NHS
County Durham
Clinical Commissioning Group

Corporate	CCG CO18 – Serious Incident Management Policy

Version Number	Date Issued	Review Date
V1.2	December 2020	December 2022

Prepared By:	Clinical Quality Manager North of England Commissioning Support
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Formally Approved:	September 2021
Approved By:	Executive Committee
Policy Adopted from:	Serious Incident Management Policy (1.1)

EQUALITY IMPACT ASSESSMENT

Date	Issues
Sept 2019	See Appendix 2

POLICY VALIDITY STATEMENT

This policy is due for review on the latest date shown above. After this date, policy and process documents may become invalid.
Policy users should ensure that they are consulting the currently valid version of the documentation.

ACCESSIBLE INFORMATION STANDARDS

If you require this document in an alternative format, such as easy read, large text, braille or an alternative language please contact cdccg.enquiries@nhs.net

Version Control

Version	Release Date	Author	Update comments
V1	April 2020	Clinical Quality Manager North of England Commissioning Support	First issue
V1.1	December 2020	Clinical Quality Manager North of England Commissioning Support	Extension request. No legalisation updates or impact to external environment factors.
V1.2	September 2021	Clinical Quality Manager North of England Commissioning Support	Amendments made in line with national guidance.

Approval

Role	Name	Date
Approval (1)	Combined Management Group	10 March 2020
Approval (1.1)	Executive Committee	December 2020
Approval (1.2)	Executive Committee	September 2021

Contents

1. INTRODUCTION

The Clinical Commissioning Groups (CCGs) aspire to the highest standards of corporate behaviour and clinical competence, to ensure that safe, fair and equitable procedures are applied to all organisational transactions, including relationships with patients their carers, public, staff, stakeholders and the use of public resources. In order to provide clear and consistent guidance, the CCGs will develop documents to fulfil all statutory, organisational and best practice requirements and support the principles of equal opportunity for all.

The NHS treats over one million patients every single day. The vast majority of patients receive high standards of care however incidents do occur and it is important they are reported and managed effectively.

The CCGs as Commissioners, seek to assure that all services which may be commissioned meet nationally identified standards and this is managed through the local contracting process. Compliance with Serious Incident (SI) and Never Event (NE) reporting is a standard clause in all contracts and service level agreements as part of a quality schedule.

The role of the CCGs as Commissioners is to gain assurance that incidents are properly investigated, that action is taken to improve clinical quality, and that lessons are learnt in order to minimise the risk of similar incidents occurring in the future. It is intended that intelligence gained from SIs will be used to influence quality and patient safety standards for care pathway development, service specifications and contract monitoring.

The revised policy is intended to reflect the responsibilities and actions for dealing with SIs and NEs and the tools available to support the process.

The policy outlines the process and procedures in place to ensure that SIs and NEs are identified, investigated and learned from as set out in the Serious Incident Framework published in March 2015 and the revised Never Event Framework published in January 2018. The updated Framework replaces those documents published in 2013.

1.1 Status

This is a corporate policy and outlines the Serious Incident (SI) Policy for the CCG.

1.2 Purpose and scope

1.2.1 The purpose of this policy is to identify what is meant by a SI or NE and to describe the role and responsibilities of commissioners and or other commissioned organisations when a SI or NE occurs.

This policy aims to ensure that the CCGs as Commissioners comply with current legislation as well as current national guidance, NHS England and requirements with regard to accident/incident reporting generally, but in particular reporting, notifying, managing, investigating and learning from SIs and NEs.

1.2.2 This policy applies to all employees of the CCGs and is recommended to independent contractors e.g. GPs, Dental Practitioners, Optometrists and Pharmacists.

1.2.3 All NHS providers including Independent Healthcare Sector providers, where NHS services are commissioned, need to comply with the CCGs' reporting requirements within this policy, which reflects the SI and NE frameworks described in section 1.

1.3 Policy Statement

It is the duty of each NHS body to establish and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare provided by and for that body. The CCGs as commissioners of services are committed to this policy and the implementation of a consistent approach to the implementation of robust arrangements for the management of SIs and NEs.

2. DEFINITIONS

The following terms are used in this document

2.1 Definition of a Serious Incident & Never Event

2.1.1 Serious incidents are events in health care where the potential for learning is so great, or the consequences to patient, families and carers, staff or organisations are so significant that they warrant particular attention to ensure these incidents are identified correctly, investigated thoroughly and most importantly, learned from to prevent the likelihood of similar incidents happening again. Serious incidents can extend beyond incidents that affect patients directly and include incidents that may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

2.1.2 NHS England has produced an information resource to support the reporting and management of serious incidents which can be found in The SI Framework and supporting appendices (Appendix 3). It is noted that NHS England has launched a Patient Safety Strategy (July 2019) which states that a New Patient Safety Incident Response Framework (PSIRF) is planned for the future which will replace the existing framework. A date for publishing is yet to be confirmed.

2.1.3 Whilst the definition of a SI is quite broad, the following criteria outline the type of incidents which should be included:

1. Unexpected or avoidable death of one or more people. This includes:

   - Suicide/self-inflicted death
   - Homicide by a person in receipt of mental health care within the recent past

2. Unexpected or avoidable injury to one or more people that has resulted in serious harm.

3. Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:

   - The death of the service user
   - Serious harm
   - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment or acts of omissions which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern slavery, coercion and control, exploitation and radicalisation

4. Never Events - All NEs are defined as serious incidents although not all NEs necessarily result in serious harm or death. Further information can be found at: https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

5. An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

   Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 5 for further information);

   - Property damage
   - Security breach/concern
   - Incidents in population-wide healthcare activities such as screening or immunisation programmes where the potential for harm may extend to a large population;
   - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards, including those for 16-17 year olds (MCA DOLS);
   - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
   - Activation of Major Incident Plan (by provider, commissioner or relevant agency)

6. Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation including national incidents such as terrorism.

2.2 Working with other Organisations/Sectors

2.2.1 *Deaths in Custody*

- People in custody, including those detained under the Mental Health Act (1983) or those detained under the police and justice system, are owed a duty of care by relevant authorities. The obligation on the authorities to account for the treatment of an individual is particularly stringent when that individual dies.

- Any death in prison or police custody will be referred to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Healthcare providers must fully support these investigations where required to do so.

- In NHS Mental Health services, providers must ensure any death of a patient detained under the Mental Health Act (1983) is reported to the Care Quality Commission (CQC) without delay. However, providers are responsible for ensuring that there is an appropriate investigation into the death of a patient detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies. In circumstances where the cause of the death is unknown and/or where there is reason to believe the death may have been avoidable or unexpected then the death must be reported to the provider's commissioner(s) as an SI and investigated appropriately.

2.2.2 *Child Safeguarding Practice Reviews and Safeguarding Adult Reviews*

- The Local Authority via the local Safeguarding Children Partnership or local Safeguarding Adult Board has a statutory duty to investigate certain types of safeguarding incidents/concerns.

- Healthcare providers must contribute towards safeguarding reviews as required to do so by the Local Safeguarding Board/Partnerships. Where it is indicated that a serious incident within healthcare has occurred.

- The interface between the serious incident process and local safeguarding policies must therefore be articulated in the local multi-agency safeguarding policy and protocol.

2.2.3 *Domestic Homicide Reviews*

- Where a Domestic Homicide is identified by the police, the Community Safety Partnership (CSP) will consider if the case meets criteria for Domestic Homicide Review (DHR)

2.2.4 *Homicide by patients in receipt of mental health care*

- Where patients in receipt of mental health services commit a homicide, NHS England will consider and, if appropriate, commission an investigation. This process is overseen by NHS England's Regional investigation teams.

2.2.5 *Serious Incidents in National Screening Programmes*

2.2.5.1 There are a number of immunisation or screening programmes which require a broader approach to handling incidents.

2.2.5.2 Public Health England's (PHE) Quality Assurance Service is responsible for surveillance and trend analysis of all screening incidents. It will ensure that the lessons learned from incidents are collated and disseminated nationally.

2.2.5.3 Screening SIs are often complex, multi-faceted incidents requiring robust coordination and oversight by Screening and Immunisation Teams working within Sub-regions and specialist input from PHE Screening Quality Assurance Service.

2.2.5.4 Further details on the management of incidents within the screening programme are available in "Managing Safety Incidents in NHS Screening Programme"

https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

2.2.5.5 For SIs linked to national screening programmes (e.g. ante natal and child health screening, retinal screening etc.) the Regional Screening Lead will provide advice to local organisations and will inform the national coordinating bodies as appropriate.

2.2.5.6 The flow chart for managing screening incidents can be found in Appendix 4.

2.3 Information Governance and Cyber Security Serious Incidents requiring Investigation

2.3.1 There is no simple definition of an information governance serious incident. The scope of an Information Governance Serious Incident may include:

- A breach of one of the principles of the Data Protection Act and/or the Common Law Duty of Confidentiality.

- Unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.
- Personal data breaches which could lead to identity fraud or have other significant impact on individuals.

2.3.2 There are many possible definitions of what a Cyber incident is, for the purposes of reporting the definition is anything that could (or has) compromised information assets within Cyberspace. "Cyberspace is an interactive domain made up of digital networks that is used to store, modify and communicate information. It includes the internet, but also the other information systems that support businesses, infrastructure and services." These types of incidents could include:

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

2.3.3 NHS Digital has provided guidance for how SIs relating to how information governance and cyber security should be included at a local level. The guidance is accessible via https://www.dsptoolkit.nhs.uk/

2.3.4 The General Data Protection Regulation (GDPR)/UK Data Protection Bill imposes legal obligations on controllers to comply with the requirement to report specific breaches to the Information Commissioner's Office (ICO) without undue delay and no later than 72 hours of becoming aware of such a breach, where the breach is likely to result in a risk to the rights and freedoms of individuals.

2.3.5 GDPR/UK Data Protection Bill requires that a controller informs individuals affected by a breach of their personal data of the breach without undue delay, where the breach is likely to result in a risk to the rights and freedoms of individuals.

2.3.6 Any incident involving the actual or potential loss of personal information that involves a high risk to the rights and freedoms of individuals should be considered as potentially serious and advice should be sought from the IG service.

2.3.7 Where an IG incident impacts upon a patient's rights and freedoms it must be reported to the Clinical Quality team so they can report it through the STEIS system as soon as possible (and no later than 24 hrs. after the incident during the working week). These must be categorised in STEIS using the "Confidential Information Leak/IG Breach" category. NHS England is responsible for notifying the Department of Health of any category 3-5 incident and will do this as soon as possible after they have been made aware of such an incident (either through STEIS or other means)

2.3.8 Individual organisations are responsible for following the Health and Social Care Information Centre's (NHS Digital) Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation. Incidents which score Level 2 or above must be reported centrally via the Information Governance Toolkit. If a CCG is unsure of the level of the incident, further guidance can be sought from the Commissioning Support Unit's Information Governance Team.

2.3.9 Consideration should always be given to informing patients/service users when person identifiable information about them has been lost or inappropriately placed in the public domain.

2.3.10 Loss of encrypted media should not be reported as a SI unless the data controller has reason to believe that the encryption did not meet the Department of Health Standards that the protections had been broken, or were improperly applied.

2.4 Serious Incidents involving controlled drugs.

2.4.1 SIs that involves controlled drugs must also be notified to the North of England Commissioning Support Medicines Optimisation Team: nescu.moadmin@nhs.net

3. REPORTING AND MANAGEMENT OF SERIOUS INCIDENTS

3.1 Independent Healthcare sector

3.1.1 The Independent Healthcare Sector (IHS) should be subject to contractual obligations for the reporting of SIs. The CCG should ensure that appropriate reporting arrangements are in place with the IHS in relation to SIs (Appendix 8).

3.1.2 The commissioning CCG should ensure that IHS SIs are reported via STEIS and investigated appropriately.

3.1.3 Once an SI is identified, the Procedure for the Reporting and Management of Independent Healthcare Sector Serious Incidents should be followed (Appendix 8).

3.2 Guidance for Commissioned Services/Providers

3.2.1 Each NHS Trust/organisation must nominate a single point of contact or lead officer for managing all SIs.

3.2.2 Organisations should ensure that mechanisms are in place to report all incidents meeting the criteria.

3.2.3 The SI lead officer must report a SI through STEIS within 2 working days of Identification of the SI, completing all relevant sections. At this stage it is important that any immediate learning is included in this report.

3.2.4 If appropriate, the SI lead officer must liaise with the organisation's communications team who will liaise directly NHS England Communications team.

3.2.5 The organisation must then submit a 72hr report to North of England Care System Support Organisation (NECS) (as the responsible delegate for CCGs) as identified in their legally binding contract. The report should include more detailed information regarding the event, immediate learning and how the Root Cause Analysis (RCA) will be conducted.

3.2.6 Under the Data Protection Act (2018) organisations need to be open and transparent with regards to investigation processes, unless there are specific exceptions. Arrangements may need to be put in place to support patients and family members through the investigation process and sharing of the outcomes of investigations. The appointment of a Family Liaison Officer may be appropriate.

3.2.7 If an incident spans organisational boundaries, **it is the responsibility of the organisation where the incident took place** to formally report it through STEIS. All other additional organisations involved must contribute and fully cooperate with the process in line with the agreed timescales. Where there is doubt about who should report the incident then clarity must be sought through the North of England Commissioning Support Clinical Quality Team.

3.2.8 If an incident involves more than one NHS organisation a decision will be made (mutually agreed) as to which is the lead investigating organisation. Where an incident involves the independent sector or contracted services, it is the role of the commissioning CCG to lead. The RASCI (Responsible, Accountable, Supporting, Consulted, Informed) model should be completed in order to assign accountability.

3.2.9 This guidance must not interfere with existing lines of accountability and does not replace the duty to inform the police and/or other organisations or agencies where appropriate. Further guidance can be obtained from the Department of Health publication *Memorandum of Understanding: Investigating Patient Safety Incidents* June 2004 and accompanying NHS guidance of December 2006. The need to involve outside agencies should not impede the retrieval of immediate learning.

3.2.10 Incidents which have impacted or have had potential to impact on children and/ or vulnerable adults must be investigated in conjunction with the identified safeguarding lead and in accordance with related guidance. Assurance must be provided by the commissioned service that multi-agency safeguarding policies and procedures have been applied. Consideration is currently being given regionally as to whether such incidents are STEIS reportable given they are managed outside of this process. Once a formal agreement is reached, this policy will be amended accordingly.

3.2.11 Where an incident is subject to the involvement of a coroner, an independent inquiry, safeguarding review or any safeguarding issues, this should be highlighted clearly within the STEIS report as this may affect closure date.

3.2.12 Where an incident meets the criteria of the Every Baby Counts programme, it is acknowledged that an independent investigation will be undertaken by the Healthcare Safety Investigation Branch (HSIB); however HSIB will be required to seek permission from the family prior to commencement. Whilst this will not prevent organisations undertaking their own investigation, the practicalities of two investigations should be taken into account. If a provider opts out of undertaking their own investigation, they will be required to submit the STEIS notification and a 72 hour report. The final report will be submitted by HSIB.

3.2.13 Organisations should undertake investigation procedures / root cause analysis (RCA) as per organisation policy and submit to the responsible body within the agreed timescales. An example for the contents of a report and action plan can be found in Appendix 6**.** To ensure confidentiality all reports submitted to the CCGs or North of England Commissioning Support Clinical Quality Team should be anonymous and sent via the agreed STEIS NHS.net account. NECS will conduct a quality assurance check on all RCAs on behalf of the relevant CCG in order to ensure the 20 day deadline is met.

3.2.14 Where an incident occurs within a service that is commissioned by NHS England (Specialised Commissioning), CCGs will receive the STEIS alert only. Any subsequent documentation prepared by the Provider will be submitted to NHS England for review and closure.

3.2.15 Where an SI occurs, the Provider must enact Duty of Candour and ensure that they are open and honest with their service users and/ or family and alert them to the incident, offer apologies and advise of the actions that will be taken as a result of this. The affected patient and /or family should also be offered the opportunity to review the final investigation report.

3.3 Independent Contractors

3.3.1 Once an SI is identified, in a CCG commissioned service, the Independent Contractors Procedure for the Reporting and Management of Serious Incidents should be followed, or where applicable NHS England should be notified. This is explicit in Appendix 7.

3.3.2 Where an SI raises professional concerns about a GP, CCG local arrangements for assuring high standards of professional performance should be invoked, where this is applicable or NHS England notified.

3.3.3 Independent Contractors should have systems in place to ensure that staff are supported appropriately following the identification of a SI.

3.4 NHS Providers

3.4.1 Once an SI is identified, the Provider's Procedure for the Reporting and Management of Serious Incidents should be followed (Appendix 8).

3.4.2 Providers should have systems in place to ensure that staff are supported appropriately following identification of a SI.

3.5 Staff Involved in Serious Incidents

3.5.1 Serious incidents can be distressing for those involved.

3.5.2 The Director, Assistant Director or appropriate Manager should ensure that staff are supported at all stages of a SI with reference to CCG Human Resources (HR) policies.

3.5.3 The Director, Assistant Director or appropriate Manager are responsible for ensuring that a de-briefing session occurs at an appropriate stage following a SI.

3.5.4 If, during the course of a SI investigation, it becomes apparent that a member of staff may be subject to a disciplinary hearing, appropriate advice and support should be taken via HR - and the relevant policy followed, including the allegations against staff policy.

3.6 Information for Education and Training Organisations

3.6.1 In the event an incident involves a student or trainee, the relevant academic institution will be notified by the NHS Trust/CCG as appropriate.

3.6.2 Where a SI concerns the commissioning or provision of medical or dental education or training, or a medical or dental trainee or trainees, there will be appropriate communication between the CCG and Health Education England.

3.7 CCG Management and Closure of Serious Incidents

3.7.1 The CCG is responsible for quality assuring the robustness of its providers' serious incident investigations and the action plan implementation.

3.7.2 The CCG is responsible for evaluating investigations and gaining assurance that the processes and outcomes of investigations include identification and implementation of improvements that will prevent recurrence of serious incidents.

3.7.3 In order to achieve this, the CCG has established the Serious Incident Closure Panel and the terms of reference can be found in Appendix 9.

4. IMPLEMENTATION

4.1 This policy will be available to all staff for use in the circumstances described on the title page.

4.2 CCG directors and managers are responsible for ensuring that relevant staff within the CCG have read and understood this document and are competent to carry out their duties in accordance with the procedures described and this will form part of staff induction processes.

5. TRAINING IMPLICATIONS

5.1 The Sponsoring Director will ensure that the necessary training or education needs and methods required to implement the policy are identified and resourced or built into the delivery planning process. This may include identification of external training providers or development of an internal training process.

5.2 The level of training required in incident reporting and management will vary depending on the level and responsibility of the individual employee.

5.3 The training required to comply with this policy is key to the successful implementation of the policy and embedding a culture of incident reporting and management in the organisation. Through a training and education programme, staff will have the opportunity to develop more detailed knowledge and appreciation of the role of incident reporting and management. Training and education will be offered through a rolling programme of incident reporting and management training.

6. FAIR BLAME

6.1 The CCG is committed to a policy of 'fair blame'. In particular, formal disciplinary procedures will only be invoked following an incident where:

- There are repeat occurrences involving the same person where their actions are considered to contribute towards the incident
- There has been a failure to report an incident in which a member of staff was either involved or about which they were aware (failure to comply with organisation's policy and procedure)
- In line with the organisation and/or professional regulatory body, the action causing the incident is removed from acceptable practice or standards, or where
- There is proven malice or intent

Fair blame means that the organisation:

- Operates its incident reporting policy in a culture of openness and transparency which fulfils the requirements for integrated governance
- Adopts a systematic approach to an incident when it is reported and does not rush to judge or 'blame' without understanding the facts surrounding it

- Encourages incident reporting in the spirit of wanting to learn from things that go wrong and improve services as a result

6.2 Support for staff, and others

When an incident is reported it can be a stressful time for anyone involved, whether they are members of staff, a patient directly involved or a witness to the incident. They all need to know that they are going to be treated fairly and that lessons will be learned and action taken to prevent the incident happening again.

7. DOCUMENTATION

7.1 Other related policy documents

7.1.1 *Legislation and statutory requirements:*

- Serious Incident Framework (March 2015)
- Revised Never Events Policy and Framework (January 2018)

7.2 Best practice recommendations

- Managing Safety Incidents in NHS Screening Programmes (August 2017)
- NHS Digital: Guide to the Notification of data Security and Protection Incidents (September 2018)

7.3 A Just Culture Guidance

In March 2018 NHS Improvement published 'A just culture guide' which replaced the National Patient Safety Agency (NPSA) incident decision tree. The fair treatment of staff supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame. Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated. The guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely.

It asks a series of questions that help clarify whether there truly is something specific about an individual that needs support or management versus whether the issue is wider, in which case singling out the individual is often unfair and counter-productive. It helps reduce the role of unconscious bias when making decisions and will help ensure all individuals are consistently treated equally and fairly no matter what their staff group, profession or background.

The guide should not be used routinely. It should only be used when there is already suspicion that a member of staff requires some support or management to work safely, or as part of an individual practitioner performance/case investigation. An individual practitioner performance investigation when it is suggested a single individual needs support to work safely (including training, supervision, reflective practice, or disciplinary action), as opposed to where a

whole cohort of staff has been identified, which would be examined as part of a safety investigation. The guide does not replace the need for patient safety investigation and should not be used as a routine or integral part of a patient safety investigation. This is because the aim of those investigations is system learning and improvement. As a result, decisions on avoidability, blame, or the management of individual staff are excluded from safety investigations to limit the adverse effect this can have on opportunities for system learning and improvement.

8. MONITORING, REVIEW AND ARCHIVING

8.1 Monitoring

The Governing Body will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

8.2 Review

8.2.1 The Governing Body will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

8.2.2 Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The governing body will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

8.2.3 For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the sponsor director and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

8.3 Archiving

The Governing Body will ensure that archived copies of superseded policy documents are retained in accordance with Records Management Code of Practice for Health and Social Care 2016.

APPENDIX 1: SCHEDULE OF DUTIES AND RESPONSIBILITIES

Council of Members	Have delegated responsibility to the governing body (GB) for setting the strategic context in which organisational process documents are developed, and for establishing a scheme of governance for the formal review and approval of such documents.
Chief Officer	The Chief Officer has overall responsibility for the strategic direction and operational management, including ensuring that CCG process documents comply with all legal, statutory and good practice guidance requirements. The Chief Officer has responsibility for ensuring that the CCG has the necessary management systems in place to enable the effective management and implementation of all risk management and governance policies and delegates the responsibility for the management of SIs to the Executive Lead for Patient Safety and Safeguarding**.**
Director of Nursing and Quality	The Director of Nursing and Quality has overall responsibility for ensuring the necessary management systems are in place for the effective implementation of serious incident reporting for the CCG and delegates management of SIs and reporting to the NECS Clinical Quality Manager. The Director or Nursing and Quality will also ensure: • The incident management process is robust and adhered to. • Incidents are maintained and managed in timely manner. • Mechanisms are in place within the organisation for regular reporting and monitoring of incident themes and lesson learned.
Line Managers	The service leads have the responsibility: • To support their staff to maintain the incident policy and to manage individual incidents in accordance with policy. • To work closely with the Director of Nursing and Quality to ensure a transparent and consistent approach to incident management across the CCG in partnership with key stakeholders. All line managers and supervisory staff are responsible for the adherence and monitoring compliance within this policy. Managers have responsibility for promoting the policy directly with their staff and, where appropriate, taking Directorate responsibility for the co-ordination of investigations in support of the Executive Lead for Patient Safety and Safeguarding, which is the Director of Nursing and Quality

All staff	All staff, including temporary and agency staff, are responsible for: • Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken. • Co-operating with the development and implementation of policies and procedures as part of their normal duties and responsibilities. • Identify the need for a change in policy or procedure as a result of becoming aware of changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising there line manager. • Attending training/awareness sessions when provided.
CCG Safeguarding Teams	The CCG Safeguarding Teams will be asked to contribute to or oversee the safeguarding component of any serious incident
North of England Commissioning Support (NECS) Clinical Quality Manager	The NECS Clinical Quality Manager will • Consider if a serious incident falls into the category of a STEIS reportable SI and report accordingly. • Review clinical quality incidents reported by the CCG. • Provide clinical quality incident reports as requested. • Provide advice and guidance to key stakeholders, including CCG staff
North of England Commissioning Support (NECS) Senior Medicines Optimisation Pharmacist	The NECS Senior Medicines Optimisation Pharmacist has Responsibility for ensuring that all SIs in relation to controlled drugs are investigated appropriately and liaison with the Controlled Drugs Local Intelligence Network (LIN).
North of England Commissioning Support (NECS) Senior Governance Officer	NECS Senior Governance Officer will: • Provide incident management support and advice. • Produce CCG reported incident reports as requested. • Identify trends, lessons learned and themes in incident reporting in order to identify any issues of concern for the CCG. • Provide training and assistance to the CCG in incident reporting and management in the SIRMS system. • Manage the administration of the SIRMS database. • Undertake an incident investigation in conjunction with CCG managers if required e.g. health and safety and IG incidents.

North of England Commissioning Support (NECS) Information Governance Lead	NECS Information Governance Lead has the responsibility to: • Provide information governance support to staff in the organisation. • Co-ordinate different areas of information governance and to ensure progress against key standards and requirements. • In collaboration with IT, develop, implement and monitor information security across the organisation. • Support the CCG in evidence collation, upload and publicise the IG Toolkit.
All Independent Contractors (e.g. GPs, Dental Practitioners, Optometrists and Pharmacists)	This policy is recommended to all independent contractors, where NHS services are commissioned by the CCG, for implementation appropriately and working across the health economy in learning and improving care for our patients and services.
All NHS provider organisations and Independent Healthcare Sector (IHS) providers	All NHS provider organisations and Independent Healthcare Sector providers providing NHS commissioned services are responsible for ensuring that their own SI policy reflects the reporting arrangements for NHS provider organisations and Independent Healthcare Sector organisations within this policy.

APPENDIX 2: EQUALITY IMPACT ASSESSMENT

As a public body organisation we need to ensure that all our current and proposed strategies, policies, services and functions, have given proper consideration to equality, diversity and inclusion, do not aid barriers to access or generate discrimination against any protected groups under the Equality Act 2010 (Age, Disability, Gender Reassignment, Pregnancy and Maternity, Race, Religion/Belief, Sex, Sexual Orientation, Marriage and Civil Partnership).

This screening determines relevance for all new and revised strategies, policies, projects, service reviews and functions.

Completed at the earliest opportunity it will help to determine:

- The relevance of proposals and decisions to equality, diversity, cohesion and integration.
- Whether or not equality and diversity is being/has already been considered for due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED).
- Whether or not it is necessary to carry out a full Equality Impact Assessment.

Name(s) and role(s) of person completing this assessment:

Name: Lisa Forster
Job Title: Senior Clinical Quality Officer
Organisation: North of England Commissioning Support Unit (NECS)

Title of the service/project or policy: Serious Incident Management Policy

Is this a;
Strategy / Policy ☒ **Service Review** ☐ **Project** ☐
Other N/A

What are the aim(s) and objectives of the service, project or policy:
The purpose of this policy is to identify what is meant by a SI or NE and to describe the role of the CCGs when a SI or NE occurs across a number of organisations.

Who will the project/service /policy / decision impact?
(Consider the actual and potential impact)

- **Staff** ☒
- **Service User / Patients** ☒
- **Other Public Sector Organisations** ☒
- **Voluntary / Community groups / Trade Unions** ☐
- **Others, please specify** N/A

Questions	Yes	No
Could there be an existing or potential negative impact on any of the protected characteristic groups?	☐	☒
Has there been or likely to be any staff/patient/public concerns?	☐	☒
Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom?	☐	☒
Could this piece of work affect the workforce or employment practices?	☐	☒
Does the piece of work involve or have a negative impact on: • Eliminating unlawful discrimination, victimisation and harassment • Advancing quality of opportunity • Fostering good relations between protected and non-protected groups in either the workforce or community	☐	☒

If you have answered no to the above and conclude that there will not be a detrimental impact on any equality group caused by the proposed policy/project/service change, please state how you have reached that conclusion below:

The policy outlines the process and responsibilities of key partners in following the NHSE guidance on managing and investigating serious incidents and never events. This will apply to all incidents that take place under the remit of the commissioners regardless of the characteristics/protected groups applicable to the EIA process.

If you have answered yes to any of the above, please now complete the 'STEP 2 Equality Impact Assessment' document

Accessible Information Standard	Yes	No
Please acknowledge you have considered the requirements of the Accessible Information Standard when communicating with staff and patients.https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf	☒	☐
If any of the above have not been implemented, please state the reason: N/A		

Governance, ownership and approval

Please state here who has approved the actions and outcomes of the screening		
Name	**Job title**	**Date**
Executive Committee	Approver	December 2020

Publishing

This screening document will act as evidence that due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED) has been given.

If you are not completing 'STEP 2 - Equality Impact Assessment' this screening

APPENDIX 3: SERIOUS INCIDENT FRAMEWORK 2015/16 AND FREQUENTLY ASKED QUESTIONS

Serious Incident Framework

http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

http://www.england.nhs.uk/wp-content/uploads/2015/03/serious-incident-framwrk-15-16-faqs-fin.pdf

Revised Never Event Policy & Framework 2015/16, Never Events list & Frequently asked questions

http://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf

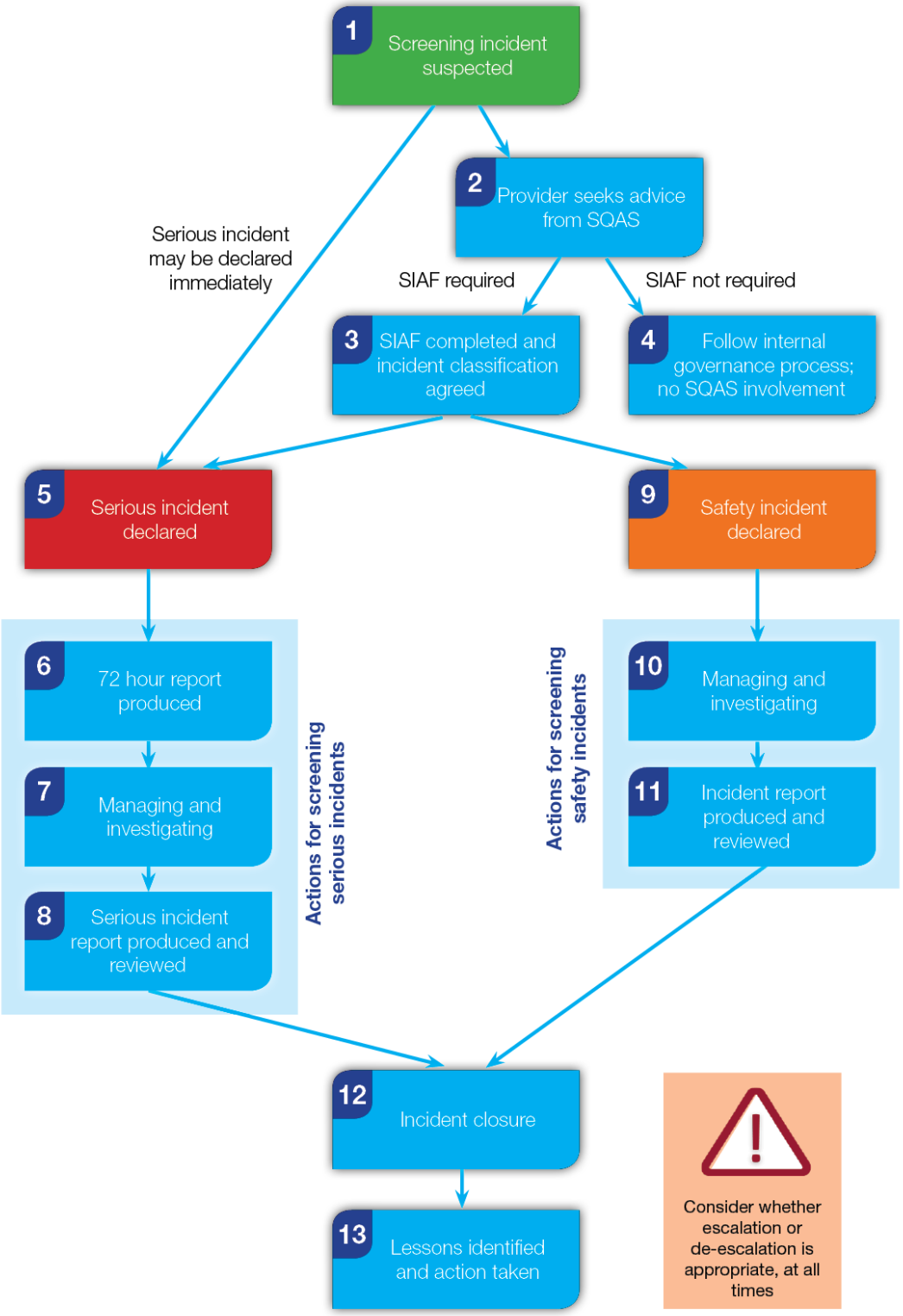
http://www.england.nhs.uk/wp-content/uploads/2015/03/never-evnts-list-15-16.pdf

http://www.england.nhs.uk/wp-content/uploads/2015/03/nepf-faqs.pdf

Patient Safety Incident Response Framework

https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v4.pdf

APPENDIX 4: REPORTING AND MANAGING SCREENING INCIDENTS AS PER PUBLIC HEALTH ENGLAND GUIDANCE



APPENDIX 5: CHECKLIST GUIDANCE FOR REPORTING, MANAGING AND INVESTIGATING INFORMATION GOVERNANCE AND CYBER SECURITY SERIOUS INCIDENTS REQUIRING INVESTIGATION

It is essential that all Information Governance Serious Incidents Requiring Investigation (IG SIRIs) which occur in Health, Public Health and Adult Social Care services are reported appropriately and handled effectively.

The purpose of this guidance is to support Health, Public Health and Adult Social Care service commissioners, providers, suppliers and staff in ensuring that

- the management of SIRIs conforms to the processes and procedures set out for managing all Serious Incidents Requiring Investigation;
- there is a consistent approach to evaluating IG SIRIs and Cyber SIRIs;
- early reports of SIRIs are sufficient to decide appropriate escalation, notification and communication to interested parties;
- appropriate action is taken to prevent damage to patients, staff and the reputation of Healthcare, Public Health or Adult Social Care;
- all aspects of an SIRI are fully explored and 'lessons learned' are identified and communicated; and
- appropriate corrective action is taken to prevent recurrence in line with the open data transparency strategy.
- Caldicott 2 recommendations (accepted by the Government) are addressed.
- Transparent reporting of incidents
- Contractual obligations are adhered to with regards to managing, investigating and reporting SIRIs in a standardised and consistent manner, including reporting to Commissioners.

The checklist guidance should be embedded within local processes and procedures and the full guidance can be accessed at https://www.igt.hscic.gov.uk/resources/HSCIC-SIRIReportingandchecklistGuidance.pdf

APPENDIX 6: EXAMPLE TEMPLATES

Guidance on Serious Incident Report and Action Plan

The report into Serious Incidents and the associated action plan should cover the following minimum information. Further work is under way with local organisations to develop and agree a common template

Report

- Introduction
- Constitution and investigation procedure
- Membership of the investigation team
- Terms of reference
- Background information
- Duty of Candour
- Safeguarding
- Chronology
- Findings – to be identified against each of the terms of reference
- Conclusions
- Root cause(s)
- Lessons learnt
- Recommendations

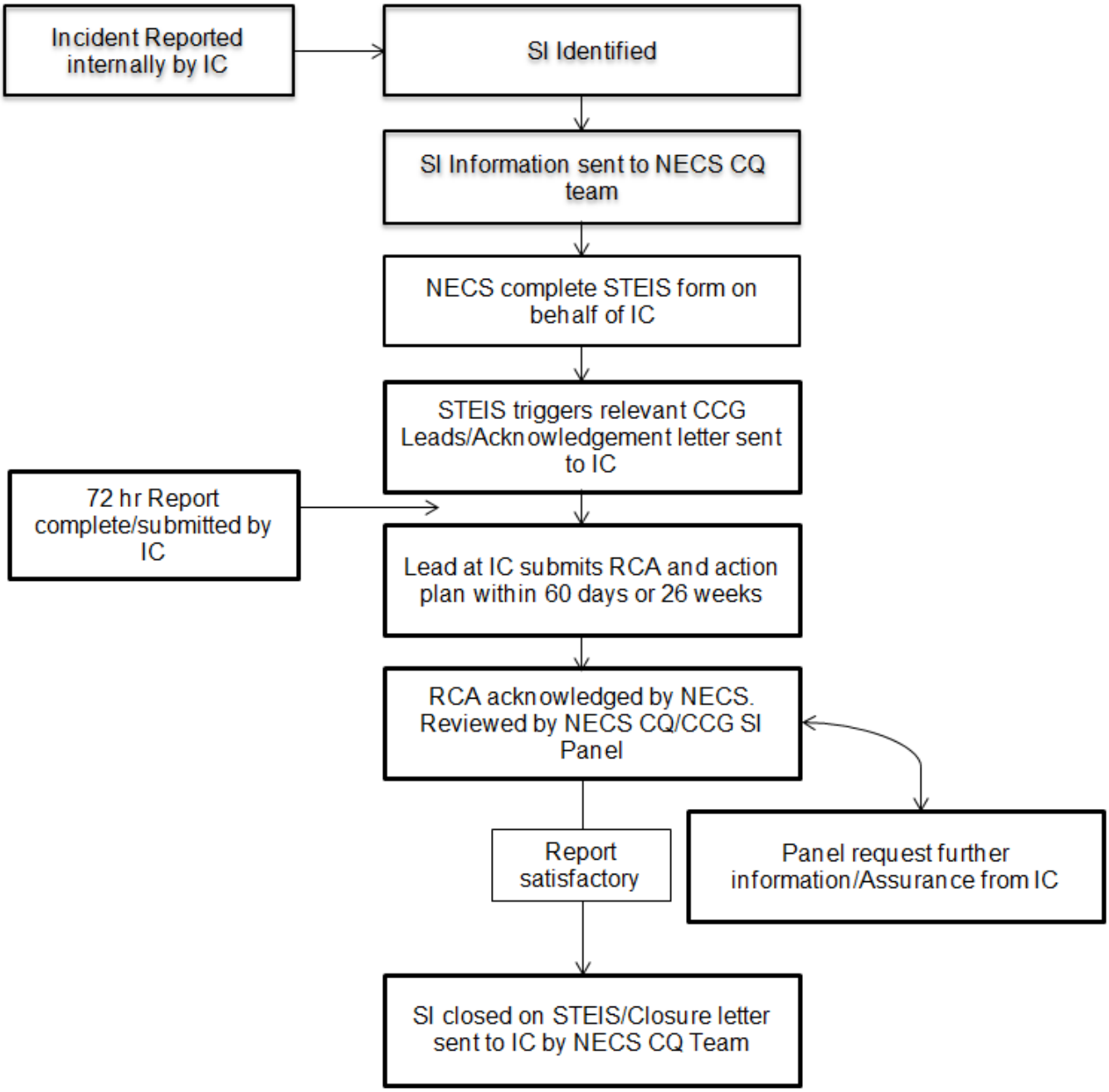
Action Plan

- Clearly set out which fall from the recommendations
- What needs to happen to achieve the outcome
- Identified title of who is responsible for the action
- Specific timescales except where incorporated in to the Trust's everyday business for example the organisation's annual programme of audit.

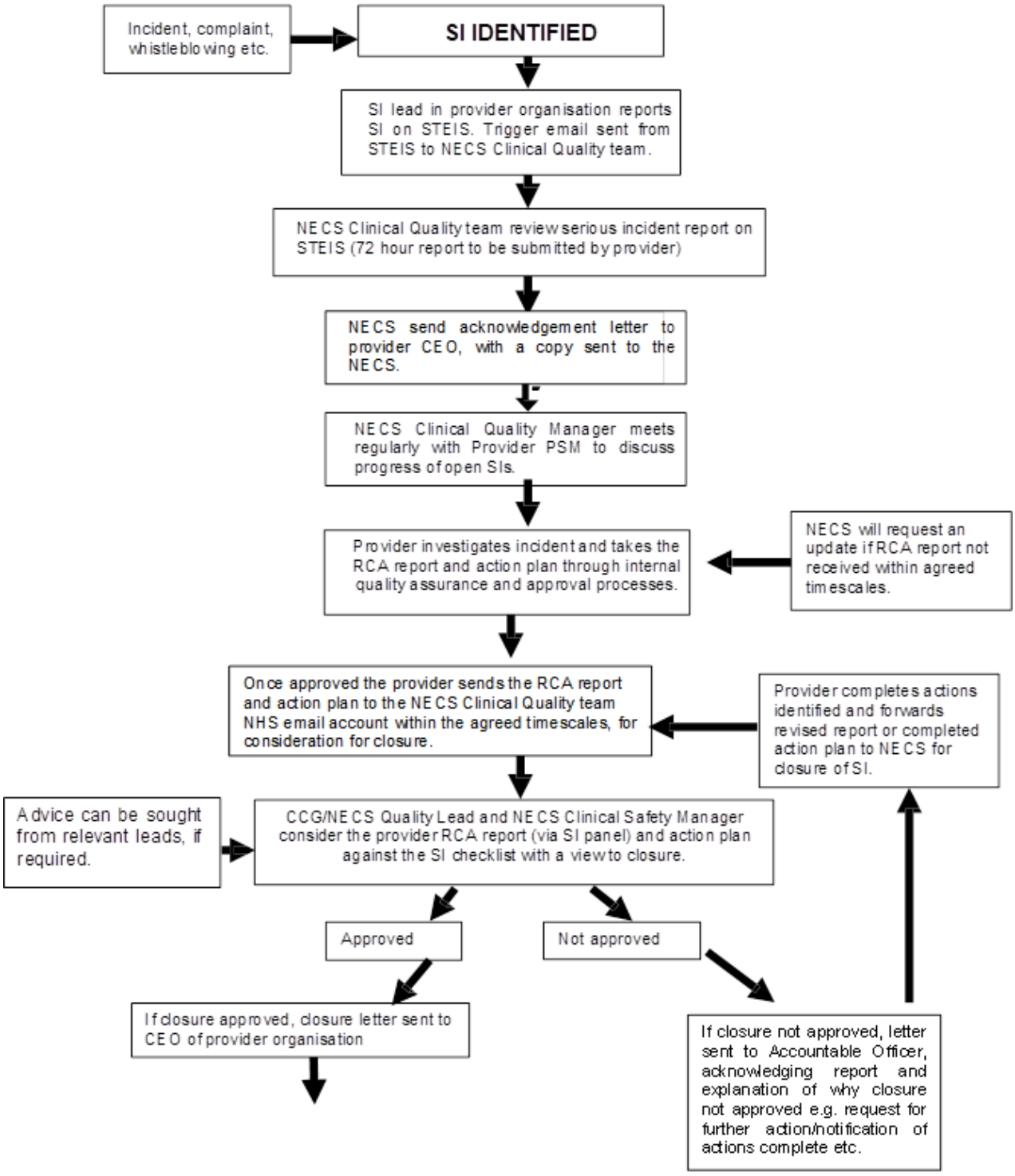
Root cause analysis tools to assist organisations in their investigation can be found at:

http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

APPENDIX 7: PROCEDURE FOR THE REPORTING AND MANAGEMENT OF SERIOUS INCIDENTS INDEPENDENT HEALTHCARE SECTOR (IHS) PROVIDERS AND INDEPENDENT CONTRACTOR (IC)



APPENDIX 8: PROCEDURE FOR THE REPORTING AND MANAGEMENT OF NHS PROVIDER SIs ONLY



APPENDIX 9: SERIOUS INCIDENT PANEL – TERMS OF REFERENCE

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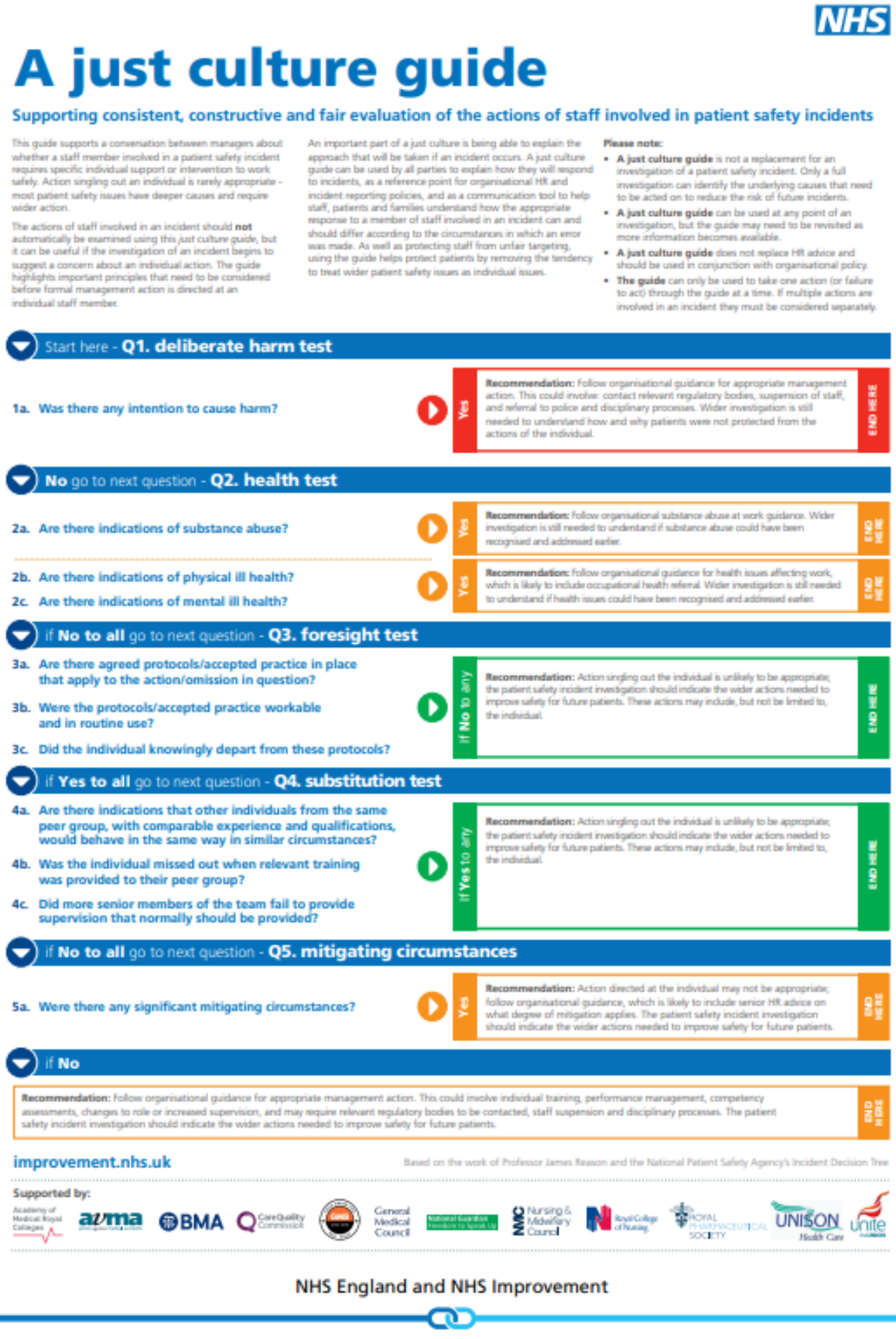
APPENDIX 10: A JUST CULTURE GUIDANCE



NHS

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. **Was there any intention to cause harm?**

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. END HERE

No go to next question - **Q2. health test**

2a. **Are there indications of substance abuse?**

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. END HERE

2b. **Are there indications of physical ill health?**

2c. **Are there indications of mental ill health?**

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. END HERE

if **No to all** go to next question - **Q3. foresight test**

3a. **Are there agreed protocols/accepted practice in place that apply to the action/omission in question?**

3b. **Were the protocols/accepted practice workable and in routine use?**

3c. **Did the individual knowingly depart from these protocols?**

If No to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. END HERE

if **Yes to all** go to next question - **Q4. substitution test**

4a. **Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?**

4b. **Was the individual missed out when relevant training was provided to their peer group?**

4c. **Did more senior members of the team fail to provide supervision that normally should be provided?**

If Yes to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. END HERE

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. **Were there any significant mitigating circumstances?**

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. END HERE

if **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. END HERE

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:

NHS England and NHS Improvement