

# Serious Incident Management Policy

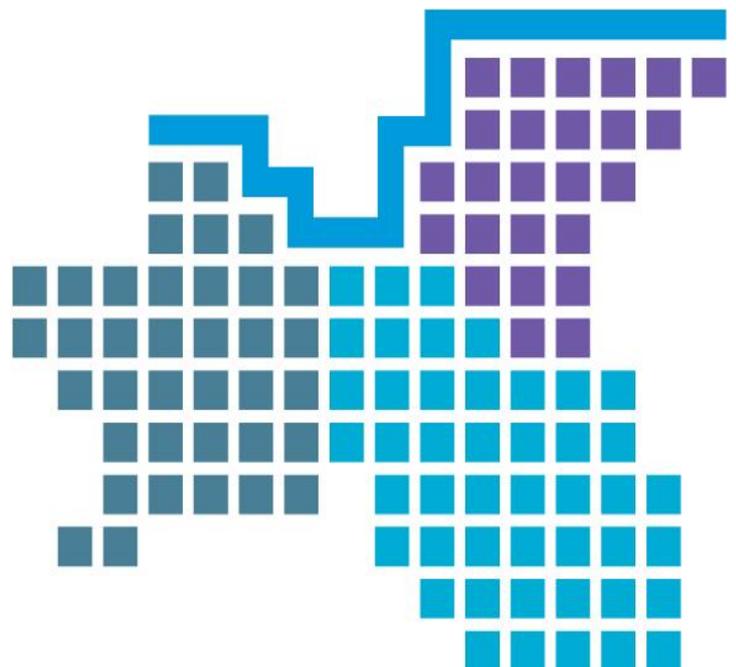
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## DOCUMENT CONTROL AND AMENDMENT RECORD

### Document Information

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Audience:	<ul style="list-style-type: none"> <li>Wandsworth CCG</li> <li>All Wandsworth CCG Provider Organisations</li> </ul>	
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### Change History

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0.1		Head of Quality and IG	May 2015 Policy Updated
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# 1. Introduction

Wandsworth Clinical Commissioning Group (WCCG) is accountable for effective governance and learning following all Serious Incidents (SI's) and seeks to work closely with all provider organisations as well as commissioning staff members to ensure all SIs are reported and managed appropriately. The Francis Report (February 2013) emphasises that commissioners should have a primary responsibility for ensuring quality, as well as providers.

SIs requiring investigation in healthcare are rare, but when they do occur, managers must make sure that there are systematic measures in place for safeguarding people, property, NHS resources, and reputation in responding to the SI's. These measures must protect patients and ensure that robust investigations are carried out, which result in organisations learning from SIs to minimise the risk of the incident happening again.

This policy has been developed by WCCG Quality Team to explain the responsibilities and actions for dealing with SIs and the tools available to help. It applies to all WCCG NHS-funded care provider organisations. Intelligence gained from SIs will be used to influence contract monitoring, quality and safety standards for care pathway development and service specifications.

This policy is based on the "Serious Incident Framework Supporting learning to prevent recurrence: March 2015:" and the "Revised Never Events Policy and Framework: March 2015". These two Guidance documents replace all previous Guidance in relation to SIs and Never Events. WCCG has adopted this framework in full and expects those commissioning on behalf of the CCG or providing NHS funded care commissioned by the CCG to adhere to the guidance contained in the framework. The revised SI framework does not fundamentally alter existing principles set out in the NPSA's 2010 National Framework for reporting and Learning from SIs and elsewhere, but does update the framework on certain key areas outlined below. The key changes to the previous 2013 Guidance are as follows:

- The definition of SI has changed
- A requirement to carry out an Initial incident review (characteristically termed the 72-hour review)
- Grading: there is now only one grade of SI
- Timescale: Investigations to be completed within 60 days (rather than the previous 45-60)
- Prescriptive list of SIs has been replaced with the new definition

Provider organisations are required to notify the Care Quality Commission (CQC) about events that indicate or may indicate risks to on-going compliance with registration requirements, or may lead to changes in the details about the provider organisation in the CQC's register. Reporting SIs is a legal requirement under CQC regulations. Therefore all SIs, including Never Events must be reported to the CQC; this obligation can be met by reporting the never event to the National Reporting and Learning Service. This requirement continues regardless of organisational changes within the NHS.

This is a living document and will be amended in response to any changes to statutory and/or local guidance. This policy will be tested and reviewed more frequently than is usual, and more effort should be made to review alternative models of provision to ensure that the original delivery model continues to be the most appropriate.

## 2 Scope

This policy is applicable to WCGG and all NHS-funded services commissioned by WCCG including acute care, Continuing Health Care, urgent care services, small contracts/providers and Nursing Homes (except where that service is commissioned by a number of CCGs and the lead CCG's policy will be used).

Note: For SI reporting by General Practices, the locally created guidance for managing Incidents should be followed, see section 9.10.

## 3 Policy Statement

WCCG is committed to identifying, managing and minimising all risks to the CCG, its commissioned services, patients, service users, staff and visitors through the Integrated Risk Management framework and Integrated Governance structures. WCCG has established SI management arrangements for the purpose of monitoring its Provider Organisations' and CCG specific SIs.

## 4 Definition of an SI requiring investigation

As per NHS England SI framework guidance, the following is the definition of an SI

- a) Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
- **Unexpected or avoidable** death of one or more people.  
This includes:
    - Suicide/self-inflicted death; and
    - Homicide by a person in receipt of mental health care within the recent past.
  - **Unexpected or Avoidable** injury to one or more people that has resulted in serious harm;
  - **Unexpected or Avoidable** injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
    - The death of the service user; or
    - Serious harm;
  - **Actual or alleged abuse**; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
    - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
    - Where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

- b) A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information; <https://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf>
- c) An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
  - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
  - Property damage;
  - Security breach/concern;
  - Incidents in population-wide healthcare activities like screening and immunisation programs where the potential for harm may extend to a large population;
  - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
  - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
  - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- d) Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care caused or contributed towards a serious outcome, but the simplest and most defensible position is to discuss openly, to investigate proportionately and to let the investigation decide.

It may be appropriate for a 'near miss' to be classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or a similar incident) occur again. Deciding whether or not a 'near miss' should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every 'near miss' should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

As a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable ameliorating action to be taken to prevent recurrence. The definition of SIs requiring investigation extends beyond those which affect patients directly, and includes SIs which may indirectly impact on patient safety or a provider organisations' ability to deliver on-going healthcare.

An SI in relation to Personal Confidential Data is defined as any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals. Such SIs should be brought to the attention of the Senior Information Risk Owner.

The NHSE SI Framework 2015 Guidance abolished prescribed lists of SIs. Organisations should have processes in place to identify incidents that indicate the most significant opportunities for learning and prevention of future harm. This is not achieved by having prescribed lists of incidents that count as serious incidents. For example, **blanket reporting rules that require every grade 3 and 4 pressure ulcer, every fall or every health care acquired infection to be treated as serious incidents** can lead to debilitating processes which do not effectively support learning.

## 5 Roles and Responsibilities

- i. **Accountable Officer:** The Accountable Officer for WCCG and the Chief Executives of the commissioned services each have responsibility for ensuring that their organisations have the necessary management systems and structures in place to enable the effective management and implementation of all risk management and governance system including SI management. WCCG will performance monitor the contract in place with each of its provider organisations as required by the Department of Health (DoH) and NHSE. Therefore, WCCG is accountable for:
  1. The effective governance of and learning following all SIs, seeking to work closely with all its provider organisations to ensure all SIs are reported and managed appropriately;
  2. Receiving timely information on all SIs and their related investigation from all provider organisations from whom they commission NHS services.
- ii. **Director of Corporate Affairs, Performance & Quality:** The Director of Corporate Affairs, Performance & Quality is the executive lead for quality and safety and is accountable for ensuring effective systems for managing all SIs are in place and the implementation of the WCCG SI Policy.
- iii. **Deputy Director of Quality:** The Deputy Director of Quality and Lead Nurse is responsible for the implementation of the WCCG SI policy. The Lead has responsibility for ensuring and monitoring effective management of SIs within its provider organisations.
- iv. **Patient Safety Lead:** Patient Safety lead has delegated responsibility for the day-to-day management and oversight of SIs reported by the providers and the CCG. This includes scrutiny of the SI submissions, review of the investigation reports and root cause, discussion with expert leads on proposed actions and act as the central point of coordination ensuring lessons learnt,

trends and themes are monitored and implemented. The Patient Safety lead will develop and maintain close working relationship with provider organisations in improving their processes, activities for disseminating and sharing lessons to allow for minimisation of risks and improvement of patient safety. This will include bi-monthly action plan implementation assurance visits.

- v. **Quality Facilitator:** The Quality and Patient Safety Facilitator is responsible for assisting the Patient Safety lead in the day-to-day management and implementation of the WCCG SI policy.
- vi. **NHS England (London Region):** Will have responsibility for commissioning independent Investigations/inquiries in SI cases which meet nationally agreed criteria. They are also responsible for sharing relevant learning including with other area teams through relevant network meetings and sharing SI summary reports.
- vii. **Contract Managers and WCCG Commissioning Leads:** The role of contract managers and commissioning leads is to make explicit reference to SI reporting in the contracts with all provider commissioned services and organisations. They also escalate issue to quality team and seek support where required and take appropriate actions as required where providers are not complying.
- viii. **Communication Team:** Has responsibility for identifying a clear communication plan for working with relevant colleagues both internally and externally to support effective management of the SIs. They will work with (the relevant parties) to prepare media statements (N.B. ensuring that patients and staff and other affected parties are informed before release of statements to the media). The communications team will also confirm proposed handling arrangements with NHSE, and the organisations where necessary.
- ix. **Clinical leads and Expert Service Leads:** They will support with review of relevant SIs, identify areas that need to be addressed and advise if actions are suitable for closure of SI.
- x. **Provider Organisations:** Each provider organisation is responsible for identifying SIs and taking effective action in each instance. It is expected that clear procedures are in place for identifying, reporting and investigating all SI's. A single point of contact or lead officer for the management of all SI's must be identified by each provider organisation. All provider organisations have a responsibility to ensure that their first priority when an SI occurs is to ensure the needs of individuals affected by the SI are attended to, including any urgent clinical care and management action that may reduce harmful impact. Internal investigations should be commenced immediately on notification of the SI in line with the individual organisation's SI policies which should incorporate the principles of 'Being Open'.

All provider organisations must:

- Ensure there are structured risk management systems and processes for collecting, collating and analysis of data on all SIs and lessons learned and reporting SIs
- Ensure compliance with the requirements identified within the NHSE SI Framework

document.

- Ensure that this policy does 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 DoH publication Memorandum of Understanding - Investigating Patient Safety Incidents (June 2004), and accompanying NHS guidance (December 2006) and NPSA guidance for Serious Incidents (March 2015). The need to involve outside agencies should not impede the retrieval of immediate learning.

## 6. Committees and Groups

- **Integrated Governance Committee (IGC):** The IGC is directly accountable to the CCG Board and provides assurance that the governance systems, processes and behaviours by which the CCG leads, are functioning and fit for purpose. It directs and controls functions in order to achieve organisational objectives, and the way in which they relate to patients and carers, the wider community and partner organisations and ensures they are integrated and effective. The IGC oversees processes and compliance issues concerning SIs, receive notification of Never Events, and inform the CCG Board of any escalation or sensitive issue in good time.
- **Quality Group:** The Quality Group will have delegated responsibility for overseeing the management and monitoring of all provider organisations SIs, including CCG SIs and receiving regular updates. The Group reports to the Integrated Governance Committee which is a subgroup of the CCG Boards, providing assurance that provider organisation SI management systems and processes are appropriate and lessons have been learned and shared.
- **SI Review Process:** The SI Review Process refers to a virtual group which consists of clinical leads, service expert leads such as infection control lead, pharmacy, IT leads etc. The virtual group is tasked with reviewing all provider organisations' and CCG SIs RCA reports to determine the robust nature of the investigations, that root causes have been appropriately identified and actions reflect the findings and subsequent recommendations , reflecting that lessons have been learned and shared. The SI review process will also confirm and challenge the content and structure of provider organisation's RCA investigation reports.
- **Clinical Quality Review Groups (CQRG):** WCCG meets monthly with providers at the Clinical Quality Review Group. The CCG has CQRG's with its main providers where it is a lead commissioner and with other providers where it is an associate commissioner. This includes St Georges NHS Foundation Trust, Chelsea and Westminster NHS Foundation Trust, Kingston NHS Foundation Trusts and many others. The CQRG's are responsible for ensuring that all contractual requirements relating to clinical care, quality and outcomes are met. SIs are a standing item on the agenda. The CQRG will be provided with monthly assurance updates on the investigation and implementation of, and outcomes from SI investigation report action plans. This may also include, thematic analysis, presentation of specific SI's , discussion on duty of candour and follow up on action plans, decision of focus areas resulting from SI and instigation of review process of areas of concern.

## 7. Being Open

Patients, families and carers involved in adverse incidents should expect openness, transparency and candour throughout the system about matters of concern from providers and the services commissioned by them, with timely communication essential to this principle. 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

For a common culture to be shared throughout the system, these three characteristics are required:

- Openness: enabling concerns to be raised and disclosed freely without fear, and for questions to be answered;
- Transparency: allowing true information about performance and outcomes to be shared with staff, patients and the public;
- Candour: “ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.” (The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013).

All care providers registered with the CQC from 1 April 2015 have a statutory duty of candour. The obligations associated with the statutory duty of candour are contained in regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Providers must, in addition to above:

- As soon as is reasonably practicable after a notifiable patient safety incident occurs, the organisation must tell the patient (or their representative) about it in person;
- There is a statutory duty to provide reasonable support to the patient. Reasonable support could be providing an interpreter to ensure discussions are understood, or giving emotional support to the patient following a notifiable patient safety incident;
- The provider must maintain a record of the disclosures to patients and their families affected by the patient safety incident.

“The argument that the existence of a criminal sanction inhibits candour and cooperation is not persuasive. Such sanctions have not prevented improvements in other fields of activity.” (The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013).

## 8. SI Management Procedure

### 8.1 Reporting a SI

All provider organisations and WCCG must **use STEIS** to report SIs where this is available (see Appendix A: Process for Management of SI including Never Events). Once an SI has occurred it should be reported as soon as possible after the incident is detected and no later than **2 working days** of the SI being identified. STEIS will automatically generate a cascade alert notification of

the SI to the WCCG SI inbox ([waccg.si@nhs.net](mailto:waccg.si@nhs.net)). For providers without STEIS access they must notify CCG using the SI form. See also section 9.1

Where the SI did not occur in the reporting organisation, but in another provider, the reporting organisation will request a de-escalation from WCCG but will also ensure they notify the organisation responsible see section 8.11. Provider is also required to complete a 72 hour report where it has been agreed to by the CCG and confirm level of investigation required.

(It is expected that the provider organisation process are then set in motion in line with NHSE guidance and NPSA for conducting an investigation to include establishing an investigation team, terms of reference, and ensuring a root cause analysis report will be ready within 60 days. Furthermore ensuring the necessary external organisations suited to type of incident are informed such as the police if there is a suggestion of a criminal offence, HSE for a H&S incident, NRLS, CQC for all safety incidents and HSCIC for IG incidents.

**Confidentiality:** The report on STEIS must not contain any confidential data relating to patients or staff. The description should be concise. Each SI is allocated a unique number and this is the reference number which should be used in any communication with WCCG quality team. **This unique number must be placed in the 'Subject' field within all email correspondence relating to the SI.**

**Updating Records:** Once a SI is reported, the provider organisation or WCCG (for CCG specific SIs) must update the STEIS record as the situation changes, which could be weeks or months after the original SI. An email must be sent to the WCCG Quality Team ([waccg.si@nhs.net](mailto:waccg.si@nhs.net)) with the STEIS number in subject line when the STEIS record is updated.

**Late Notification:** Where reporting of a SI is not within the national requirement of 2 working days, provider organisations or WCCG (for CCG specific SIs) must provide a rationale for the delay on the 'further information' section of STEIS. For monitoring processes and provision of regular reporting, the date the SI was entered onto STEIS would be the date used to calculate delay in notification.

**High Risk/ High profile SIs:** Where the SI has already attracted and/or has the potential of attracting media attention, it should be highlighted by selecting the Media interest option on STEIS including informing the WCCG Quality Team: Patient Safety Lead immediately by telephone (See section 8.7 Contacting WCCG Quality Team includes Out of Hours contact).

If it is out of hours, the expectation is that the provider organisation (where the SI occurred) will contact NHSE out of hours directly with an email sent to the WCCG Quality Team (See section 8) NHSE will expect to be notified by both the provider organisation and the CCG of high risk SIs within 24 hours, with out of hour's notification via their on-call system (See section 8.7 Contacting WCCG Quality Team includes Out of Hours contact).

**Notification of SI to Expert leads/Stakeholders:** WCCG Patient Safety lead and/or the Quality Facilitator will notify the relevant key stakeholders of the SI, for e.g. Safeguarding Leads, Information Governance Leads, NHS 111Clinical Lead, etc. where applicable.

## 8.2 Actions Following Notification of SI

The WCCG Quality Team will review new SIs within 3 days to:

- Identify any high risks (any need for immediate contact with the Provider Organisation);
- Identify any additional and/or further relevant information required;
- Ensure no patient confidential information included;
- Confirm SI is not a Never Event;
- Assess whether the SI type needs to be re-categorised;
- Ensure STEIS is updated with relevant information by providers or when CCG logs individual SI's.

The WCCG Quality Team will:

- Check submitted 72 hour report where it has been agreed by the CCG;
- Send weekly notification of collated SIs to Senior Management;
- Commence identification of trends and themes arising from SIs;
- Identify SIs that will be discussed at the CQRG.

## 8.3 Report Format

Providers are free to create their own templates for reporting format, so long as they support a RCA methodology, and that the methodology and the template are agreed between the provider and the CCG Quality Team. For small providers with little experience in conducting RCA investigation, the Quality Team will support with templates, dependent on the level of complexity.

In accordance with Caldicott principles, SI RCA investigation reports must not contain patient or staff confidential information. The title of the reporter and titles of the investigation panel members should be used. Electronic reports should be saved by STEIS number rather than any person confidential information. It is the responsibility of the provider organisation that generated the investigative report to retain the document for a period of 30 years. Copies shared with other provider organisations may be destroyed in accordance with the local confidentiality procedure once the report is no longer of use.

## 8.4 Action Plans Format

Following the investigation of a SI, the submitted SI RCA investigation report must include an action plan which sets out how each recommendation from the investigation will be implemented. The action plan must include the following minimum requirements:

**Recommendations:** these should be the analysis and findings of the investigation – the recommendations from the report and every recommendation must have clearly articulated action(s);

**Identified Action:** This should be actions that the organisation needs to take to resolve the contributory factors and root causes. This should also identify whether the action needs to be taken at:

- Unique: specific to the area;
- Common: organisation specific;
- Universal: have regional/national significance.

**By Whom:** Identifies who in the provider organisation will ensure the action is completed and a responsible person (job title only) must be identified for each action point.

**Planned action completion date:** This is the target dates for proposed completion of actions.

**Resource requirements:** to be able to complete the action, what resources are required; this should also identify which provider organisation committee will be responsible for monitoring action plan implementation and completeness.

**Evidence of completion:** description of the form of evidence that will be available to confirm completion; this should include any intended post action plan reviews or audits; measures of success: evidence of changes brought about to improve patient safety (this may include changes to practice, education and training).

**Sign-off:** details (name, date, etc.) of when the action plan was signed off by the provider organisation's Executive level lead.

**SMART approach** to action planning is recommended. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound.

Note: Providers are encouraged to make sure of the NPSA and NHSE guidance and templates as much as possible so as to ensure their reports are comprehensive enough and in line with this guidance.

## 8.5 Submission of Final Report

Final SI RCA investigation reports with accompanying action plan should be submitted to [waccg.si@nhs.net](mailto:waccg.si@nhs.net) inbox within the timescales stipulated:

Please see Appendix B for the definition of the following: 60 working days of the SI being notified;

6 months of the SI being notified requiring Investigation Level 3 (Independent RCA) (see Appendix B).

## 8.6 SI RCA Investigation Report Evaluation and Sign-off Process

Once an SI RCA investigation report is received, the Patient Safety Lead will coordinate with relevant expert leads to ensure each individual case is evaluated using. The SI Review Process will review reports, grant extensions, agree that reports are final and agree sign-off.

Expert advice as appropriate will be taken to determine whether all aspects of the SI have been investigated adequately and whether there are clear action points to address each root cause and contributing factor.

Following review by the WCCG SI Review process an extension may be granted (see section 8.12 Extension of Submission Period). Once WCCG has agreed that the report is final and agrees sign-off, STEIS must be updated with the completion of the investigation

## 8.7 Contacting WCCG Quality Team

The WCCG Quality Team can be contacted:

In Hours: 020 8812 6600 and ask for Patient Safety Lead;

Out of Hours: 0844 822 2888 and quote NHS01. This will put you in touch with an NHS England (London) senior manager on-call who can access the out of hours communication team if necessary or Phone 020 8870 2032/020 8874 3200 and ask for the on-call Manager. The out of hours contact is used if provider thinks the SI is high risk /high profile;

Email correspondences: [waccg.si@nhs.net](mailto:waccg.si@nhs.net)

## 8.8 Monitoring

Once a week the Quality Team will produce a briefing report for the Executive Team of WCCG updating them of all SIs reported and alerting them to any pertinent issues.

**Action Plans:** All SI RCA investigation report action plans should be completely implemented within **6 months** of reporting the SI with extensions by agreement with the Patient Safety lead. Through quarterly SI Assurance Meetings, or related platform agreed with provider such as contract meetings the WCCG Patient Safety lead will:

- Ensure implementation of actions agreed as a result of SI investigations;
- Ensure that evidence of demonstrable outcomes from SI action plans is available;
- Agree dissemination of learning from SIs;
- Review any identified action plan trends.

The CQRGs will receive regular update report on action plan implementation (new actions, completed actions, outstanding actions, improvement outcomes, themes, actions, exceptions). All contracts for services commissioned by WCCG will identify SI reporting requirements. The WCCG

Patient Safety lead will monitor provider organisations' or WCCG's (for CCG specific SIs) compliance with this policy and national requirements through the provision of regular reports and completion of an annual checklist.

## 8.9 Learning from SIs

All organisations with a responsibility for notifying or receiving details of SIs have a responsibility for:  
Ensuring arrangements exist for the dissemination of relevant learning and recommendations from SI investigations across the organisation and more widely as appropriate;

Carrying out regular thematic reviews of SIs to identify trends and patterns and ensure the wider implications of key learning points are disseminated;

The CCG will ask provider to produce a regular learning the lessons report. This report will include action themes identified, an update on all actions implemented, outstanding actions and improvement outcomes as a result of actions.

If there is evidence to indicate that a SI could be part of a cluster or trend, or where the circumstances or consequences of the SI are of particular concern, a wider review may be instigated. It is difficult to be prescriptive, as the extent of that case review will depend upon the nature of the SI. In order to facilitate, sharing the lessons from SIs, certain SI investigations will be discussed at CQRGs or relevant contract meeting/available platform with provider

## 8.10 Information Sharing

The reporting provider organisation must ensure that any reports (SI preliminary analysis investigation reports or STEIS reports and/or correspondence) are sent via the recommended and secure email domains only such as \*NHS.net, \*gsi.gov.uk, \*gsx.gov.uk, \*cjsm.net or \*gcsx.gov.uk. WCCG will support the development of processes which allows for sharing of information between organisations and other sectors to ensure lessons are learned. A variety of approaches will be utilised to facilitate this process.

The Health and Social Care (Safety and Quality) Act 2015 has amended Section 251B (duty to share information) in Part 9 of the HSCA 2012, making it a legal requirement for NHS staff to disclose lawfully required health related information during investigations. This also applies to commissioners as well as providers.

## 8.11 De-escalation Process

SIs can sometimes be reported based on limited information which on further investigation does not meet criteria for an SI. De-escalating a record on STEIS means that it is not recorded as attributed to the organisation who declared it.

Provider organisations or WCCG (for CCG specific SIs) should request for de-escalation from WCCG Quality Team by emailing the SI inbox [waccg.si@nhs.net](mailto:waccg.si@nhs.net). The request will be reviewed

through the SI Review Process for clinical expertise (or area specific expertise) input and the Patient Safety Lead will inform the provider organisation or WCCG investigation Lead (for CCG specific SIs) of the decision within 10 working days.

Completely de-escalating records from STEIS will be managed by the NHSE London Region Patient Safety Team. WCCG SI Review process approved SIs for de-escalation will be emailed to the NHSE London Region Patient Safety Team ([london.sui@nhs.net](mailto:london.sui@nhs.net)) with the STEIS number of the case being de-escalated. The Patient Safety Team will then arrange for this record to be de-escalated. The NHSE London Region Patient Safety Team will arrange for this record to be de-escalated but this will take up to a week for the system to update. Any de-escalation requests sent by provider organisations to the NHSE London Region Patient Safety Team will be forwarded to the WCCG for a decision. WCCG will provide the provider organisation with regular reports on SIs de-escalated by the WCCG SI Review process.

## 8.12 Extension of Submission Period

It is recognised that in certain circumstances provider organisations will find it impossible to complete a final report within the national framework timescales. In such cases an extension for exceptional circumstances can be requested from WCCG Quality Team. A request for extension will be made via email and the reasons for the request confirmed by telephone. Any request for an extension must be made at least **5 working days prior** to the due date of the final report, otherwise an extension cannot be granted and the report will be recorded as overdue. Extensions will be agreed by WCCG Quality Team in consultation with the CCG expert leads and will start from the day on which the SI report was due for submission.

Following review through the WCCG SI Review process an extension may be required if further information is requested. The provider organisation or WCCG investigation Lead (for CCG specific SIs) will be informed of this decision within 10 working days of the review. The WCCG Patient Safety lead will update the 'Expected SI Completion Date' section on STEIS to reflect when an extension has been granted.

# 9. Additional Guidance

## 9.1 NHS Funded Provider Organisations with no access to STEIS

Any SI involving a patient in receipt of NHS-funded care provided by an independent sector healthcare provider must be reported by that provider to the commissioning organisation with responsibility for the contract. As part of the contractual requirements, all NHS funded providers are expected to have procedures for identifying and handling SIs. All provider organisations should report SIs via the STEIS system, where the provider organisation/service has no access to STEIS are expected to notify WCCG immediately using the SI report form on the WCCG website (<http://www.wandsworthccg.nhs.uk/pages/Home.aspx>). Completed forms should be sent to

- In hours - [waccg.si@nhs.net](mailto:waccg.si@nhs.net) OR **020 8812 6600**;

- Out of Hours: for high risk SIs Only contact NHSE London : **08448 222 888** and quote **NHS01**;
- OR Phone **020 8870 2032 / 020 8874 3200** and ask for the on-call Manager) within **2 working days** of the SI occurring.

The WCCG Patient Safety lead will log the SI on the STEIS system on behalf of that provider organisation. The provider organisation/service must ensure that the investigation is completed and submitted within the framework identified within section 8.3 – 8.5: Submission of Final Report.

Note: For provider without STEIS access, they can use their own forms to submit to the CCG for STEIS entry as long as the forms cover the basis fields similar to CCG form

## 9.2 Coroner's Verdicts

Some SIs involving patient deaths need to have a verdict from a coroner. Where this is the case, the SI final report should be submitted within the appropriate timescale, and not delayed in order to incorporate the coroner's verdict. It must be made clear in the report that a coroner's verdict is awaited and as a result the report will not be closed, the provider organisation must send the verdict (a summary, not the coroner's report) to [waccg.si@nhs.net](mailto:waccg.si@nhs.net).

If the coroner's verdict does not present any issues not already covered in the SI final report then it will be closed (assuming it satisfies the criteria for closing an SI). If the verdict presents issues not covered in the final report, then the provider organisation will be required to revise the SI report in order to incorporate these issues and to re-submit.

## 9.3 Never Events

The Revised Never Events Policy and Framework: March 2015 has made some significant changes to the previous Guidance. The focus of change has been on the rationale behind a type of serious incident being included on the Never Events list that there are barriers to prevent it from occurring and guidance is in place to ensure it should never happen. They are **wholly preventable**, where guidance or safety recommendations that provide strong systemic protective barriers **are available at a national level, and should** have been implemented by all healthcare providers.

Given the seriousness of these events, there will be a greater level of scrutiny. NHSE and WCCG will be ultimately responsible for closure of Never Event SIs. Closure of the SI will only be achieved where a provider organisation is able to demonstrate evidence of implementation of all actions points within 6 months.

In cases where there is uncertainty around the status of a SI as a Never Events, WCCG and the provider organisation must discuss and agree the categorisation to come to a conclusion as a matter of urgency. Where an agreement cannot be reached by WCCG and the provider organisation, NHSE will be contacted for a conclusion.

Never events Policy: <https://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf>

#### **9.4 Never Events Cost Recovery Process**

In accordance with applicable guidance, recovery of the cost of the procedure and no charge to commissioner for any corrective procedure or care applies. Commissioners should seek to withhold payment for the cost of the episode of care in which a Never Event has occurred and any subsequent costs involved in treating the consequences of a Never Event.

WCCG is able to decide to waive these contractual terms depending on individual circumstances, applying the principles of proportionality and taking into account previous performance and the Provider's response to the Never Event occurring. This decision should be taken in discussion with the Provider, although the default should be to recover costs. The new Guidance recommends a cap of £15,000.

#### **9.5 Previous Mandatory SI's**

Previous SI guidance from 2013 had a prescriptive list of mandatory SIs reporting such as Ambulance delays, grade 3 and 4 Pressure ulcers, unexpected admission to NICU and many others. Using the new framework, where the definition of a Serious Incident is met, the incident should be reported and investigated according to the principles set out in the Serious Incident Framework. Clearly some of what used to be mandatory will meet the definition but some will not e.g. an infected category 2 pressure ulcer may lead to septicaemia and death whereas a very small category 3 pressure ulcer on the ear (designated as category 3 because cartilage will be exposed with any loss of overlying skin) may not have serious consequences for the patient. Consideration must be given to the circumstances of each case. If providers are in doubt the CCG should be consulted.

#### **9.6 Maternity**

There are a number of maternity related SIs which were also mandatory, in addition to regular SIs in previous guidance. These included: Unexpected Admission to NICU (neonatal intensive care unit), Intrapartum Death, Suspension of Maternity Services, Maternal Unplanned Admission to ITU, Maternal Death, Child Death, Post-Partum Haemorrhage, Intrapartum Death, and Unplanned Hysterectomy – this is not an exhaustive list. These will only now be a SI if it meets the criteria set out in the 2015 SI Framework Guidance.

#### **9.7 MRSA Bacteraemia and Clostridium Difficile (CDiff) deaths**

For the MRSA Bacteremia and Clostridium deaths (i.e. Part 1a of Death certificate) may be classed as SIs and RCAs will be reviewed through the SI Review process with input from the Infection Control Specialists.

## 9.8 Deaths in Custody

A death in custody must be referred to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC), or the Care Quality Commission who are responsible for carrying out the relevant investigations. However, the provider of any WCCG commissioned care must also inform WCCG.

## 9.9 SIs Involving a Child/Infant and Adult at Risk

In all cases, the safety of the child/siblings and/or adult at risk is paramount. All significant safeguarding concerns should be declared as an SI in the first instance until adequate investigation have been undertaken to prove beyond doubt that it does not meet the new SI criteria definition summarised in section 4 above and as detailed in the NHS England SI Framework Guidance March 2015 . If after investigation it has been determined that the safeguarding concern did not wholly meet the criteria, a request for de-escalation can be made. When reporting the SI, the organisation who will undertake the majority of the investigation should be the one to report onto STEIS

The SIs will be managed in accordance with this policy and the set local Safeguarding Procedures. SIs impacting on children and/or adults at risk will be overseen by the Safeguarding leads for Children and adults.

This definition of a Serious Incident in the context of safeguarding is likely to meet the criteria for a Serious Case Review; therefore, a Serious Case Review declared by the Local Authority will also be recorded as a Serious Incident on STEIS.

There is no other specific national guidance to advise on other safeguarding concerns meeting criteria of SI therefore the new criteria definition should always be applied until proven beyond doubt that it does not indeed meet this criteria. It is also likely that most cases of abuse which meet the criteria of serious harm including those graded under the NPSA definition of severe harm will meet the criteria of SI. It is also recommended to consider the following aggravating elements which can easily be overlooked:

- Staff assaulting patients;
- Previous history of assaultive behaviour from the alleged perpetrator;
- The nature of the vulnerability of the victim;
- The protracted nature of the abuse;
- Serious harm to one or more patients, where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);
- Any other factor which professionals believe meets the criteria.

The above list is a guide and not designed to fetter the discretion of any professional in relation to declaring abuse as an SI.

SIs involving SCRs will not be closed on STEIS until the SCR has been completed and published by the Local Safeguarding Children Board (LSCB) and/or the local Safeguarding Adult Board. On occasions this will mean waiting until other processes such as a court case or Coroner's inquests have also been completed. In these cases the term 'STOP THE CLOCK' should be entered in the comments section of STEIS report to enable it to be recognised as a report where closure will be delayed.

### **9.10 SIs for Primary Care**

CCG has created a process for managing SI that arise from GP practices. The Guide to managing SI for primary care should be followed. This guidance has been shared with all practices but can also be accessed here <http://bhcic.co.uk/wp-content/uploads/2016/10/Guide-to-Primary-Care-incidents-Final-Sep-2016.pdf>

### **9.11 SI linked with National Screening Programmes**

There are a number of screening programs such as breast, cervical, antenatal screening, child health screening, retinal screening etc. which require a broader approach to handling SIs. In addition to normal reporting, the commissioning organisation should also be notified. Local processes created to manage these with the commissioning organisation should be followed. Further details on the management of incidents within the breast screening programme are available in "Guidelines for Managing Incidents in the Breast Screening Programme"  
<http://www.cancerscreening.nhs.uk/breastscreen/publications/pm-09.html>

And the new guidance from Oct 2015 on managing screening incident  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/472611/Managing\\_Safety\\_Incidents\\_in\\_National\\_Screening\\_Programmes\\_gateway\\_291015.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/472611/Managing_Safety_Incidents_in_National_Screening_Programmes_gateway_291015.pdf)

### **9.12 SI linked with Public health, Specialised Commissioning & Offender Health**

Some health services provided by CCG lead provider are commissioned by other organisations such as public health and NHSE. These services include (but not limited to) Offender health, school nursing sexual health, and drugs and alcohol services. Due to the London lead commissioner model set up it means all these SI are routed through to the CCG, CCG has set up process to work with the relevant commissioner to ensure they are aware when these SI come in and are also involved in the review of the RCA report

### 9.13 Information Governance SI

The requirement for reporting information governance (IG) SIs will be consistent with the National Framework for Reporting and Learning from SIs Requiring Investigation guidance. All IG SIs will be led by the WCCG IG Manager. Details of how IG SI will be managed are explained in Annex E. Reporting of IG SI will be via STEIS or completing of the form stated in sections above for providers who do not have access to STEIS (in the first instance) as with all other SI types. Further HSCHC reporting processes will be implemented as per details in Annex E.

### 9.14 Handling Freedom of Information (FOI) Requests

Information relating to SIs (including information held on national systems such as STEIS, local databases and internal reports, investigation reports and RCA and other documents) could be subject to a request for disclosure under the Freedom of Information Act. A request for information regarding SIs should follow the WCCG Freedom of Information Guidance.

WCCG is obliged to consider the disclosure of this information when it is requested. Since it is information that concerns individual provider organisations or WCCG (for CCG specific SIs), it is important that they have the opportunity to comment on what is intended to be provided to requestors. Provider organisations or WCCG should be aware that all information relating to SIs including investigation reports could be subject to a request for disclosure under the Freedom of Information Act. Therefore, provider organisations and WCCG are advised to ensure that reports are suitably anonymised.

SI FOI requests will most commonly be requests for the number of SIs reported by provider organisations and the types of SIs. Provider organisations do provide a description of the SI when they report it on STEIS; however, those descriptions may not be appropriate for release due to the clinical or technical terminology. On STEIS the 'Line being taken by the organisation' should be used to provide a brief description of the SI that the provider organisation accept may be released in the event of an FOI request. This should be written so that it is comprehensible to a lay person that is, without acronyms or highly clinical or technical terminology. Providing this description should not delay reporting on STEIS in the event of a SI. The provider organisation does not have to complete the 'Line taken...' box immediately.

In the event of a FOI request the provider organisation likely to be affected by the request will be contacted and informed of the FOI request. WCCG will make a decision regarding how to proceed with meeting the FOI request within a given period. The SI category that is entered onto STEIS will be the category WCCG may have to report in the event of a FOI request. Therefore, it is important that provider organisations ensure they are satisfied that STEIS is accurate and up to date. If, for example, a coroner's verdict has ruled that a suspected suicide was actually due to some other unexpected circumstances it is the responsibility of the provider organisation to update STEIS accordingly.

### 9.15 Handling Media Interest

SIs can be triggers for media coverage and increased public scrutiny. A well-planned, structured media management protocol is vital in managing SIs effectively. Every SI has potential for adverse media interest and for this reason the NHSE and other relevant parties must be notified. The Patient Safety lead will:

Keep WCCG Communications Lead informed of any SIs reported that are of high risk/high profile, where the Communications Manager will advise on the appropriate actions required.

- In Hours [SLCSU.Media@nhs.net](mailto:SLCSU.Media@nhs.net) call 020 3049 3333 OR
- Out of hours call 07876 448 602 OR

Seek guidance from WCCG's Solicitors as necessary

See Section 8.1 for how high risk SIs will be handled. In forensic/criminal cases, all communications with the media should be led by the Police in partnership with the relevant agencies involved with the SI.

#### 9.16 Reporting to NHS England London (NHSEL) Regional Office:

Where an SI of particular gravity occurs (high risk/high profile), it should be reported to the NHSE London regional office immediately. The SI should be reported as soon as possible after the incident is detected and no later than **2 working days** of the SI being identified. The NHSE London Patient Safety Team can provide advice on the management of SIs and can be contacted as follows

- During normal office hours once CCG is notified, CCG will contact: **020 3 182 4972** OR [london.sui@nhs.net](mailto:london.sui@nhs.net)
- Out of office hours, provider can notify NHSE via **0844 822 2888** (Page one communications) and quote NHS01.

The out of office will gain access to the Emergency Planning manager on call, who will also have access to a Senior Manager and Director for the organisation. Please note that the pager number is for Page One Communications and that the call sign is NHS01 (NHS **zero** one).

Messages need to include the requesting organisation and a contact phone number so that NHS01 can return the call, and should not include any patient identifiable information

#### 9.17 NRLS

All serious patient safety incidents must be reported to the NRLS system for the purpose of national learning and to comply with CQC registration requirements regarding the reporting of incidents

leading to severe harm or death. This should be done without delay. All provider organisations must have agreed processes for reporting patient safety incidents via the NRLS.

The Patient Safety lead will have arrangements in place to assure the WCCG SMT that SIs are reported by provider organisations to the NRLS and other bodies as appropriate; a monthly report will be provided to IGC and Quality Group in this regard. Most of the requirements for the CQC as defined in current guidance are met by providing incidents reports about SIs and deaths via the NRLS. The NRLS will forward relevant information to the CQC but if there is any doubt, the CQC can be informed directly. All Independent sector healthcare providers should report patient safety incident to the NRLS (e.g. via the e-Form of the NRLS). They are also responsible for reporting the incident directly to the CQC.

### 9.18 Involvement of Multiple Provider Organisations:

Deciding on which organisation reports the SI may be complex and differs depending on the circumstances. When more than one provider organisation is involved in an SI, it is the responsibility of the provider organisation identifying the SI to liaise with the other provider organisation involved to agree which organisation will report on STEIS within **2 working days**.

WCCG through a facilitated meeting will determine the provider organisation leading on the investigation. This decision will be made based on the provider organisation with the most significant involvement in the SI.

All organisations are required to contribute and fully co-operate with the RCA investigation process in a timely, responsive and cooperative manner. It is the responsibility of the provider organisation leading on the investigation of the SI to coordinate and monitor the investigation process through their own systems, liaising and providing requests for information and/or feedback to any participating provider organisation and WCCG if necessary and appropriate.(see Appendix C: Involvement of Multiple Provider Organisation Algorithm).

The WCCG Patient Safety lead will liaise with key stakeholders and other commissioners to ensure that all relevant parties are notified and involved in the monitoring of the SI. The final RCA investigation report should be submitted to the [waccg.si@nhs.net](mailto:waccg.si@nhs.net) within the national timescale of 60 working days. Evaluation of the SI will follow the process identified within section 8.6: SI RCA investigation Report Evaluation Process.

Following the investigation of a SI, the submitted SI RCA investigation report must include an action plan which sets out how each recommendation from the investigation will be implemented. Each provider organisation allocated actions to be delivered will be responsible and accountable for the delivery.

## 8. Dissemination and Implementation

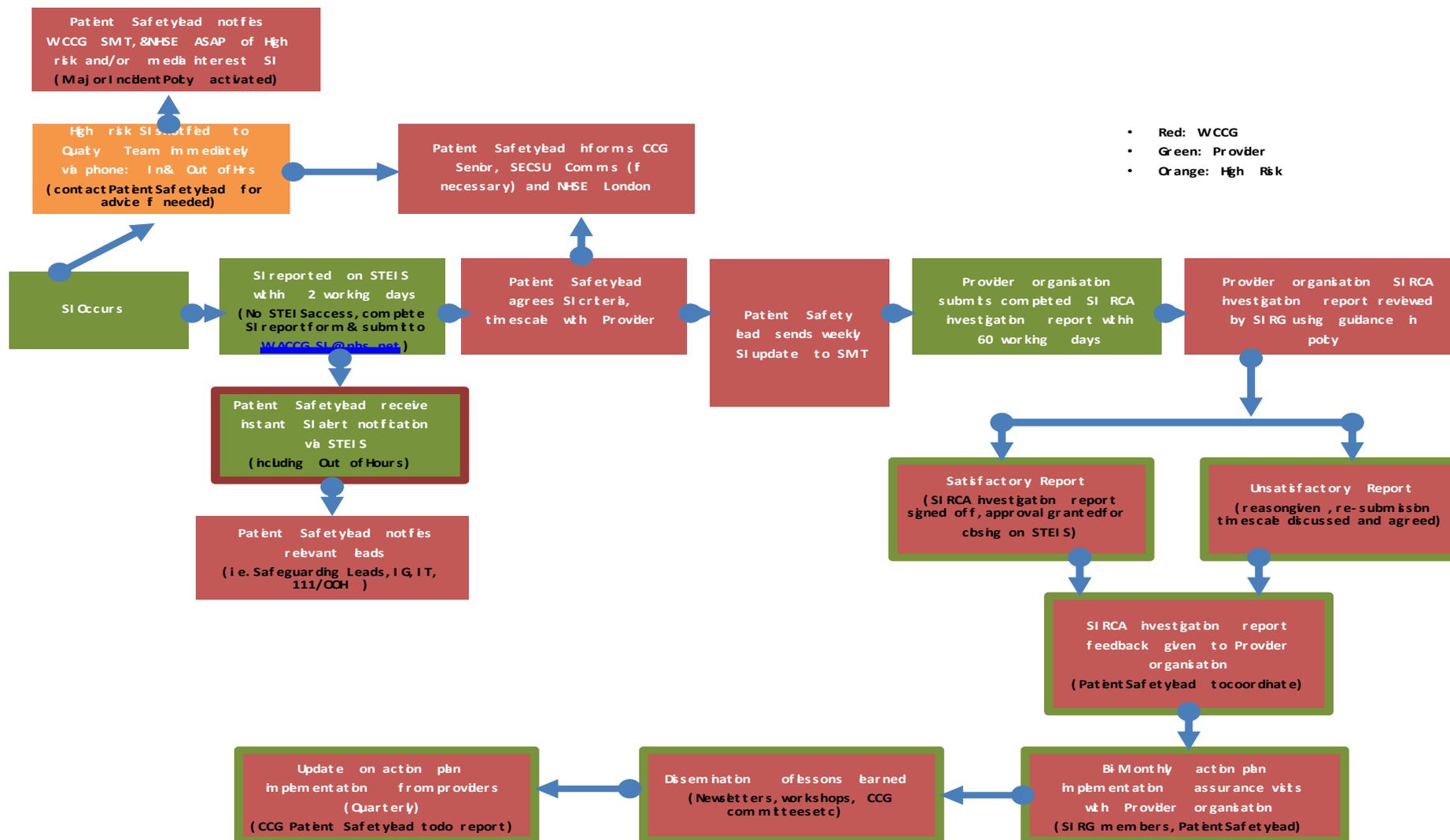
The audience of this document should be aware that a physical copy may not be the latest version. The latest version, which supersedes all previous versions, is available at the location indicated in the document control section of this document. Those to whom this protocol applies are responsible for familiarising themselves periodically with the latest version and for complying with protocol requirements at all times.

The updated Policy, once approved, will be shared with all staff through the all staff email, updated on the intranet and team briefing. Awareness of the policy will be checked through a staff survey and spot checks on at least an annual basis.



# Annex A - Process for managing SI and Never Events

## Process for Management of Serious Incidents (SI) including Never Events



## Annexe B – Types of RCA investigations

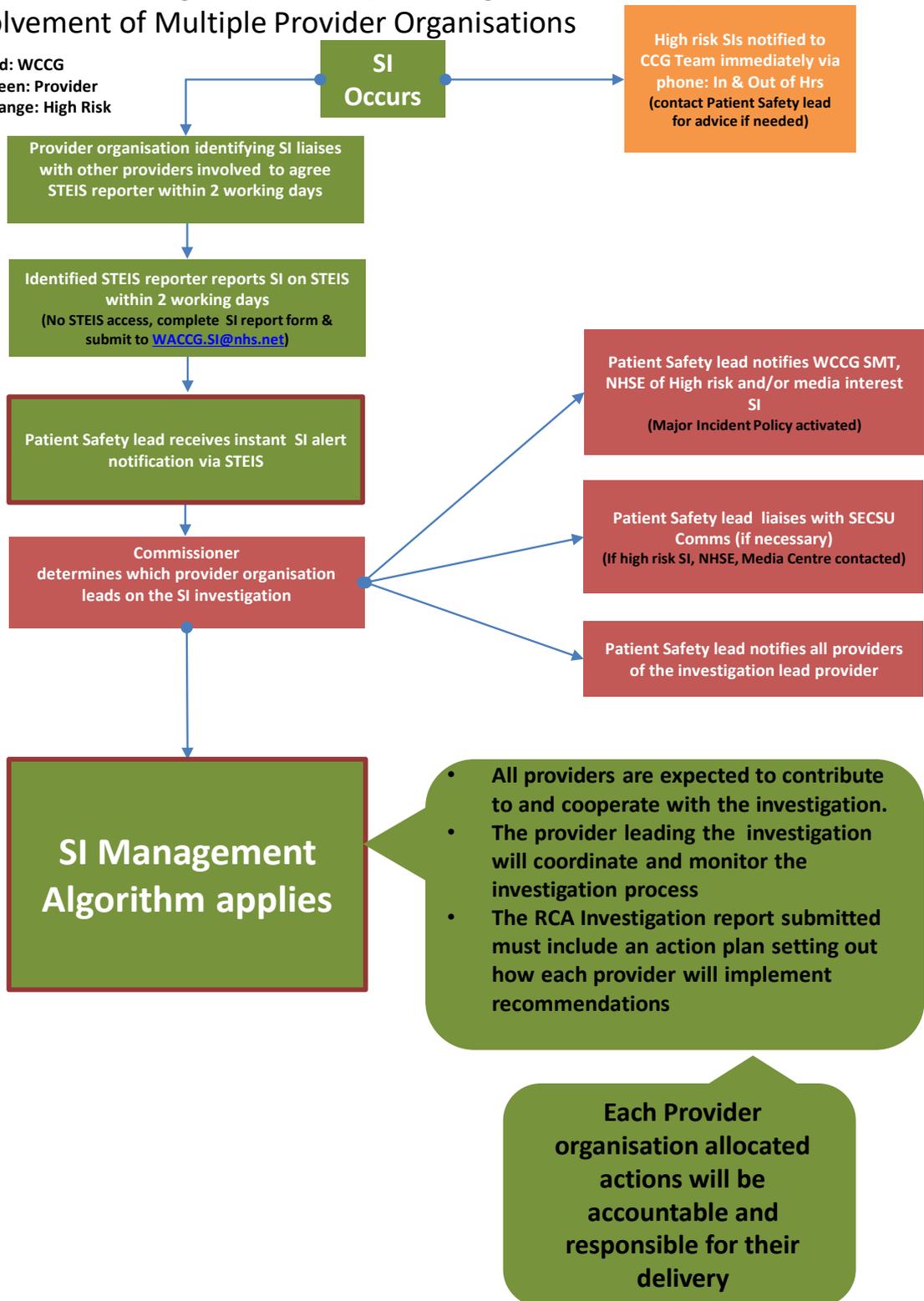
Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach.

Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 <b>Concise internal investigation</b>	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 <b>Comprehensive internal investigation</b> (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	6 months from the date the investigation is commissioned
Level 3 <b>Independent investigation</b>	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved	Comprehensive investigation report including all elements of a credible investigation	The investigator and <b>all</b> members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	

# Annexe C – Involvement of Multiple Provider Organisations

Process for Management of SIs (including Never Events):  
Involvement of Multiple Provider Organisations

- Red: WCCG
- Green: Provider
- Orange: High Risk



## Annexe D – Details of Information Governance SIs

Process for reporting and management of IG SIRI for the CCG will be in line with the process flow detailed in Appendices D of this SI policy and through STEIS etc. However, the document linked below is new guidance from HSCIC that should be followed in addition to ensure the IG SIRI are handled in line with national DH requirements including Cyber security SI's.



Additional  
Information on Manaç

### **Categorising IG SIRI's Incident**

The following process should be followed to categorise an IG SIRI:

***Step 1: Establish the scale of the incident. If this is not known it will be necessary to estimate the maximum potential scale point. Baseline Scale***

Baseline		
0	Information about less than 10 individuals	
1	Information about 11-50 individuals	
1	Information about 51-100 individuals	
2	Information about 101-300 individuals	
2	Information about 301 – 500 individuals	
2	Information about 501 – 1,000 individuals	
3	Information about 1,001 – 5,000 individuals	
3	Information about 5,001 – 10,000 individuals	
3	Information about 10,001 – 100,000 individuals	
3	Information about 100,001 + individuals	

***Step 2: Identify which sensitivity characteristics may apply and the baseline scale point will adjust accordingly. Sensitivity Factors (SF) modify baseline scale***

Low: For each of the following factors reduce the baseline score by 1	
-1 for each	No clinical data at risk
	Limited demographic data at risk e.g. address not included, name not included
	Security controls/difficulty to access data partially mitigates risk

Medium: The following factors have no effect on baseline score	
0	Basic demographic data at risk e.g. equivalent to telephone directory
	Limited clinical information at risk e.g. clinic attendance, ward handover sheet

High: For each of the following factors increase the baseline score by 1	
+1 for each	Detailed clinical information at risk e.g. case notes
	Particularly sensitive information at risk e.g. HIV, STD, Mental Health, Children
	One or more previous incidents of a similar type in past 12 months
	Failure to securely encrypt mobile technology or other obvious security failing
	Celebrity involved or other newsworthy aspects or media interest
	A complaint has been made to the Information Commissioner
	Individuals affected are likely to suffer significant distress or embarrassment
	Individuals affected have been placed at risk of physical harm
	Individuals affected may suffer significant detriment e.g. financial loss
	Incident has incurred or risked incurring a clinical untoward incident

**Step 3: Where adjusted scale indicates that the incident is level 2, the incident will be reported to the ICO and DH automatically via the IG Incident Reporting Tool.**

#### **Final Score**

	<b>Level of SIRI</b>
1 or less	Level 1 IG SIRI (Not Reportable)
2 or more	Level 2 IG SIRI (Reportable)

#### **Breach Types**

This is a summary of the varied IG breach type. More details can be found on page 26 of the guidance

<https://www.igt.hscic.gov.uk/KnowledgeBaseNew/HSCIC%20IG%20SIRI%20%20Checklist%20Guidance%20V2%200%201st%20June%202013.pdf>

#### **List of Breach Types:**

- Corruption or inability to recover electronic data
- Disclosed in error
- Lost in transit
- Lost or stolen hardware
- Lost or stolen paperwork
- Non-secure Disposal - hardware
- Non-secure Disposal – paperwork
- Uploaded to website in error
- Technical security failing (Including Hacking)
- Unauthorised access/Disclosure
- Other

#### **Publication of IG SIRI by the Information Centre**

All information recorded under a 'Closed' IG SIRI on the IG Toolkit Incident Reporting Tool will be published quarterly by the Health and Social Care Information Centre (HSCIC). CCG must therefore check the content recorded within the IG Incident report before closing the record to ensure that you do not include any information that we would not normally provide or publish ourselves if requested under the Freedom of Information Act 2000. Other IG SIRIs marked as 'Open', 'Withdrawn' or 'Duplicate' will not be published by the HSCIC.

#### **Publishing the Incident reports on Annual report**

Incidents classified at a IG SIRI severity level 2 (see categorisation) are those that are classed as a personal data breach (as defined in the Data protection Act) or high risk of reputational damage, basically reportable to the Department of Health and the Information Commissioner's Office. These incidents need to be detailed individually in the annual report in the format provided on page 22 of this guidance

<https://www.igt.hscic.gov.uk/KnowledgeBaseNew/HSCIC%20IG%20SIRI%20%20Checklist%20Guidance%20V2%200%201st%20June%202013.pdf>. All reported incidents relating to the period in question should be reported, whether they are open or closed incidents.

## Annex E – Glossary

**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 by No Secrets for adults.

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'.

**Being Open** Open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare.

**Carers** Family, friends or those who care for the patient. The patient has consented to them being informed of their confidential information and to their involvement in any decisions about their care.

**Child** The Children Act 1989 and the Children Act 2004 define a child as being a person up to the age of 18 years. The Children Act 2004 states that safeguarding, protection and cooperation between services may, in certain circumstances, be continued through to a young person's 19th birthday or beyond.

**Commissioner** A person with responsibility for buying services from service providers in either the public, private or voluntary sectors.

**Clinical Commissioning Group** Clinically-led organisation, created by the Health and Social Care Act 2012 that commission's NHS-funded healthcare on behalf of its relevant population. CCGs will not commission primary care or specialised services.

**Culture** Learned attitudes, beliefs and values that define a group or groups of people.

**Equipment** Machines and medical devices used to help, prevent, treat or monitor a person's condition or illness. The term may also be used to refer to aids that may support a person's care, treatment, support, mobility or independence, for example, a walking frame, hoist, or furniture and fittings. It excludes machinery or engineering systems that are physically affixed and integrated into the premises.

**General Practitioner** A medical practitioner who provides primary care and specialises in family medicine. General practitioners treat acute and chronic illnesses and provide preventative care and health education for all ages and tender.

**Healthcare** The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in social care settings.

**Healthcare Professional** Doctor, dentist, nurse, pharmacist, optometrist, allied healthcare professional or registered alternative healthcare practitioner.

**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, visitor or member of the public.

**Independent Healthcare** Private, voluntary and not-for-profit healthcare organisations that are not part of the NHS.

**Independent Providers** Independent providers include Independent Hospitals, Nursing Homes and Hospice Care, as well as provider contracts with the voluntary sector providers. Where there will be an expectation that this policy will be interpreted and inclusive of their operations.

**Investigation** The act or process of investigating – a detailed enquiry or systematic examination.

**Major Incident** A major incident can be defined as “any occurrence which presents a serious threat to the health of the community, disruption to service, or causes (or is likely to cause) such numbers or types of casualty as to require special arrangements to be implemented”.

**Major surgery** surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, tissue or (if an extensive orthopaedic procedure is involved, the surgery is considered ‘major’).

**Medical Device** Any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) (including software intended by its manufacturer to be used for diagnostic and/or therapeutic purposes and necessary for its proper application), intended by the manufacturer to be used for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, alleviation of or compensation for an injury or disability, investigation, replacement or modification of the anatomy of a physiological process, and/or control of conception, and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

**Near Miss** A near miss is an incident that had the potential to cause harm but was prevented.

**Never Events** Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare provider.

**NHS-Funded Healthcare** Healthcare that is partially or fully funded by the NHS, regardless of the location.

**Notification** The act of notifying to one or more organisations/bodies

**Patient Safety** The process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient-related risks, the reporting and analysis of incidents, and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring. The term ‘patient safety’ is replacing ‘clinical risk’, ‘non-clinical risk’ and the ‘health and safety of patients’.

**Patient Safety Incident** Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. The terms ‘patient safety incident’ and ‘prevented patient safety incident’ will be used to describe ‘adverse events’/‘clinical errors’ and ‘near misses’ respectively.

**Permanent Harm** Permanent lessening of bodily functions; including sensory, motor, physiological or intellectual.

**Primary Care** refers to services provided by GP practices, dental practices, community pharmacies and high street optometrists and commissioned by the NHS England from April 2013.

**Professional Body** An organisation that exists to further a profession and to protect both the public interest, by maintaining and enforcing standards of training and ethics in their profession, and the interest of its professional members.

**Prolonged pain and/or prolonged psychological harm** Pain or harm that a service user has experienced or is likely to experience, for a continuous period of 28 days.

**Provider Organisation** Provider organisations include community health services, mental health services, learning disabilities, acute services and other health services providing services to residents in CCG areas.

**Provider (or Healthcare provider)** Organisation that provides healthcare including NHS Trusts, NHS Foundation Trusts, general practitioners, pharmacists, optometrists, dentists and non-NHS provider.

**Quality Surveillance Groups** Virtual teams established across a health economy either at the level of the relevant area team or the relevant regional team, bringing together

organisations and their respective information and intelligence gathered through performance monitoring, commissioning, and regulatory activities. By collectively considering and triangulating information and intelligence, QSGs will work to safeguard the quality of care that people receive.

**Risk** The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.

**Risk Management** Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.

**Root Cause Analysis (RCA)** A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

**Safety** A state in which risk has been reduced to an acceptable level.

**Safeguarding** Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults, on empowerment, independence and choice.

**Secondary care** Defined as a service provided by medical specialists who generally do not have first contact with patients. Secondary care is usually delivered in hospitals or clinics and patients have usually been referred to secondary care by their primary care provider (usually their GP). Secondary care services will be commissioned by CCGs from April 2013.

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

**Specialised services** Defined as those services with a planning population of more than one million people. This means that a specialised service would not be provided by every hospital in England. Specialised services will be commissioned by the NHS England from April 2013.

**Strategic Executive Information System (STEIS)** A means of reporting SIs to CCGs and NHS England.

**Treatment** Broadly, the management and care of a patient to prevent or cure disease or reduce suffering and disability.

**Unexpected Death** Where natural causes are not suspected. Local organisations should investigate these to determine if the incident contributed to the unexpected death.

**Working Day** Days that exclude weekends and bank holidays