will be led by the acute trust. These cases will be attributed to the acute trust objective

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Clostridium difficile

Clostridium difficile cases need reporting as an SI as follows:

- Classified as 1a and 1b on the death certificate where it is clear Clostridium difficile has made a significant contribution to cause of death. The Consultant responsible for managing patient care at time of patient's death is accountable /required to decide whether Clostridium difficile was a contributory factor of death.
- Cases where a serious complication including colectomy arise due to Clostridium difficile

All the following Hospital and Community based infection outbreaks should be reported as SIs:

- Result in high mortality for staff, patients or the community
- Involve highly virulent and transmissible organisms

- Require control measures that have an impact on the care of other patients, including limitation of access to healthcare services or where business continuity will be affected
- Are sufficiently serious to require the convening of an incident team and/or are transmissible with an impact on staff, patients or the community
- Infected healthcare worker or patient incidents necessitating consideration of look back investigation (e.g. TB, vCJD, blood borne infections)

Significant breakdown of infection control procedures with an actual or potential for cross-infection (e.g. release of products from a failed sterilisation cycle, contaminated blood transfusion).

Norovirus Out-Breaks
In December 2010 NHS East Midlands issued instructions for the reporting of Norovirus out-breaks as SIs and these still apply:

"Inpatient Providers *(Including Acute Trusts, Mental health and Learning Disabilities, Prison Health, Community Providers). Either of the following two triggers will result in the organisation reporting an SI 1. One or more wards closed due to Norovirus 2. An outbreak meeting has been called.*

For all other providers (Nursing Homes, Residential Home, Care Homes) *The current system will remain in place where all outbreaks will be reported to the HPA. The HPA will share the information they have with all Directors of Infection Control in Primary and Secondary care, Public Health England, Public Health, Microbiologist and Ambulance Trust. On the occasion where a HCAI is relevant to more than one organisation it is expected that organisations work together to ensure an appropriate investigation is undertaken and lessons learned and disseminated. The commissioning organisation will act as arbitrator where any doubt as to ownership.*

Definitions
Cases are defined as suspected or confirmed as follows:

A suspected case of Norovirus:
a) Vomiting: Two or more episodes of vomiting of suspected infectious cause* occurring in a 24 hour period
b) Diarrhoea: Two or more loose stools in a 24 hour period*
c) Diarrhoea and vomiting: One or more episodes of both symptoms occurring within a 24 hour period *

*not associated with prescribed drugs or treatments and not associated with reaction to anaesthetic or an underlying medical condition or existing illness.

A confirmed case of Norovirus:
a, b or c above with microbiological confirmation

Norovirus outbreaks:
Suspected outbreak - two or more cases, as defined above, occurring in a functional care unit within the hospital without laboratory confirmation.

Confirmed outbreak - as above with laboratory confirmation

3.17 Maternity Services

Maternal death
Death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or

aggravated by the pregnancy or its management but not from accidental or incidental causes (WHO 2011). This will include:

Direct
Deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above (Centre for Maternal and Child Enquiries, 2011).

Indirect
Deaths resulting from previous existing disease, or disease that developed during pregnancy and which is not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy (CMACE 2011).

Pregnancy-related death
Death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of death where cause of death attribution is inadequate (WHO 2011)

Late Maternal death
Deaths occurring between 42 days and 6 months after delivery or end of pregnancy that are the direct result of *Direct* maternal causes.

Unexpected death
Deaths occurring after 42 days following delivery or end of pregnancy that are a result of *Indirect* maternal causes.

Trusts will need to follow the guidance on reporting and investigating SIs from the LSA (http://www.eastmidlands.nhs.uk/about-us/the-local-supervising-authority-midwifery/).

The following national maternity and new born categories have been added to STEIS and need to be reported as SIs. In some cases the investigation of these incidents will be in addition to the Local Supervising Authority of Midwives investigation. Where possible they should be aligned:

- Maternal death- specifically those that occur whilst under booked care
- Intra uterine deaths- those over 37 weeks gestation
- Intra partum death- specifically those that die during labour or during an inpatient admission
- Unexpected neonatal death- specifically from 37 weeks gestation to 28 days post delivery
- Maternal unplanned admission to ITU (Level III admissions only):
  - Patients requiring advanced respiratory support alone or
  - basic respiratory support together with support of at least two other organs
  - Includes complex patients requiring support for multi-organ failure
- Unexpected admission to NICU (neonatal intensive care unit)-specifically those with Apgar Score below 4 at five minutes
- Serious Drug Administration Errors will be reported as per SI Policy
- Surgical Operative Obstetric Errors as per SI Policy
- Lost Cytology/Histopathology Tissues or Errors as per SI policy

3.18 Loss of Confidential Information

Trusts will need to follow the latest Department of Health Guidance – Checklist for Reporting, Managing and investigating Information Governance Serious Incidents Jan 2009: http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/security/risk/ which states that “any incident involving the actual or potential loss of personal

information that could lead to identity fraud or have other significant impact on individuals should be considered as serious".

The immediate response to the incident and the escalation process for reporting and investigating will vary according to the severity of the incident. An incident should be categorised at the highest level that applies when considering the characteristics and risks of the incident. Trusts should report all incidents rated as 1 – 5. This scale is usually referred to as the Matthew Swindell's scale or checklist.

SI LEVEL 0	SI LEVEL 1		SI LEVEL 2		
0	1	2	3	4	5
No significant reflection on any individual or body. Media interest very unlikely.	Damage to an individual's reputation. Possible media interest e.g. celebrity involved	Damage to a Team's reputation. Some local media interest that may not go public.	Damage to a service's reputation. Low key local media coverage.	Damage to an organisation's reputation. Local media coverage.	Damage to NHS reputation. National media coverage.
Minor breach of confidentiality. Only a single individual affected.	Potentially serious breach. Less than five people affected or risk assessed as low e.g. files were encrypted.	Serious potential breach and risk assessed high e.g. Unencrypted clinical records lost. Up to 20 people affected.	Serious breach of confidentiality. E.g. Up to 100 people affected.	Serious breach with either particular sensitivity e.g. sexual health details or up to 1000 people affected.	Serious breach with potential for ID theft or over 1000 people affected.

The AT Communication Team will be responsible for notifying the DH of any category 3-5 incident reported by forwarding details to the appropriate dedicated mailbox established within the DH. Incidents falling within the top row definitions must be notified to DH Comms. Incidents falling within the definitions in the darkest shaded area must be reported to both DH Comms and the NHS Business Unit.

A checklist and guidance for IG incidents can be seen in appendix 7.

Additional Guidance for SIs Linked to IT Incidents

*NHS Clinical Safety Management System aims to ensure that IT systems implemented in hospitals, GP practices, pharmacies, prisons and other healthcare environments are delivered, deployed and operate in an acceptably safe manner for patients (**NHS Connecting for Health (CfH) Clinical Safety Incident Management Process)** and comply with DSCN 14/2009 (System Suppliers) and 18/2009 (Organisations).*

Serious Incidents (including near misses that have put patients at risk) because of IT system failure/misuse, must be reported in accordance with this policy. Examples are:

- *Loss of clinical data due to adverse event with no back up available;*
- *Data corruption, such as incorrect merging of clinical records;*
- *Inappropriate access to clinical records, such as incorrect procedure followed to ensure correct patient identified;*
- *Misuse of access rights, such as using smartcard to view persons clinical records where no legitimate relationship (not under individual or services care) for clinical care exists;*
- *IT related Clinical incidents involving software within the CfH product set should also be reported to the IT Local Help desk initiating CfH processes to be undertaken in parallel*

3.19 Screening Incidents

National screening programmes are public health interventions, which aim to identify disease or conditions in defined populations in order to either reduce morbidity or mortality. Screening programmes are sometimes made complicated because the activity of screening often takes place within pathways across several organisations.

Often there are a wider range of organisations involved including those at a national level and organisations who externally quality assure the screening programmes. Therefore the management of a SI becomes complicated with the potential to cause delay or confusion. For this reason a policy for managing serious incidents in screening has been developed by the regional Directors of Public Health.

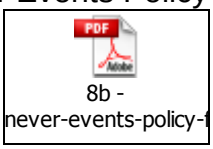
The policy states that a screening SI is: An actual or possible failure at any stage in the pathway of the screening service, which exposes the programme to unknown levels of risk that screening, and assessment or treatment of screen-positive people have been inadequate, and hence there are possible 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.

3.20 Never Events

Never events are serious, largely preventable patient safety incidents that should not occur after the preventable measures have been implemented. The *Never events Framework -2012/13* (updated January 2012) provides the list of never events: http://www.dh.gov.uk/health/2012/01/never-events-update/

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 or HLA-incompatible Organs
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

For further information regarding Never Events please refer to the embedded version of the Never Events Policy below:



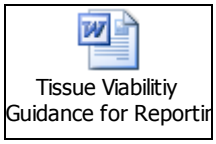
Area Team have stipulated that additional information is required from providers: When a Never Event is reported provider organisations are required to provide the following specific (anonymised) information for each member of staff involved:

- When was their last appraisal
- Did it the appraisal include (relevant to the issue) adherence to the WHO Surgical Checklist
- Whether this is the first issue with which the individual has been involved
- What remedial or disciplinary action has/ is being considered or has been taken to that point
- Referral to a professional body - GMC, NMC, HPC, status of that referral to date.

This information should form part of the 72 hour (early management) report and this should be submitted to the commissioners. The final investigation report must also include a full update on this issue. The Commissioner will forward the 72 report to the Area Team Patient Safety Team. Organisations may wish to use a recognised tool such as the Incident Decision Tree, when assessing whether management action may be appropriate.

3.22 Pressure Ulcers

Pressure ulcers of grade 3 and 4 are to be reported as a serious incident on STEIS and to clarify the process reporting guidance has been developed by called Tissue Viability Guidance or Reporting and Safeguarding, see embedded below.



3.23 Health and Safety

NHS Nottingham West, Rushcliffe and Nottingham North and East CCGs have a separate Health and Safety Policy which provides a framework for the management of health and safety. It relates to an organisation's responsibility to its employees, contractors and visitors and clarifies the individual legal responsibilities for health and safety and the roles of individuals within each organisation.

Accidents, incidents and near misses are reported by completing an Incident Report form which is logged onto the incident database by the Quality Team employed by NHS Nottingham North and East CCG. A member of the Quality Team will ensure that an investigation is carried out by the relevant manager and that this is also logged onto the incident database.

If the incident is building related, the NHS Property Services Incident/Near Miss Reporting form should also be completed.
Any incident which falls within the categories outlined in Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR), is reported by the Quality Team within the time scales set out in the Regulations (RIDDOR 1995). The HSE website (www.hse.gov.uk/riddor/what-must-i-report.htm) gives information about what must be reported, as well as what does not have to be reported.

The Director of Quality and Patient Safety is responsible for ensuring that the individual Governing Bodies are apprised of health and safety matters.

The Health and Safety Policy sets out a proactive approach to the management of health and safety, outlining a system of risk assessment and management which will assist the CCGs to identify and eliminate hazards and control risks associated with their business.

SECTION 4.0

Duties

4.1 ***Area Team –*** The AT, as part of its assurance and performance role is required by the Department of Health to receive information on all serious incidents via the healthcare commissioners and the contractual arrangements with the providers from whom they commission services for NHS patients. This will encompass all providers of health in the region care to NHS patients, including foundation trusts, primary care independent contractors, independent sector treatment centres, prison healthcare and any others providing care to NHS patients. The Area Team will support the commissioners as a critical friend supplying them with benchmarked information and offering solutions for improvement.

The Area Team will work in partnership with Commissioners and provider organisations to provide leadership and vision for patient safety throughout the region, encouraging openness and the development of a learning culture, providing support and expert advice to shape and train the workforce enabling Commissioners and CCGs to have the capacity and capability to effectively undertake their role, and support providers in carrying out local investigations.

Where Commissioners have a SI within its own working practices, the AT will monitor the progress of the investigation and assure itself that a robust, systematic investigation has been conducted.

Area Team also has statutory responsibility for the regional Local Supervising Authority for Midwifery Services. All SIs, as defined in the LSA Guideline '*Reporting and Monitoring of Serious Incidents and Events'* July 2006, must be reported to the LSAMO and reported as a SI on the Strategic Executive Information System (STEIS). Other midwifery incidents which are not deemed a SI but are reportable under the LSA guideline do not require reporting on STEIS (please see page 12 for the link).

Area Team remains responsible for reviewing all homicides committed by mental health service users and other very serious incidents as determined by the Policy for Managing and Investigating the Most Serious Events in Mental Health Services, June 2008. The AT will inform the Commissioners where this is the case. The AT will therefore subsequently review the internal investigation reports to establish whether the criteria for commissioning an independent investigation has been met. Where indicated Area Team will commission the investigation and liaise with relevant stakeholders where appropriate, publish the findings, ensure an action plan is developed locally and share learning across the NHS. It will also performance monitor action plans to ensure safety is paramount.

Communications and media relations is an integral part of the SI process. Area Team will work with commissioners and provider organisations to ensure that where a serious incident could attract media attention, appropriate media handling strategies are put in place. Where political interest is likely the Area Team will liaise with the NHS Business Unit at the Department of Health on behalf of the region.

4.2 ***The Commissioner*** will, as part of their commissioning role, performance monitor the contract in place with all its provider organisations as required by the AT. They will receive from their provider's information regarding all Serious Incidents and related investigation reports. This is required to:

- Inform future commissioning discussions
- Ensure that questions from the public and or media can be managed appropriately
- Support good governance

- Ensure any relevant remedial action is made as soon as possible
- Ensure appropriate engagement in a joint investigation.

Some provider organisations provide services to two or more commissioners, where this is the case local agreement needs to be reached as to how the contract will be performance monitored. This function is the responsibility of the Co-ordinating Commissioner. The Co-ordinating Commissioner therefore needs to provide board to board assurance to all key stakeholders that the commissioning arrangements for managing serious incidents are in place and robust.

The Commissioners of the reporting providers will provide clarity to all organisations when more than one provider within its locality is involved in a serious incident and if required, the Commissioner will advise on whom the co-ordinating organisation should be and identify the key stakeholders. If however any of the providers involved are outside of the commissioner's boundary then the AT must be informed. The AT will then assist in the decision as to the co-ordinating organisation.

Where the majority of its services are commissioned out of region, further discussions will need to take place with the relevant Strategic Health Authorities to ensure there is clarity in the responsibilities and expectations of each.

Throughout the year, the Commissioners will produce and review at board level reports on provider SIs. At the end of the financial year it is expected that the Commissioners will report to the public part of their Board, the total number of never events and incidents of data loss for their provider organisations.

4.3 ***Provider Organisations*** - providers of healthcare to NHS patients are required to report to the Commissioner those incidents that fulfil the SI criteria outlined within this policy. This would include NHS Foundation Trusts, the Independent Sector, and Care Homes where the NHS is paying for the care provided.

Chief Executives of the provider organisations are required to identify an Executive Lead for the management of incidents. The Executive Lead will be required to implement an effective risk management system, providing staff with a clear framework for prompt incident reporting, including training and support ensuring that appropriate actions are taking place, that risk is mitigated and there is a strong culture of learning and improvement.

If more than one provider within the locality is involved in a SI, the organisation that has identified the incident will inform its co-ordinating commissioner. The provider organisations will decide on who the co-ordinating organisation will be and notify the respective commissioner. If however any of the providers involved are outside of the commissioners locality or region then the AT will be informed and advise. The co-ordinating organisation will, in discussion with the aforementioned organisations, arrange a meeting that includes all key stakeholders to establish the scope of the investigation and terms of reference. At this meeting a lead professional of an appropriate level and seniority will be nominated to lead the investigation. All key stakeholders will contribute and work together with the nominated lead to ensure a comprehensive report is produced.

All provider organisations need to ensure they have a mechanism in place for regularly reporting all incidents, including SIs to the NHS England Patient Safety Team through the Reporting and Learning System.

Provider organisations must inform the commissioner if they are considering commissioning services (or parts of) through other organisations. The Commissioners will assist the provider in developing a robust contract / Service level agreement to ensure patients safety is incorporated in line with this policy.

Provider organisations are responsible for the completion of all relevant sections on STEIS and updating the account with the outcomes of the RCA/PIR investigation.

SECTION 5.0

Reporting Requirements

5.1 In addition to an executive lead identified to manage the SI process, each Provider will nominate an appropriate senior member of staff to be the main contact with the Commissioner. In their absence, including out of hours, a suitable deputy will be available (e.g. Director on call).

5.2 In Office Hours 09:00 to 17:00

The Commissioner will ensure that all SIs that fulfil the national SI definition are reported by their provider organisations within 2 working days of becoming aware that an SI has occurred. If the provider organisation is unclear that an incident fulfils the SI reporting criteria they must discuss with the commissioner who will advise on the necessity of reporting on to STEIS and the grade of incident to be reported. The 'Grade 0' incident category can be used where there is uncertainty if an incident fulfils SI criteria. In these cases the provider will need to update the status of the incident within 3 working days once it has been established whether it is an actual SI. STEIS link: www.performance.doh.gov.uk/steis.

The Commissioner will ensure that providers in the interests of confidentiality and the Data Protection Act complete entries to STEIS and subsequent investigation report entries/submissions with anonymised information. It must not contain the names of practitioners or patients. To this end reporting from any service will be anonymous, with the proviso that there is an audit trail on a 'need to know' basis. If the SI merits the necessity of identifying the individual(s) concerned, a senior member of the Area Team will contact the Trust to discuss the incident and ascertain more detailed information. The Data Protection Act (1998) will be adhered to at all times.

Trusts experiencing difficulties completing STEIS may contact their commissioners for guidance. The regional administrator can with the agreement of the provider and commissioning organisation transfer or remove duplicate or inaccurate STEIS entries.

If the commissioner becomes aware of an incident that is high profile and likely to attract media attention / other external interest the CCG must have a robust process in place so that Area Team Clinical Directorate on 0115 968 4521 is contacted immediately.

5.3 Out of Hours 17:01 to 08:59

It is the responsibility of the provider organisation to ensure that internal Out of Hours systems are in place to support the reporting of high profile SI's to the Commissioner Director On-Call (see page 3 for telephone number). Please provide the following information in your message:

- Name
- Organisation
- Message and contact telephone number

The following incidents must be reported by the CCG in a timely manner to the Area Team Director On Call. Where there is any doubt, the Commissioner is required to contact the Area Team Director on call for advice:

- Incidents which necessitate activation of the NHS Trust or CCG Major Incident Plan and where the Area Team needs to take action e.g. attendance of Area Team Director required at multi-agency gold command.
- Incidents that will give rise to significant media interest or will be of interest to other agencies such as the Police or other external agencies.

- Incidents that will be of significant public concern.

The Director receiving the call out of hours will in discussion with the NHS organisation make the decision to notify other Area Team senior managers out of hours and the DH Media Centre. Area Team will contact the NHS organisation on the next working day to receive a verbal progress report and discuss ongoing management of the SI, briefing other senior managers and the DH media centre as appropriate. The SI module of STEIS should be completed as Appendix 1 flow chart.

SECTION 6.0

Reporting and investigation outcomes

6.1 The Commissioner will review all SIs reported within 2 working days. Where a SI is reported by a provider organisation which is graded Level 2 and involves another organisation out of Area Team boundary, discussions with the AT will take place to ensure appropriate management.

The Commissioner will ensure that all SIs reported by their provider organisations are subject to a systematic investigation at a level appropriate to the seriousness of the incident and should meet the 'Minimum Standards for Investigation, Reports and Action Plans' (appendix 8, 9 and 10).

If the police or Health and Safety Executive (HSE) are involved in any SI then the principles outlined in the Memorandum of Understanding between the Police, HSE and DH should be followed (DH Guidance 22/11/2006). The purpose of the protocol is to promote effective working relationships setting out general principles when liaising with each other. A decision to report an incident to the Police or HSE needs to be made at a sufficiently senior level.

All NHS organisations must comply with the Data Protection Act, therefore when reporting a SI the investigation reports must not contain names or identifiable information. It is the responsibility of the organisation that generated the investigative report to retain the document for a period of 30 years. Copies shared with other organisations must be transported safely (physically or electronically) between organisations and in accordance to local policies and procedures. Those copies shared may be destroyed in accordance with the local confidentiality procedure once the report is no longer of use.

6.2 Grading of Serious Incidents

Once an incident has been reported the provider organisation will allocate a grading; 0, 1 or 2. Reported incidents are reviewed by the Commissioner within 2 working days. If the organisation has not graded within 3 working days the Commissioner will apply a grade. Please see following table outlining the relevant timescale per grade:

This table provides a guide to the grading of serious incidents for investigation purposes.

Incident Grade	Example Incidents (these are suggestions, not definitive)	Investigation Grade and action	Timeframe	Commissioner responsibility
1	**Grade 1 incident examples:** Apparent suicide of people currently under the care of community mental health services. Mental health inpatient attempted suicides. Avoidable or unexplained death. Failure to meet standards for ambulance service response times, resulting in patient death/severe harm HCAI outbreaks. Grade 3 and 4 pressure ulcers. Data loss & information security (DH Criteria level 2)[xiv]. Adult safeguarding incident.	**Investigation Level 1** Concise root cause analysis (RCA) for incidents involving No Harm and Low Harm and/or where the circumstances are very similar to other previous incidents. In these cases it is more proportionate to use a concise RCA to ensure there are no unique factors and then focus resources on implementing improvement than conducting comprehensive investigations that will not produce new learning. These will be a small minority of cases. **Investigation Level 2** Comprehensive RCA for incidents involving moderate and severe harm or death. This should be the default level for most incidents	Following **initial** reporting **within 2 working days**, the provider organisation must submit a completed investigation **within 45 working days**	Seek assurance and evidence from the provider that relevant policies and procedures are in place and implemented, for example by reviewing a sample of incident investigations and action plans as well as monitoring serious incident data trends. Close incidents after receipt of evidence demonstrating that local monitoring arrangements are in place to ensure action points are going to be implemented.
2	**Grade 2 incident examples:** Inpatient suicides (including following absconsion) Maternal deaths Child protection incidents Never events Accusation of physical misconduct or harm Data loss and information security (DH Criteria level 3-5)[xv]	**Investigation Level 2** Comprehensive RCA (note NHS trusts should directly notify the NTDA of Grade 2 serious indcidents)	Following **initial** reporting **within 2 working days**, the provider organisation must submit a completed investigation **within 60 working days**	Likely to involve specific assistance with and contribution to the incident response and investigation. Close incident after receipt of evidence demonstrating that each action point has been implemented is required
	Selected Grade 2 incidents: The need for independent investigations is identified and arranged by the commissioner or NHS CB, for example a major system failure with multiple stakeholders Homicides following recent contact with mental health services require an independent investigation[xvi]. These will be commissioned by the relevant NHS CB area team.	**Investigation Level 3** Independent RCA (note NHS trusts should directly notify the NTDA of Grade 2 serious incidents)	Following **initial** reporting **within 2 working days** independent investigators should be commissioned to complete an investigation **within 6 months**	As for Grade 2 above but in addition, commissioning the independent investigation.

Requesting 72 hour reports

There may be occasions when the Commissioner requires additional information following any STEIS notification dependent on the detail provided within the initial STEIS notification. This is most likely (but not restricted) to apply to grade 2 and above incidents. The Commissioner will contact the relevant Provider for additional information (72 hour reports) as required. This report should, as a minimum, contain an overview of events (as understood at the time of reporting), any key critical questions which the investigation will be seeking to examine and actions taken to mitigate any identified risks and to minimise the risk of recurrence. Providers should ensure that reports are submitted promptly and within three working days of the request.

6.3 Senior Briefing

To ensure that Directors and their deputies are informed of potentially volatile SIs, the Clinical Quality and Patient Safety Team at the AT occasionally provide a senior briefing to the executives at the Regional Commissioning Board. Each SI reported on to STEIS is individually reviewed by the AT for senior briefing.

Below is a list of incidents that require briefings; however this is not an exhaustive list:

- Unexpected deaths related to out of hours or urgent care
- SIs involving high profile prisoners
- All unexpected child deaths and cases that may lead to serious case review or domestic homicide review
- Adult protection
- Never events
- Significant data losses

6.4 Investigation Timescales

The amount of time allowed for an investigation differs depending on the grade of incident. (see table above guide to grading).

MRSA bacteraemia cases have a 7 calendar day timescale to complete a Post Infection Review starting from the date the case was reported on the HCAI Data Capture System. Ref: Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections from April 2013 – NHS Commissioning Board

6.5 Extensions

Extensions may be requested in accordance with the Extension Criteria on the appropriate form (see appendix 12 and 13). The extension request should be submitted in a timely manner and will be agreed on a case by case basis.

6.6 Level of Investigation/Root Cause Analysis (RCA)/Post Infection Review

Provider organisations will ensure that they have staff trained in best practice root cause analysis methodologies and techniques. It is good practice to assemble an investigation team for an incident allowing a wider range of areas to be considered. Members of the investigation team must have no conflict of interest in the incident concerned. Once a team is assembled, Terms of Reference should be drawn up to ensure each member of the investigation team is aware of their responsibilities.

Comprehensive Root Cause Analysis (RCA Level 2) Investigation
A comprehensive (RCA level 2) investigation will be:

- Conducted with a high level of detail, including all elements of a thorough and credible investigation
- Conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s).
- Where possible, conducted by staff not involved in the incident, locality or directorate in which it occurred.
- Overseen by a director level chair or facilitator.
- Led by person(s) experienced and/or trained in RCA, human error and effective solutions development.
- Includes patient/relative/carer involvement and should include an offer to patient/relative/carer of links to independent representation or advocacy services in line with Being Open.
- May require management of the media via the organisation's communications department.
- Includes robust recommendations for shared learning, locally and/or nationally as appropriate.
- Results in full report with an executive summary and appendices.

Independent (RCA level 3) Investigation
An independent (RCA level 3) investigation will be:

- Commissioned and co-ordinated by the Area Team and independent to the provider organisation service/s and organisation/s involved in the incident
- Commonly considered for incidents of high public interest or attracting media attention.
- An independent investigation must be conducted for mental health homicides (where there has been recent contact with mental health services) that meet Department of Health guidance.
- Should be conducted where Article 2 of the European Convention on Human Rights is, or is likely to be, engaged.

6.7 Risk assessments

Following a Serious Incident, as with all untoward incidents and near misses, all related risk assessments must be reviewed and the risk register updated.

6.8 Action Plans (see appendix 9 for action plan minimum standards and appendix 11 for action plan template)

Each investigation will provide an action plan to ensure, where possible, reduced risk of recurrence, addressing both latent and active failures.

Each recommendation determined by an investigation should have a corresponding action with a clear deadline and responsible person allocated. Implementation and completion of action plans will be monitored through Commissioner SI Review Groups/Meetings.

The Commissioner CCG will review all submitted investigations within 20 working days and feed back their findings to the provider organisations, requesting further development and/or information were necessary within agreed timescales.

Organisations should ensure that any relevant patient safety alerts (such as Central Alert System [CAS] or Rapid Response Reports [RRR]) have been referenced and considered.

The provider organisation will confirm completion of the action plan by email to the commissioner.

6.9 Patient Involvement

Patients, families and carers involved in adverse incidents should expect openness and honesty from providers and the services commissioned by them, with timely communication essential to this principal. Effective communication with patients begins at the start of and throughout their care and this should be no different when a patient safety incident occurs. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the physical and psychological consequences of what happened. This principle is called Being Open, in line with the Duty of Candour. Where a provider is found to have failed to be open, through a direct or indirect notification received from a patient or someone acting on their behalf (including a clinician), or through any other means, the commissioner shall implement the consequences outlined in the Duty of Candour

It is equally important that they continue to receive support to cope with the physical and psychological effects of an incident and receive the appropriate required care. Patients, families and carers should also be kept informed of any changes implemented or ongoing actions as a result of an adverse event, and receive assurances that similar events will not occur again. Adopting an open and honest approach when things go wrong is fundamental to the partnership between patients and those who provide their care.

If patients, carers or families decide not to be involved in the investigation process or informed of an investigation outcome they will be informed that they may change their mind and request the information at any time.

6.10 Quality Critique of Final Reports

Commissioners to critique the quality and content of all final RCA reports received (see Appendix 6 for critique tool)

6.11 Updating STEIS/HCAI DCS with investigation outcomes

When the investigation has been completed provider organisations will update the ‘root causes and lessons learnt’ section of STEIS / HCAI DCS. The information provided should include key details of the investigation including an overview of the incident, findings, contributory factors, root causes, recommendations and actions.

SECTION 7.0

Monitoring Compliance

7.1 The Commissioner will performance manage Providers against:

- Appropriateness of the Incident Reporting Policy that the provider has in place.
- Appropriateness of reporting - The number of incidents reported in total, the number of incidents reported that do not fulfil the criteria.
- Timeliness of reporting in accordance with the standards laid out in this policy – The time lapse between the date the incident occurred and the date reported (verbally as well as on STEIS). The majority of SIs should be reported within 48 hours or 2 working days.
- Quality of investigation and report provided (fulfils at least the minimum requirement as laid out in the policy as appendix 8).
- Reported incidents are reviewed by the Commissioner within 3 working days. If the organisation has not graded within 3 working days the Commissioner will grade.
- Investigation conducted within agreed timescale.
- Commissioner reviews investigation report within 20 working days.
- Learning is disseminated.
- Action plans are implemented within agreed timescales

7.2 This information will be measured through a variety of methodologies such as performance data, audit and review of documentary evidence which demonstrates compliance (linked to CQC Standards and NHSLA).

SECTION 8.0

Related Documentation

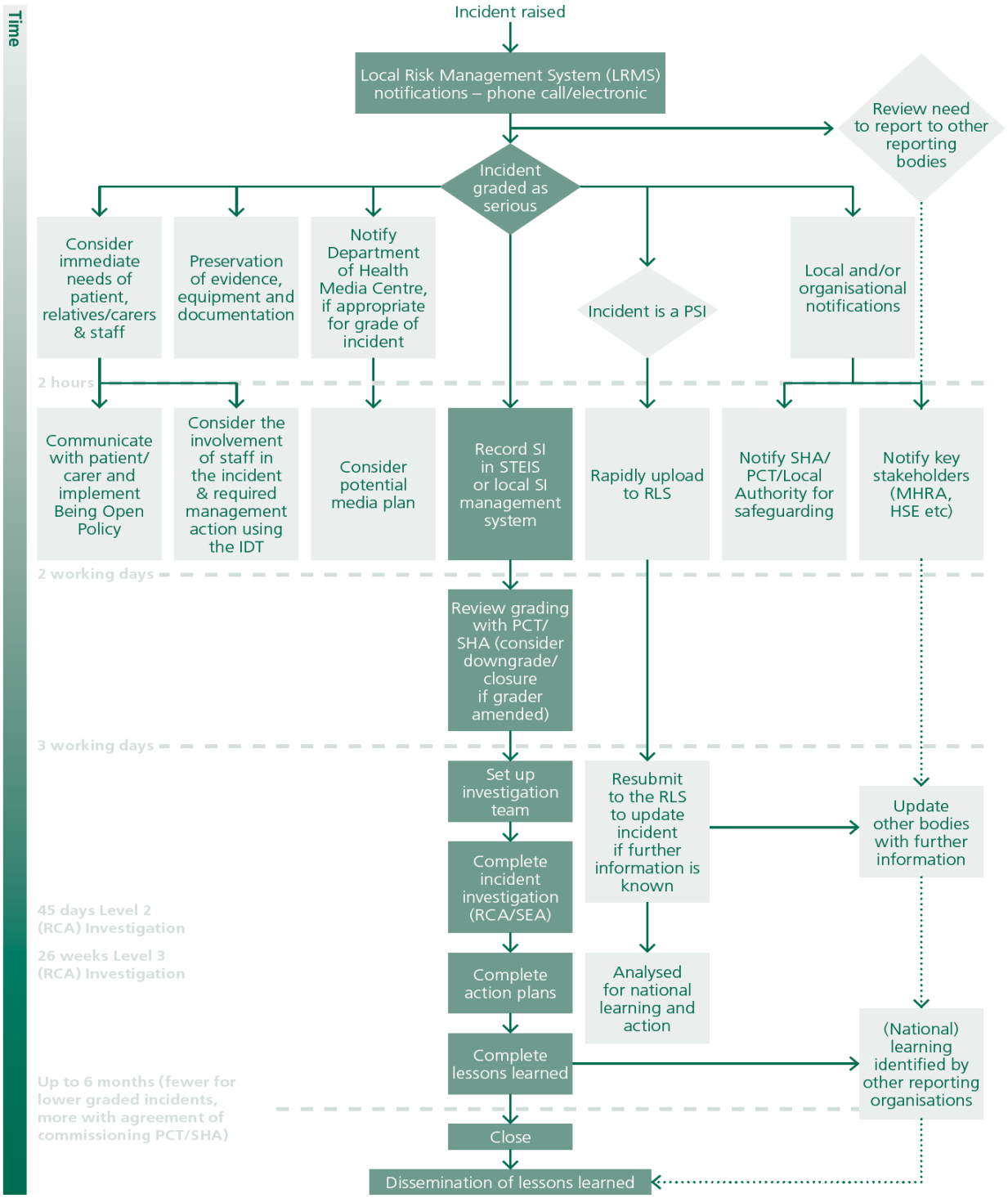
8.1 A number of documents relate to the management of SIs, which should be followed as appropriate in individual cases:

- Child protection procedures in respect of children who have been or are suspected of being abused
- Safeguarding Adults policies
- DH guidance on Serious Adverse Events relating to the discharge of mentally disordered people and their continuing care in the community relating to: violent incidents, victims under 18 years of age, or homicides and suicides (HSG (94) 27 and amendments).
- Retained Organs Good Practice guidance
- NHS Complaints Procedure
- Major Incident Plan/Event policies
- Memorandum of Understanding
- Being Open Policy
- Policy framework for the reporting and briefing of incidents and issues in high security hospitals
- Deaths in Custody Guidelines
- Protocol on Managing Adverse Events in Mental Health Services
- Information Governance and Code of Conduct guidelines
- Tissue Viability Guidance or Reporting and Safeguarding

APPENDIX 1

REPORTING FRAMEWORK FLOWCHART

Serious Incident Reporting Process

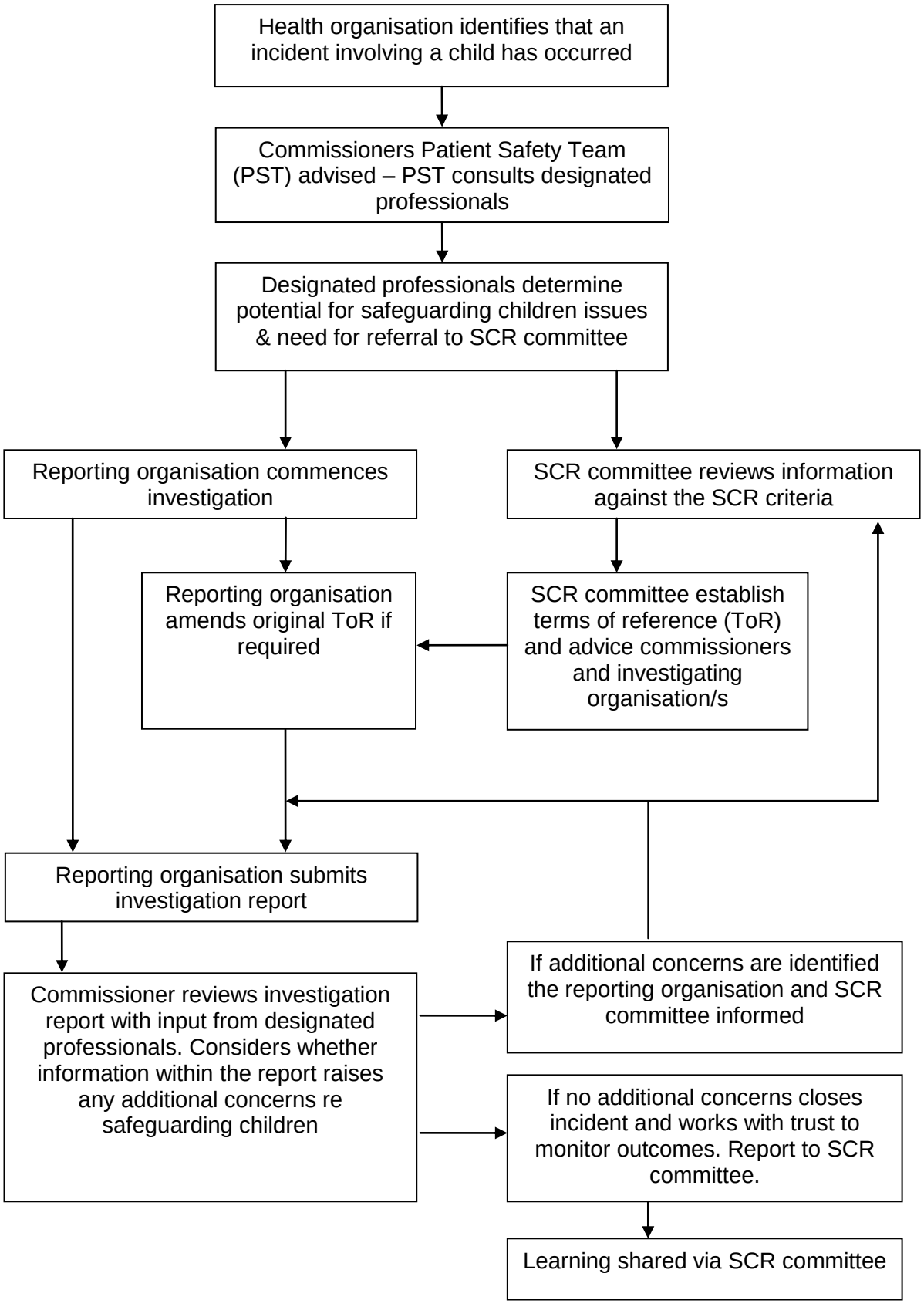


Abbreviations:

IDT: Incident Decision Tree
PSI: Patient Safety Incident
RLS: Reporting & Learning System
SEA: Significant Event Audit
RCA: Root Cause Analysis
SI: Serious Incident

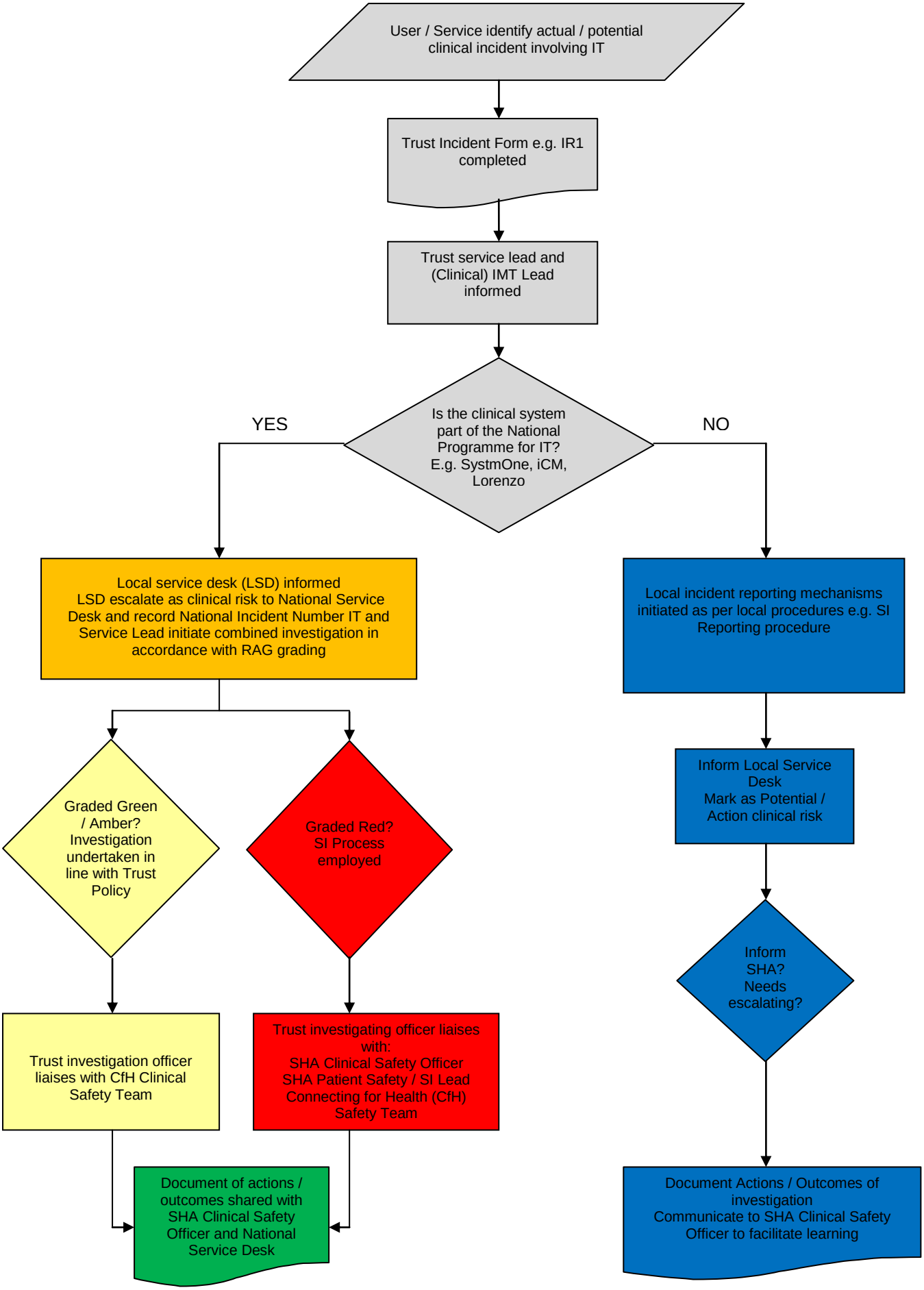
APPENDIX 2

FLOWCHART – INTERFACE BETWEEN SERIOUS INCIDENTS AND SERIOUS CASE REVIEW



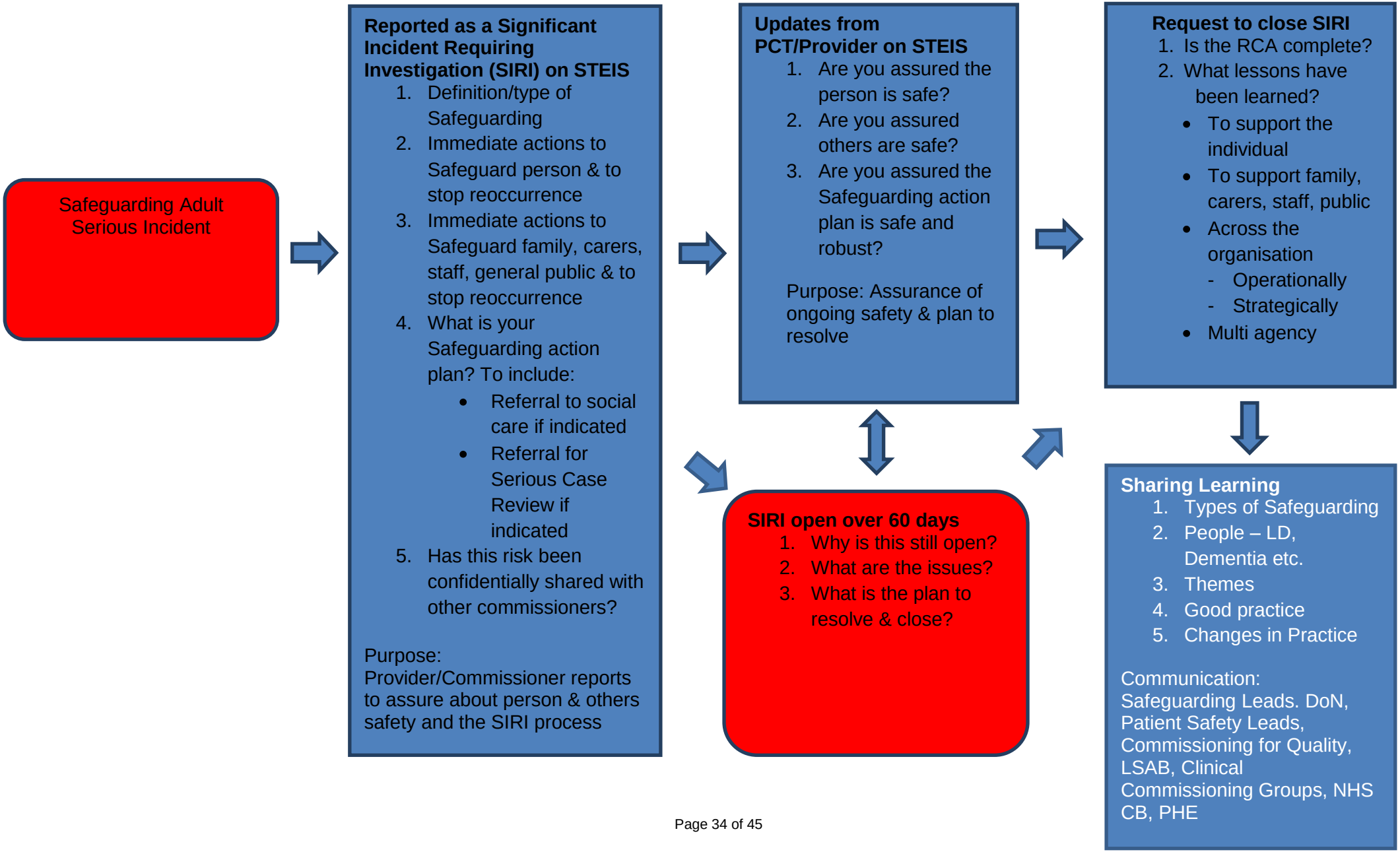
APPENDIX 3

IT CLINICAL INCIDENT MANAGEMENT PROCEDURE



APPENDIX 4

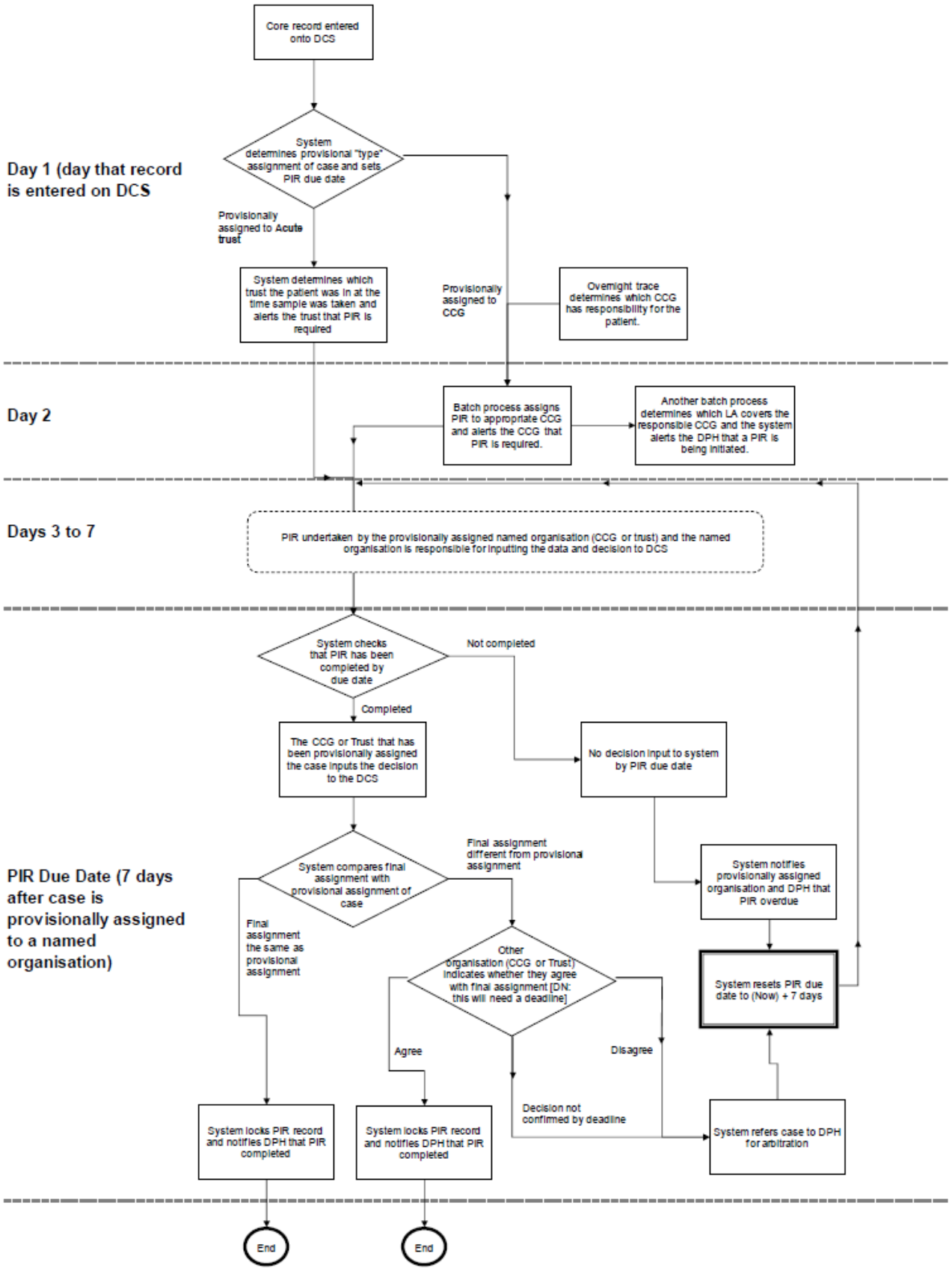
Safeguarding Adults – Serious Incident Reporting Flowchart



APPENDIX 5

PIR PROCESS

Completing the PIR



APPENDIX 6

FINAL REPORT CRITIQUE TOOL

PART 1 - CLINICIAN TO CRITIQUE THE REPORT			
REPORTING ORGANISATION:		**GRADE**	
SI INCIDENT TYPE:		**STEIS NUMBER:**	
DATE SUBMITTED FOR CLOSURE:		**JOINT Area Team CLOSURE**	
CRITIQUED BY:		**DATE CRITIQUED:**	

REPORT SECTIONS	SECTION REQUIREMENTS	RATING	COMMENTS / RECOMMENDATIONS
Cover page	Organisation Logo		
	STEIS Number		
	Authors		
	Report date		
	Document version		
1. Executive Summary	Executive Summary Included		
	Brief Incident description		
	Recommendations		
	Actions taken		
2. Investigation Procedure & Methodology	Terms of Reference - outline of investigation plan, scope & Investigation team membership and who commissioned the investigation		
	How/what information is to be gathered e.g. interviews, case note reviews etc. List of Data Sources.		
	Incident type		
	Level and type of investigation conducted		
3. Introduction	Brief description of the patient, history of previous care/relevant patient information and diagnosis/reason for admission/treatment provided.		
	Outline of relevant local and national policy / guidance in place at time		
4. Incident Description	Incident description		
	Incident type/Category		
	Specialty / Service(s) involved, description and size of clinical team		
	Actual effect on patient + or service		
	Concise incident description including brief chronology		

	Severity of incident		
5. Analysis & Findings	Timeline (referencing the appendix timeline tool)		
	Chronology of Events (including dates, events and notable practice)		
	Clearly identifies Care & Service delivery problems (E.g. Tabular timeline, barrier analysis)		
	Identify any themes or ongoing issues		
	Clearly Identifies any contributory factors including, where applicable, the Root Cause (E.g. 5 whys, fishbone, NPSA taxonomy)		
	Findings are evidence based, factual (not opinion)		
6. Being Open	Description of support provided for patient, relatives and staff		
7. Actions Taken	Outline actions that have been taken		
8. Conclusion	Should answer the critical questions in the ToR and links back to analysis and findings		
9.Recommendations	Directly linked to the contributory factors and the investigative opinion.		
10. Lessons learned	Positive features		
	Mitigating factors		
	Changes already made		
11. Action plan & Monitoring Arrangements	Adopts 'SMART' principles (Specific, Measurable, Achievable, Responsible and Timed)		
	Action plan addresses contributory factors and recommendations		
	Description of arrangements for monitoring action plan.		
	Expected Completion Date		
12. Follow up and sharing	Where and how will the information be shared and what will be the follow up arrangements		
13. Appendices	List of documents reviewed		
	Terms of Reference		
	Action Plan		
	Any other appendices		
Overall report features	Anonymous		
	Jargon free / plain English		
	Clinical content is appropriate		
	Critically evaluating care provided in a non-defensive/open manner		
Totals per RAG rated colour:		**0**	**0**	**0**
Overall Report Rating:			

Colour Key:	**Green** = Yes / Good / Satisfactory (able to close)	**Amber** = No / Average / Adequate (further info/work required)	**Red** = No! / Poor/Not Provided / Inadequate (Re-submission required)

APPENDIX 7

IG CHECKLIST

Information required by the Department of Health for category 3+ SI Unique SI Reference:	
Initial assessment of level of SI (1-5):	
Area Team:	
Local Organisation(s) involved:	
Required Information	**Check**
01 Date, time and location of the incident	
02 Confirmation that DH guidelines for incident management are being followed and that disciplinary action will be invoked if appropriate	
03 Description of what happened: Theft, accidental loss, inappropriate disclosure, procedural failure etc.	
04 The number of patients/ staff (individual data subjects) data involved and/or the number of records	
05 The type of record or data involved and sensitivity	
06 The media (paper, electronic, tape) of the records	
07 If electronic media, whether encrypted or not	
08 Whether the SI is in the public domain and whether the media (press etc.) are involved or there is a potential for media interest	
09 Whether the reputation of an individual, team, an organisation or the NHS as a whole is at risk and whether there are legal implications	
10 Whether the Information Commissioner has been or will be notified and if not why not	
11 Whether the data subjects have been or will be notified and if not why not	
12 Whether the police have been involved	
13 Immediate action taken, including whether any staff have been suspended pending the results of the investigation	
14 Whether there are any consequent risks of the incident (e.g. patient safety, continuity of treatment etc.) and how these will be managed	
15 What steps have been or will be taken to recover records/data (if applicable)	
16 What lessons have been learned from the incident and how will recurrence be prevented	
17 Whether, and to what degree, any member of staff has been disciplined – if not appropriate why?	
18 Closure of SI – only when all aspects, including any disciplinary action taken against staff, are settled.	
Notes:	

APPENDIX 8

MINIMUM STANDARDS FOR INVESTIGATION REPORTS

Body of report must contain:

Cover Page	Organisation Logo Author(s) Incident Number (STEIS) Headline Report date Document Version Page & Paragraph should be numbered
Contents Page	List of sections and page numbers
Executive Summary (Graded Level 1 or 2)	Max 2 sides of A4 to include: Incident description and consequences Level of investigation conducted Care + service delivery problems Contributory factors (root cause) Recommendations Sharing arrangements Action plan (part of full report)
Terms of reference	At what point does the investigation start and stop e.g. episode of care. Outline the terms of reference agreed by the key stakeholders (including family where appropriate)
Summary of the incident	Outline briefly the incident and what makes this incident a SI. Incident type, specialty involved, effect on patient and severity of incident should be included.
Background	Include a brief description of the patient, their medical needs, the care and treatment provided. The service type, size of clinical team, the experience and skills of the staff involved in the incident and their training records. Also explain the relevance of local and national policy / guidance at the time of the incident.
Investigation methodology	Brief description of the type of investigation – narrow / broad, single / aggregate. How the information was gathered – e.g. interviews, clinical records, statements, management reports. Type of RCA tool used
Being open	Description of support provided to the patients involved, their relatives and staff.
Chronology of events	Description of the event taken from the tabular timeline (this should be attached as an appendix)
Discussion – **Analysis and findings**	This section should demonstrate critical analysis of the event and provide findings and conclusions based on evidence. This section needs to clearly identify the care and service delivery problems and analysis of each using a recognised RCA methodology to identify the causal factors The contributory factors will fall into one of the NPSA taxonomies, it may be useful to identify these:

	• Individual Factors • Team and Social Factors • Communication Factors • Task Factors • Education and Training Factors • Equipment and Resource Factors • Working Conditions • Organisational and Strategic Factors • Patient Factors
Lessons Learnt	Things that went well and things that went badly. This could relate to the incident or the investigation process.
Recommendations	These need to directly link to the key learning points (care and service delivery problems) and address the problem not the symptoms. Be clear and concise and kept to a minimum and designed to reduce the likelihood of recurrence or severity. They need to be specific, measureable, realistic and timed (SMART)
Conclusion	Summary of the key findings and should answer the questions posed in the terms of reference.
Implementation, monitoring & evaluation	Describe the arrangements for the local monitoring of the action plan, arrangements for evaluating long term solutions i.e. risk register
Arrangements for sharing and learning	Describe how the lessons learned will be disseminated with staff, other organisations such as the Commissioner for local learning, the SHA for regional learning, and the NPSA for national learning.
Appendices	• List of documents reviewed • Root Cause Analysis tools; timeline, fishbone diagrams, 5 whys etc • Any associated policies / guidelines that are too complicated to explain fully in the report • Terms of Reference • Action Plan

APPENDIX 9

MINIMUM STANDARDS FOR ACTION PLANS

The action plan must define:

- Who has agreed the action plan
- Who will monitor the implementation of the action plan
- How often the action plan will be reviewed
- Who will sign off the action plan when all actions have been completed

The action plan must contain:

Recommendations based on the contributing factors	These should be the analysis and findings of the investigation – the recommendations from the report
Action agreed	This should be the actions the organisation needs to take to resolve the contributory factor.
Level of recommendation	Does this action need to be taken as: • Unique – specific to the area • Common – organisation specific • Universal – have regional / national significance
By who	Who in the Trust will ensure the action is completed
Planned Action Start Date	Date at which the organisation intends to start the particular action.
Planned Action End Date	Target date for completion of the action.
Resource requirements	To be able to complete the action, what resources are required?
Evidence of completion	What evidence will be available to demonstrate that the action has been completed?
Sign-off	Date when the action has been completed.

APPENDIX 10

MINIMUM STANDARDS FOR 72 HOUR REPORT

Body of report must contain:

Cover Page	Organisation Logo Author(s) Incident Number (STEIS) Headline Report date Page & Paragraph should be numbered
Summary	Incident Description (What happened) Incident Type (Category of Incident i.e. Delayed Diagnosis) Speciality / Service Actual effect on patient and or service (Any immediate risks must be identified and mitigation of outstanding risks) Severity of incident (e.g. Size of incident, number affected)
Investigation Information	Immediate Action(s) Taken Chronology of Events (including dates, events and notable practice) Investigation Plan (Terms of Reference if completed. Clearly state any other agencies involved and / or notified)
Being open	Description of anticipated support to the patients involved, their relatives and staff.

APPENDIX 11

ACTION PLAN TEMPLATE

Action Plan Developed by:		***Date:***	
Action Plan signed off by:		***Date:***	

Recommendations	**Level of Recommendation Unique Common Universal**	**Agreed Action**	**By Whom**	**Planned Action Start Date**	**Planned Action End Date**	**Resources Required** (risk vs benefit vs cost)	**Expected Outcome**	**Evidence of Completion**	**Sign Off**

APPENDIX 12

EXTENSION PROCESS

All providers are given 45 working days to complete a full RCA and produce a Final Report and Action Plan following a Serious Incident. If circumstances arise that result in the provider organisation being unable to meet the timescales an extension can be requested, however these will only be granted under the following circumstances:

REASON	RATIONALE	GENERAL SIs
Sickness / availability / absence of a **key** individual (Failure by the provider to co-ordinate internal discussions is not a sufficient reason and no extension will be granted)	If short-term sickness / absence – CCG to consider length of absence and extend accordingly **If long-term sickness / absence (exceeds 20 working days) – a contingency plan must be in place to ensure that the report is investigated within the agreed timeframe.**	Negotiation of extension up to a **MAXIMUM** of 20 working days
Multi-agency / third party involvement or referral to Professional body CCG expect a written update at time of (each) extension request	If a serious incident investigation involves multi-agencies and a delay is encountered	Negotiation of extension up to a **MAXIMUM** of 20 working days (or at discretion of CCG when appropriate)
Other exceptional circumstances	Anything that does not fit within the above categories will be considered on a case-by-case basis.	Negotiation of extension up to a **MAXIMUM** of 20 working days

ANY REQUEST FOR AN EXTENSION SHOULD BE PUT FORWARD TO THE CCG AS SOON AS THE PROVIDER IS AWARE THAT THE DEADLINE WILL NOT BE MET.

APPENDIX 13

SERIOUS INCIDENT FINAL REPORT EXTENSION REQUEST FORM

1. ORGANISATION & SI INFORMATION

Reporting Organisation:	
Name of person completing the form:	
STEIS Number:	
Headline:	
B/F Date (issued by CCG):	
Date extension request made:	

2. REASON FOR EXTENSION:

Reason for Request:	**Please tick one box:**
Short term sickness / absence	☐
Multi-agency involvement	☐
Other	☐
If 'Other' was selected, please specify details:	
Please specify the length of extension required by the number of working days	☐ **days** (not to exceed 20 working days)

3. FORWARDING THE REQUEST

Once this form has been completed, please email it to your Commissioning SI Monitoring Team at the following email address:
liz.gundel@nottinghamnortheastccg.nhs.uk