NHS
Warwickshire North
Clinical Commissioning Group

Serious Incident Reporting & Management Policy & Procedure

Quality & Equality First

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21/11/2013	V1	Policy approved by the Clinical Quality, Safety and Governance Committee
23/1/2014	V2	Policy ratified by the Governing Body with minor amendments.
31/03/2014	V3.1	Revised policy approved by Patient Safety and Quality Group - Subject to tailoring for individual CCG's
17/04/2014	V3.2	Revised policy presented to the Clinical Quality Safety and Governance Committee for approval.
17/04/2014	V3.2	The Clinical Quality, Safety and Governance Committee reviewed and approved the policy with amendments. Revised Policy recommended by the Committee to the Governing Body for approval to adopt.
22/05/2014	V4	The Governing Body approved the adoption of the policy.
15/10/2015	V4.1	The Clinical Quality, Safety and Governance Committee received and approved the policy updated to reflect revised NHSE Serious Incident Framework and Never Events Framework. Updated policy recommended by the Committee to the Governing Body for approval to adopt.
26/11/2015	V5	The Governing Body approved the adoption of the Policy.

Contents

1. Introduction

Organisations providing NHS funded care in England are required to demonstrate accountability for effective governance and learning following a Serious Incident (SI) or Never Event (NE).

Warwickshire North Clinical Commissioning Group (The CCG) is committed to the establishment of a safety culture which promotes an open and fair culture towards the reporting of incidents their management and investigation. Incidents will be investigated, reviewed and analysed for the purposes of learning and improving safety and not to attribute blame. However, where the investigation reveals deliberate contraventions of acceptable policy and practice, action will be taken in accordance with professional registration and contract management arrangements. The CCG's make explicit in its contracts with all providers its expectations regarding incident reporting and management, and the indicators and the process for performance management.

This policy is intended to support the CCG's commitment to ensure that patients receive the best quality of care delivered through services which are safe, clinically effective and patient centred.

The CCG recognises that within the complex environment of healthcare, things will sometimes go wrong. Therefore the NHS has a duty to ensure that systematic measures are in place to respond to incidents in order to safeguard people, property, resources and reputation.

The role of the CCG is to gain assurance from its provider organisations that SI investigations are robust and that improvements aimed at preventing recurrence are implemented. In line with the CCGs clinical governance framework the CCG will triangulate information from SI reports with other intelligence to inform actions that continuously improve services. The CCG will share intelligence with relevant regulatory and partner organisations through locally established mechanisms.

In line with the NHS England Serious Incidents Framework (March 2015) WNCCG will be informed of any SI's that have occurred within any of its commissioned services as listed below:

- George Eliot Hospital NHS Trust (GEH)
- Independent and Private Providers, commissioned to provide NHS services for the CCGs population, including NHS commissioned placements and service provision in nursing homes
- Any other provider of NHS commissioned services affecting the patient population of Warwickshire North CCG for e.g. University Hospitals Coventry and Warwickshire NHS Trust (UHCW), Coventry and Warwickshire Partnership Trust (CWPT) and South Warwickshire Foundation Trust (SWFT)

As a minimum all commissioned and contracted NHS services organisations must:

- Ensure that their staff understand what constitutes an SI or NE, have appropriate procedures in place to ensure that such serious incidents are reported and investigated fully
- Have appropriate governance processes in place to ensure that local learning takes place following incidents to reduce future risks.

This document reflects national policies in relation to serious incidents including:

- Serious Incident Framework – NHS England (March 2015)
- Never Events Framework and Policy NHS England (March 2015)
- Statutory Duty of Candour

2. Purpose

The purpose of this policy is to outline the overarching governance arrangements for SI's and NE's, and to describe the process for reporting and management. This will ensure that incidents are appropriately managed within commissioned and contracted services. The responsibility of individuals in this process is explained in section 6.

The policy is intended to compliment and not replace the robust incident reporting systems which are already in place within NHS organisations. Providers should read this policy in context with other policies they have in place to ensure compliance with the Health and Social Care Act (2012) and local arrangements for ensuring staff, patients, carers and relatives receive support following an SI.

This policy does not replace the duty to inform other authorities of SI's, for example the Police, Social Services or Local Safeguarding Boards for Children and Adults, where appropriate. Other regulatory, statutory, advisory and professional bodies (listed in appendix 2 of the NHSE Serious Incident Framework) should be informed about serious incidents depending on the nature and circumstances of the incident. All serious incidents which meet the definition for a patient safety incident should also be reported separately to the NRLS for national learning.

Brief Summary of Contents;

Definition of an SI, Key roles and responsibilities, SI reporting and investigation processes, communication and escalation, monitoring trends and themes**.**

Organisational Related Policies and Procedures
Incident Reporting Policy

Legislation
This policy complies with national serious incident guidance as defined by Department of Health, NHS England and the National Patient Safety Agency (see reference list)

Review
The CCG's SI Policy will be reviewed every two years or sooner in the event that there are significant changes within legislation, good practice guidance or case law in respect to the investigation and management of SI's and/or there are significant changes to organisational infrastructure within the CCG.

Equality Impact Assessment
A full Equality Analysis has been completed on this policy.

Distribution
This policy will be available for all CCG and Arden Gem Commissioning Support (AGCS) staff and stored in a shared folder. Managers of staff without direct access to the intranet must provide access to an up to date paper copy of the policy. The policy will also be published on WNCCG website.

Glossary of Acronyms

CCG	Clinical Commissioning Group
CQRM	Clinical Quality Review Meeting
HCAI	Healthcare Associated Infection
HSE	Health and Safety Executive
IGSI	Information Governance Serious Incident
ICO	Information Commissioners Office
NE	Never Event
NHS	National Health Service
NHSE	NHS England
NMC	Nursing and Midwifery Council
NPST	National Patient Safety Team
RCA	Root Cause Analysis
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
SI	Serious Incident
SIRI	Serious Incident Requiring Investigation
STEIS	Strategic Executive Information System
CQSG	Clinical Quality, Safety and Governance Committee

3. Scope of Policy

This policy aims to ensure that:

- All members, staff and/or employees working for or on behalf of WNCCG are aware of their duties when reporting, investigating or managing incidents.
- Providers of commissioned services report SI's in a timely manner, respond appropriately and learn from their occurrence.
- WNCCG has an open and honest approach to provider incidents affecting patients, relatives and carers; and a commitment to sharing lessons learned.
- Lessons learned from incidents and trends are fully acted upon by commissioned providers and shared across the wider health economy.

4. Definitions

Serious Incident

The definition below sets out circumstances in which an SI must be reported. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that will require open and honest discussion between the CCG and the provider to agree an appropriate and proportionate response.

Serious Incidents which might occur in the NHS include:

- 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 caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission). This includes suicide/self-inflicted death; and homicide by a person in receipt of mental health care within the recent past. This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually.

    - 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.

- 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)

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

    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues.
    - Property damage.
    - Security breach/concern.
    - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population.
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act (MCA), Deprivation of Liberty Safeguards (DOLS).
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or a series of incidents, which necessitate ward/ unit closure or suspension of services), or
    - Activation of Major Incident Plan (by provider, commissioner or relevant agency)

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

Death due to natural causes
A death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice would not be classified as a Serious Incident.

Near Miss
It may be appropriate for a 'near miss' to be a classed as an SI 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 an SI 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 an SI but, where there is a significant existing risk of system failure and serious harm, the SI process should be used to understand and mitigate that risk.

5. Roles and Responsibilities

The roles and responsibilities of NHS England, commissioners and providers are clearly outlined in the NSHE Serious Incident Framework 2015.

NHS England
NHS England has a direct commissioning role as well as a role in leading and enabling the commissioning system. As part of the latter role, NHS England maintains oversight and surveillance of serious incident management within NHS-funded care and assures that CCGs have systems in place to appropriately manage serious incidents in the care they commission. They are responsible for reviewing trends, analysing quality and identifying issues of concern. They have a responsibility for providing the wider system with intelligence gained through their role as direct commissioners and leaders of the commissioning system.

WNCCG
The role of the CCG is to ensure the quality of commissioned services and to hold providers to account for their responses to SI's. This includes:

- Ensuring there is timely reporting of SI's by providers and feedback from the CCG.
- Engaging in open and honest discussion with providers.
- Gaining assurance that providers are operating an open and just culture, where staff are encouraged to report incidents without fear of inappropriate or unjust blame and where patients are informed and involved in investigations when they have been affected by an incident.

- Evaluating and quality assuring the robustness of their providers' SI investigations.
- Managing concerns raised in relation to the management of the investigation process.
- Agreeing a mechanism with providers to ensure that action plan implementation is undertaken and robust monitoring of actions takes place.
- Triangulating SI data with other intelligence obtained from day to day interactions with providers to inform actions that continuously improve services
- Liaising with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating and responding to safeguarding concerns.
- Complying with the statutory obligations and requirements of health services in relation to domestic homicide reviews
- Facilitating joint investigations between providers as appropriate.
- Establishing mechanisms for sharing intelligence with relevant regulatory and partner organisations.
- Sharing information with members of their local NHSE Quality Surveillance Group (QSG).
- Ensuring that SI trend data informs quality reviews and commissioning decisions.

Provider organisations

The CCG requires commissioned providers to meet the requirements outlined in the NHSE Serious Incident Framework. The leadership at a provider organisation is ultimately responsible for the quality of care that is provided by that organisation. The principles and processes associated with robust serious incident management must be endorsed within an organisation's Incident Reporting and Management Policy.

6. Accountabilities

Accountable Officer

Overall accountability within the CCG lies with the Accountable Officer who has responsibility for ensuring that the CCG has the necessary processes and procedures in place to support the effective management of implementation of all risk management and governance policies. In WNCCG responsibility for the management of SI's is formally delegated to the Director of Quality, Safety and Personalised Care.

Director of Quality, Safety and Personalised Care

The Director of Quality, Safety and Personalised Care has been designated by the Accountable Officer as the managerial lead for patient safety and safeguarding. The Director of Quality, Safety and Personalised Care has executive responsibility for ensuring that the necessary management systems are in place for the effective implementation of SI reporting for commissioned services and independent contracts.

Head of Quality and Safety / Patient Safety Lead (Arden and Gem Clinical Support Unit)

The Head of Quality and Safety/Patient Safety Lead is responsible for the leadership, coordination and operational management of the SI reporting process, ensuring there is a consistent and robust approach in line with policy specifically having;

- An overview of the management of incident notifications.
- Authority to make decisions regarding any withdrawal or extension requests received from provider organisations.
- Responsibility for sign off and closure of incidents.
- Attendance at provider Serious Incident Group meetings.
- Identification and analysis of themes and trends from SI's, RCA reports and action plans and providing reports to the Clinical Quality and Governance Committee.
- Responsibility for ensuring that local policies and procedures reflect national guidance.

Patient Safety Team

The Patient Safety Team is responsible for administration of incident reporting systems (SORD and STEIS) and management of associated databases, including:

- Acting as a point of contact for provider organisations to report any SI's/NE's via Serious Incident telephone.
- Notifying the CCG of any incidents reported on SORD and STEIS and any investigation updates/reports submitted by provider organisations
- Maintenance and administration of the SORD database and additional local databases
- Creating and updating serious incident records on SORD and STEIS for providers that cannot access the database (e.g. Nursing Homes)
- Producing a monthly report in respect of the quality and safety of commissioned services.
- Extracting additional data and reports in line with WNCCG requirements
- Attendance at provider Serious Incident Group meetings

WNCCG Contract Managers

Contract Managers will ensure that explicit reference to SI management and reporting is included in contracts with all commissioned provider services including the process for performance management.

WNCCG Communications Team

On behalf of WNCCG the communications team will prepare briefings in relation to serious incidents as required.

7. Interfaces with Other Sectors

In certain circumstances the SI process will coincide with other procedures. In order to minimise duplication and confusion, WNCCG will work collaboratively with partner agencies. Ideally, only one investigation should be undertaken to meet the needs/requirements of all parties. However, where investigations have different aims and purposes, joint investigations may not be possible but efforts should be made to ensure duplication of effort is minimised.

Serious Case Reviews (SCR) and Safeguarding Adult Reviews (SAR)

Healthcare providers must contribute towards safeguarding reviews and enquiries as required to do so by the Local Safeguarding Board. Where it is evident that an SI has occurred, this must be reported in the usual manner. Whilst the Local Authority will lead SCRs, SARs and initiate Safeguarding Enquiries, the CCG must be able to gain assurance that, if a problem is identified, appropriate measures will be undertaken to protect individuals that remain at risk and ultimately to identify the contributory factors and the fundamental issues to minimise the risk of further harm and/or recurrence.

The interface between the SI process and the local safeguarding adult procedures are outlined in the West Midlands Adult Safeguarding Multi-agency Policy and Procedure.

The arrangements for interagency working in respect of safeguarding children are outlined in the Safeguarding Children Boards' Policies and Procedures for both Coventry and Warwickshire. The Director of Quality, Safety and Personalised Care is a member of both Coventry and Warwickshire Safeguarding Children's Boards and liaises regularly with the Local Authority Safeguarding Executive Leads.

8. Reporting of Serious Incidents

SI's must be reported by the provider to the commissioner by telephone via the CSU without delay and no later than 2 working days after the incident is identified, or at the earliest point thereafter with an explanation for any delay.

An SI must be reported by recording the incident on the NHS serious incident management system (STEIS or its successor system) and the local Serious incident Online Reporting Database (SORD). Where providers are unable to access STEIS (e.g. nursing homes) the provider should submit a Serious Incident form to the CSU who will enter the incident onto STEIS and SORD and report to the CCG on the provider's behalf. The SI escalation proforma/entry must not contain any patient or staff names and the description should be clear and concise.

Incidents falling into any of the categories below should be reported immediately to the relevant commissioner by telephone as well as electronically:

- Incidents which activate the NHS Trust or Commissioner Major Incident Plan.
- Incidents which will be of significant public concern.
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police, the local health protection unit (Public Health England) or other external agencies.

Out-of-hours, the local on-call management procedures must be followed.

Safeguarding Incidents

The Serious Incident Framework requires that incidents involving actual or alleged abuse are to be reported as SI's where:

- Healthcare providers did not take appropriate action/intervention to safeguard against such abuse occurring. (This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment; or share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment)
- The abuse occurred during the provision of NHS-funded care.

Abuse includes:

- sexual abuse, physical or psychological ill-treatment
- acts of omission which constitute neglect
- exploitation
- financial or material abuse
- discriminative and organisational abuse
- self-neglect
- domestic abuse
- human trafficking
- modern day slavery

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.

From April 2015, the Care Act (2014) provides a statutory footing to safeguard adults, thereby replacing previous guidance such as *No Secrets* (2000). The Care Act (2014) creates a legal framework to promote a shared approach by all agencies with responsibilities for adult safeguarding to work together to keep adults at risk safe.

Unexpected Child Death

In the event of an unexpected child death providers are required to complete a notification form and return this to the CCG (appendix F). All forms will be reviewed by the Designated Nurse for Safeguarding Children in line with the unexpected child death Serious Incident process (appendix E). The Local Safeguarding Children Board is responsible for ensuring that a review of each death of a child normally resident in the LSCB's area is undertaken by a Child Death Overview Panel. The process for review of child deaths is outlined in Working together to Safeguard Children (2015).

NHS Screening Programme Serious Incidents

The national guidance for screening programme SI's is currently under review. The final guidance will be issued in summer 2015. Until that point the revised national guidance in relation to screening incidents issued in March 2015 should be followed. The guidance details the accountabilities for reporting, investigating and managing screening safety incidents. It covers the management of safety concerns, safety incidents and serious incidents in screening programmes.

Pressure Ulcer Serious Incidents

The revised Serious Incident Framework states that that blanket reporting of all grade 3 and 4 pressure ulcers by providers can lead to debilitating processes which do not effectively support learning. However, providers should continue to report pressure ulcers where they meet the SI criteria. From May 2015, Grade 3 Deep Tissue Injuries are not reportable as SI's unless they remain unresolved 14 days following identification.

For patients admitted or transferred to a healthcare setting without any obvious signs or symptoms of skin damage, the development of a grade 3 or 4 pressure ulcer within 72 hours of admission to that institution is likely to be related to pre-existing damage incurred prior to admission or transfer of care. Any pressure area damage arising after 72 hours is likely to be related to care provided within the healthcare setting and must be regarded as a new event.

It is anticipated that further guidance will be issued by NHS England to support the multi-incident investigation root cause analysis (RCA) model. This model provides a useful tool for thoroughly investigating reoccurring problems of a similar nature (such as a cluster pressure ulcers in a similar setting or amongst similar groups of patients) in order to identify the common problems, contributing factors and root causes. The tool allows one comprehensive action plan to be developed and monitored and, if used effectively, moves the focus from repeated investigation to learning and improvement. CRCCG is working toward developing a system wide approach to learning from pressure ulcers.

Information Governance (IG) Incidents

Information Governance incidents that fulfil the criteria of being an SI must be handled in accordance with the Department of Health's Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation June 2013. This guidance can be accessed at

https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf

SI's relating to information governance must be reported on SORD and STEIS, as well as the IG toolkit as required by the Health and Social Care Information Centre (HSCIC) guidance. The severity of the incident must be assessed using the scale and severity factors outlined within the HSCIC guidance and all incidents which reach the threshold for a level 2 IG related serious incidents should be reported publicly via the IG toolkit and reported and investigated as serious incidents. All IG incidents should be referred to the Director of Integrated Governance who will liaise with the Arden & GEM CSU Information Governance Team with regard to reporting the incident on the IG Toolkit.

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

a) Level 1 = Confirmed IG SIRI but no need to report to ICO, DH and other central bodies
b) Level 2 = Confirmed IG SIRI that must be reported to ICO, DH and other central bodies

A further category of IG SIRI is also possible and should be used in incident closure. This is where it is determined that it was a near miss or the incident is found to have been mistakenly reported. Such cases should be immediately highlighted to the CCG so that they can be removed from STEIS. In respect to all IGSIs the following process should be followed to categorise the incident:

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 Score	
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 must be reported via the Information Governance Toolkit IG SIRI module.

Final Score	Level of SIRI
1 or less	Level 1 IG SIRI (Not Reportable)
2 or more	Level 2 IG SIRI (Reportable)

There is no simple definition of a serious IG incident, but as a guide, any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious. This definition applies irrespective of the medical information involved and includes both loss of electronic media and paper records. Specialist Information Governance advice should be sought if there is any doubt.

All incidents rated as Serious Incidents are to follow the SI process and the following additional information should be provided in each case:

a) A short description of what happened including the actions taken and whether the incident has been resolved;
b) Details of how the information was held – paper, memory stick, disc, laptop etc;
c) Details of any safeguards such as encryption that would mitigate risk;
d) Details of the numbers of individuals whose information is at risk;
e) Details of the type of information – demographic, clinical, bank details etc;
f) Whether a) the individuals concerned have been informed, b) a decision has been taken not to inform, or c) this has not yet been decided;
g) Whether a) the Information Commissioner has been informed, b) a decision has not yet been taken to inform, or c) this has not yet been decided;
h) Whether the SI is in the public domain and the extent of any media interest and/or publication.

Duty of Candour

Recommendation 174 of the Francis Report February 2013 states:

"Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information."

A statutory requirement has been introduced to ensure health care providers operate in a more open and transparent way. The regulation for Duty of Candour applied to health service bodies from 27 November 2014, and was extended to all other providers from 1 April 2015. This regulation requires an NHS body to:

- ensure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity
- tell the relevant person in person as soon as reasonably practicable after becoming aware that a 'notifiable safety incident' has occurred, and provide support to them in relation to the incident, including when giving the notification provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification
- advise the relevant person what further enquiries the health service body believes are appropriate
- offer an apology
- follow this up by giving the same information in writing, and providing an update on the enquiries
- keep a written record of all communication with the relevant person

The duty of candour section of the STEIS reporting form must be completed for all incidents reported. It is noted that the contractual requirements of Duty of Candour are clearly set out within Provider Contracts.

Caldicott Principles, Data Protection and Information Governance

Reporting organisations must comply with Caldicott Principles, Data Protection and Information Governance requirements when reporting an SI. Particular attention must be paid to confidentiality, sensitivity and person identifiable information – apart from the name of the reporter within STEIS all other reports and correspondence should not contain any patient or staff identifiable information. The incident will be given a unique identifier which should be quoted as a reference during all associated correspondence.

Managers should be aware of Department of Health guidance that may exempt details of individual serious incidents being made available to third parties, under either or both Section 31(2) and Section 40 (2 and 3) of the Freedom of Information Act.

Media Interest

Where potential media interest exists, it is important that the reporting organisation prepares a media response based on the available information. The Commissioner must be informed of the media approach/strategy being taken by the reporting organisation so as to ensure any necessary media management is proportionate and well managed. The communication team should be alerted in accordance with local CCG guidance. Where a number of organisations are involved, a lead organisation will be agreed to manage and coordinate any external communications. Management of Serious Incidents.

Initial Review of Incident Notifications

Following notification of an SI an initial review will be undertaken by an appropriate member of the WNCCG/AGCSU Quality and Safety Team. Where required specialist advice will be sought. A 72 hour update may be requested from the provider at the discretion of the CCG in order to provide assurance that any necessary immediate actions have been taken to ensure the safety of staff, patients and the public; and to assess the incident in more detail. The update should be uploaded onto the SORD system by the provider.

Where an SI indicates an issue/problem that has significant implications for the wider healthcare system, or where an incident may cause widespread public concern, the initial reviewer will consider the need to share information with NHS England and other partner agencies as required.

Investigation of serious incidents

The responsibility for investigating SI's lies with the reporting organisation, however the CCG has a responsibility to quality assure the robustness of the providers investigation.

The investigation should be underpinned by clear terms of reference, a robust management plan and communication/media handling strategy (as required). Investigations should follow root cause analysis (RCA) methodologies and an investigation toolkit can be accessed from National Reporting and Learning Service. The table below outlines the levels of investigation currently recognised for NHS serious incident investigations.

Additional Investigation Requirements

All reporting organisations must have policies and processes in place to ensure that employees are supported and managed where professional standards are found through investigation to be short of the high professional standards expected ensuring that appropriate remedial action, performance or regulatory action is taken to safeguard patients.

In addition to a comprehensive root cause analysis of SI's and NE's managers should where relevant consider use the NPST's Incident Decision Tree to inform their decision on what initial action to take with the staff involved in the incident, ensuring a consistent and fair approach. The result of applying the Incident Decision Tree and details of any actions taken against healthcare professionals or other alternatives explored should where relevant be included within the appendices of the RCA investigation report.

The Incident Decision Tree is a simple to use web-based tool accessible on the NPST's website: https://report.NPST.nhs.uk/idt2/(S(e0t3zjipvl5ln2m0hmglgp3z))/index.aspx

Withdrawal of Incident Report

If at any time during an SI investigation, it becomes apparent that the incident does not constitute an SI it may be withdrawn. The provider must make a formal request to the CCG for consideration, including a clear rationale for withdrawal. At this point the incident will be removed from SORD and STEIS but be recorded on a local database for audit purposes if agreed.

Timescales for Investigation

SI reports and action plans must be submitted to the relevant commissioner within 60 working days of the incident being reported, unless an independent investigation is required, in which case the deadline is 6 months from the date the investigation commenced. In certain circumstances, Trusts may find it difficult to complete a final report within these timescales due to:

- enforced compliance with the timetable of an external agency, such as police, Coroner, Health and Safety Executive or Local Children Safeguarding Board or Safeguarding Adult Board;
- investigation of highly specialised and multi-organisation incidents, such as those involving a national screening programmes; or
- Incidents of significant complexity.

Extensions to timescales may also be approved in circumstances meet the CCGs local criteria, including:

- awaiting outcome of court proceedings
- awaiting forensics post-mortem findings
- awaiting toxicology results

The CCG should be notified of extension requests in writing including the reason for the delay, the anticipated delay period and a new reporting timescale. Where a compelling reason is provided an extension may be agreed by the CCG and a “clock stop” will be recorded on STEIS and SORD. It is essential where a clock stop is in place that providers ensure that the CCG is regularly updated on the progress of the investigation.

Final Report and Action Plan

Providers must upload the final Root Cause Analysis report to SORD upon completion of the investigation. Providers who cannot access SORD must submit the report via the CSU secure email address (ACSU.patietnsafety@nhs.net). The CCG recommends that providers utilise the locally agreed templates for the final report and action plan.

This policy does not contain the report and action plan templates as these are currently subject to review in line with the national guidance.

9. Quality Assurance and Closure of the Investigation

The CCG will undertake a quality assurance review of each investigation report within 20 calendar days (an alternative timescale may be agreed if appropriate).

An appropriate member of the WNCCG/AGCSU Quality and Safety Team (according to the nature of the incident) will review the report and complete a locally agreed closure checklist (Appendix B) to ensure that the report meeting the standard for a robust investigation and action plan. A secondary review may be requested by another member of the team where concerns have been identified. Any concerns or areas requiring further action will be logged on the RCA review database and highlighted to the provider as appropriate to facilitate action and resolution of any issues raised.

Where the CCG requires additional assurance in relation to the implementation of an investigation action plan, the incident may remain open on SORD and STEIS to ensure close review and monitoring or preventative actions.

10. Dissemination of Learning

SI investigations are conducted for the purposes of learning to prevent recurrence. In line with the national Serious Incident Framework WNCCG aims to facilitate learning by:

- seeking assurance that providers have a fair, open, and just culture
- quality assuring incident investigation reports to ensure that areas for improvement are identified and incorporated into robust action plans
- ensuring providers have systems in place to monitor the implementation of actions plans
- identifying systemic issues in order to prevent recurrence and developing quality improvement plans, e.g. through thematic review and triangulation of incident data with other intelligence

- challenging "the status quo" and prompting providers to undertake "deep dive" reviews into areas of concern
- sharing patient safety information with other local CCGs and partner agencies as appropriate
- participating in the Coventry and Warwickshire Learning Forum
- supporting smaller providers (e.g. nursing homes) to report and investigate incidents
- encouraging providers to share investigation reports where appropriate

11. Monitoring and Reporting Committees and Groups

<u>WNCCG Governing Body</u>
The Governing Body has oversight of the management of serious incidents through the minutes of the Clinical Quality and Governance Committee.

<u>Clinical Quality Safety and Governance Committee (CQSG)</u>
The Clinical Quality and Governance Committee is a sub-group of the WNCCG Governing Body which provides assurance that robust processes are in place to monitor the clinical quality and safety of commissioned services. The Committee will receive regular reports to provide assurance in relation to serious incidents. Key areas of concern will be escalated as appropriate.

To comply with national guidance for Never Events the CQSG will monitor Never Events within WNCCG commissioned services and publicly report through Governing Body on the national Never Events list as part of annual quality reporting arrangements. This will include the frequency and type of Never Events which have occurred and a summary of the actions that these providers have implemented following root cause analysis of significant event audit.

Clinical Quality Review Meeting (CQRM)
WNCCG makes explicit reference to expectations regarding serious incident reporting and management within provider contracts. In order to ensure continuous improvement a range of key performance indicators are built into provider contracts which are monitored via each providers CQRM. The relevant CQRM will monitor performance of SI management and highlight any concerns in relation to trends, robustness of actions and lack of assurance regarding quality and safety.

Cross CCG Patient Safety & Quality Group
The Patient Safety and Quality Group meets quarterly to facilitate collaborative review of SI's and NE's by WNCCG, Coventry and Rugby CCG and South Warwickshire CCG.

Coventry and Warwickshire Learning Forum
The Coventry and Warwickshire Learning Forum meets quarterly and aims to ensure that learning from SI's and NE's is shared across local CCGs and providers, the NHSE Area Team and other interested parties from the wider health economy.

12. Themed Reviews

In cases where there is evidence that an incident is part of a trend or where the circumstances or consequences of the incident are exceptionally serious the CCG may instigate a wider investigation or themed review.

13. Training & Awareness

Staff will be made aware of this policy through the staff induction process, when directed to review policies and procedures of the organisation. The policy will be held on the Internet.

14. Equality and Diversity

Reporting organisations must comply with Equalities and Human Rights requirements and legislation when reporting, managing, and preventing SI's. Understanding and upholding the rights and dignity of patients from protected groups can aid in the early identification of potential risks and risk groups. The policy identifies a number of protected characteristics including older people who are frail, maternity, and mental health that may potentially be at higher risk of an SI.

Reporting organisations are required to collect patient equality monitoring information by gender, ethnicity, and age via STEIS, and are encouraged to supply any additional relevant equality information in the additional text section. The CCG's may also from time to time request additional equality information.

The CCG's will undertake regular analysis of this information in order to identify any trends, as part of its on-going routine monitoring processes. The identification of any concerning equality trends or issues will prompt an immediate themed investigation by the CCG's.

15. Policy Review

The CCG's Serious Incident Policy will be reviewed bi-annually or sooner in the event that there are significant changes within legislation, good practice guidance or case law in respect to the investigation and management of serious incidents and/or there are significant changes to organisational infrastructure within the CCG.

Appendices

Appendix A - Definitions

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

Clinical Governance
A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Information Governance
All Information Governance SI's are to be handled in accordance with the guidance developed by the Department of Health "Checklist for reporting Managing and Investigating information Governance Serious Untoward Incidents". This guidance includes details on assessing the severity of the incident and reporting requirements via the Information Governance (IG) Toolkit.

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.

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.

Safeguarding
Safeguarding is effectively protecting children and vulnerable adults from abuse or neglect. All NHS commissioned services have a key role to play in safeguarding and promoting the welfare of children and vulnerable adults, as safeguarding is everybody's business. Safeguarding children is a statutory duty under section 11 of the Children Act 2004 and in accordance with government guidance in 'Working Together to Safeguard Children' 2015.

UNIFY/STEIS
UNIFY is the source of Performance Management information for the Department of Health and NHS. It brings together the data collection and performance reports for the NHS and Social Care System in England. It is a source of Performance Management information for NHS England

The Strategic Executive Information System (STEIS) is one of the modules of UNIFY. Users are enabled to electronically log, track and report serious incidents. The STEIS module is password protected to ensure effective data protection and has different passwords to the other modules in UNIFY. Each NHS Trust has been provided with a unique username and password for the system. STEIS can be accessed at *http://nww.steis.doh.nhs.uk/steis/steis.nsf/main?readForm*

SORD (Serious Incident On-line Reporting Database)
SORD is the local risk management database used in parallel to STEIS to record SIs for all contracted and commissioned services. SORD is used to facilitate local reporting, monitoring and trends analysis. It also allows secure document storage, aggregates data collection and an online methodology for commissioners to score the quality of provider investigation reports against best practice.

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Appendix B - References and Further Reading

Serious Incident Framework 2015, NHS England
http://www.england.nhs.uk/ourwork/patientsafety/serious-incident/

Revised Never Events Policy and Framework 2015, NHS England
http://www.england.nhs.uk/ourwork/patientsafety/never-events/

National Reporting and Learning Service investigation toolkit
https://report.nrls.nhs.uk/rcatoolkit/course/index.htm

National Patient Safety Agency, 'Seven Steps to Patient Safety'', 2004 – 2009
http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

National Patient Safety Agency, 'Being Open: communicating patient safety incidents with patients, their families and carers', November 2009
http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726

National Patient Safety Agency Tools and training resources to support RCA investigation in the NHS
http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

National Patient Safety Agency information for multi-incident investigations
http://www.nrls.npsa.nhs.uk/resources/?entryid45=75355

CQC Regulation 20: Duty of candour Guidance for NHS bodies November 2014
http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf

Royal Colleague of Surgeons (2015) Duty of Candour Guidance For Surgeons And Employers
https://www.rcseng.ac.uk/news/docs/1-duty-of-candour-web-final.pdf

NHS Litigation Authority Advice on saying sorry
http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf

Health and Social Care Information Centre guidance (HSCIC) Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (2015)
https://www.igt.hscic.gov.uk/KnowledgeBaseNew/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf

Managing Safety Incidents in NHS Screening Programmes – updated interim guidance (March 2015)
http://www.screening.nhs.uk/incidents

Working Together to Safeguard Children A guide to inter-agency working to safeguard and promote the welfare of children (2015)
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419595/Working_Together_to_Safeguard_Children.pdf

Guidance for adult safeguarding concerns
http://careandsupportregs.dh.gov.uk/category/adult-safeguarding/

NHS Emergency Preparedness Framework, May 2015
http://www.england.nhs.uk/ourwork/eprr/gf/

Prison and Probation Ombudsmans Guidance for Clinical Reviews
http://www.ppo.gov.uk/updated-guidance-for-clinical-reviews/

Guidance on running Quality Surveillance Groups, *National Quality Board, 2nd Edition, March 2014*
http://www.england.nhs.uk/wp-content/uploads/2014/03/quality-surv-grp-effective.pdf

Quality in the New Health System, Main*taining and Improving Quality.* National Quality Board, January 2013
https://www.gov.uk/government/publications/quality-in-the-new-health-system-maintaining-and-improving-quality-from-april-2013

Human Rights Review (2012) Article 2: The Right to Life
http://www.equalityhumanrights.com/sites/default/files/documents/humanrights/hrr_article_2.pdf

Mental Capacity Act: making decisions
https://www.gov.uk/government/collections/mental-capacity-act-making-decisions

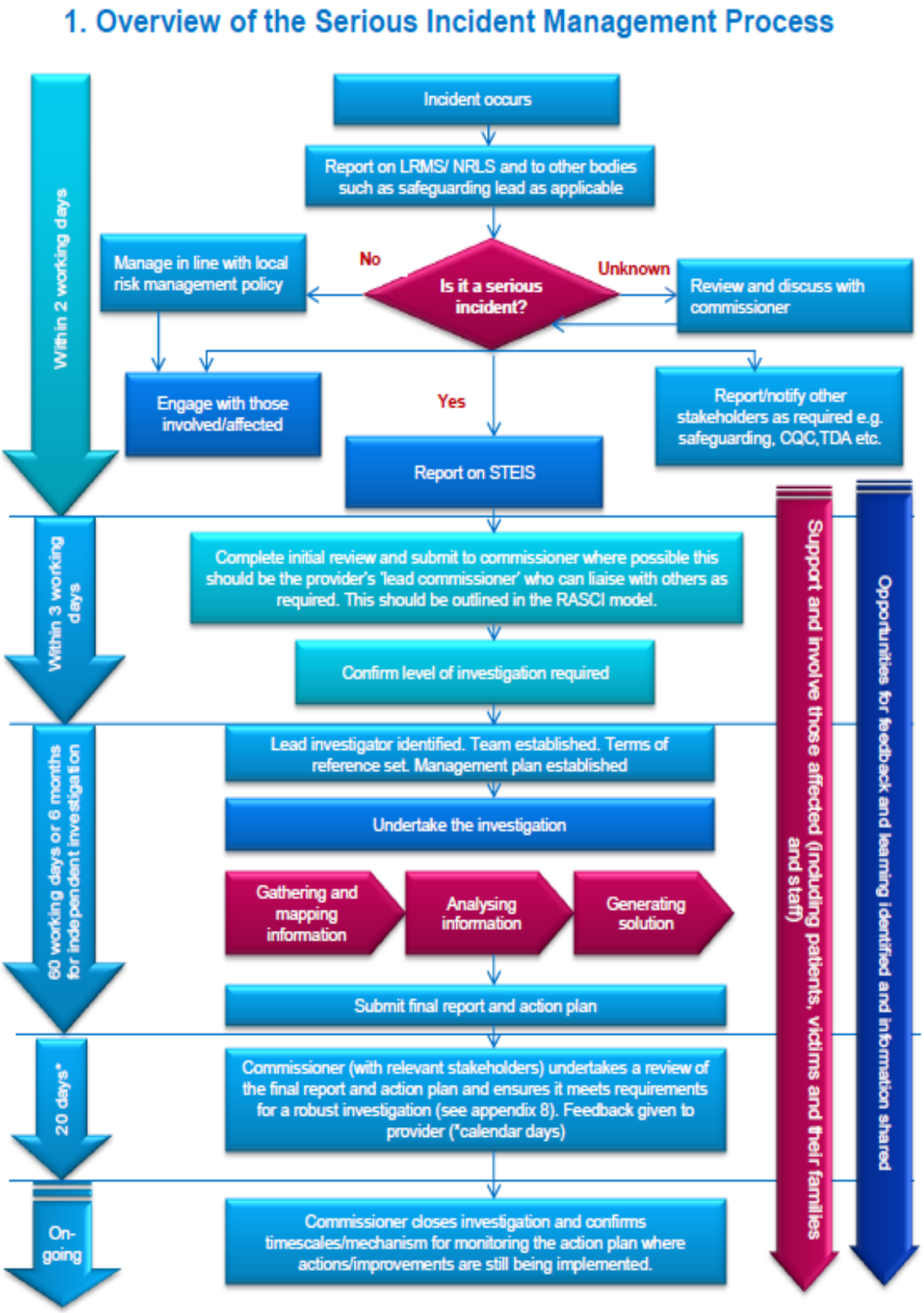
Mental Capacity Act 2005: Deprivation of liberty safeguards - Code of Practice to supplement the main Mental Capacity Act 2005 Code of Practice
http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085476

Care Act 2014
http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted

Warwickshire Safeguarding Children Board (WSCB) – resources
http://www.warwickshire.gov.uk/wscbresources

Coventry Safeguarding Children Board Procedures Manual
http://coventryscb.proceduresonline.com/chapters/contents.html

Appendix C – Overview of the Serious Incident Management Process



Appendix D – WNCCG RCA Report Closure Checklist

Provider:		**Date Received:**	
Category:		**Date Reviewed:**	
SORD No.		**Reviewer:**	
STEIS No.			

Phase of Investigation	Element	Yes/No	If no, was there a robust rationale that prevents this affecting the quality of the investigation?
Set up/ preparation	Is the Lead Investigator appropriately trained?		
	Was there a pre-incident risk assessment		
	Did the core investigation team consist of more than one		
	Were national, standard NHS investigation guidance and process used		
Gathering & Mapping	Was the appropriate evidence used (where is was available) i.e. patients notes/records, written account		
	Were interviews conducted		
	Is there evidence that those with an interest were involved *(making use of briefings, de-briefings, draft reports etc)*		
	Is there evidence that those affected *(including patients /staff/victims/perpetrators and their families)* were involved and supported appropriately		
	Is a timeline of events produced		
	Are good practice guidance and protocols referenced to determine what should have happened		
	Are care and service delivery problems identified *(this includes what happened that shouldn't have and what didn't happen that should have. There should be a mix of care (human error) and service (organisational) delivery problems)*		
	Is it clear that the individuals have not been unfairly blamed? *Disciplinary action is only appropriate for acts of wilful harm or wilful neglect)*		
Analysing Information	Is there evidence that the contributory factors for each problem have been explored		
	Is there evidence that the most fundamental issues / or root causes have been considered		
Generating Solutions	Have strong and targeted recommendations and solutions (targeted towards root causes/ contributory factors/ service delivery issues) been developed? Are actions assigned appropriately?		
Throughout	Is there evidence that those affected have been appropriately involved and supported		
Next Steps	Is there a clear plan to support implementation of change and improvement and method for monitoring		

TRENDS & THEMES

Please tick all those which apply	Themes:
	Individual Staff Issue
	Team and Social Factors
	Communications Factors
	Task Factors
	Education and Training
	Equipment / Resources
	Working Environment / Conditions
	Organisational / Strategic Factors
	Staffing
	Patient Factors

ISSUES TO BE RAISED WITH PROVIDER

REFERRED FOR SECOND REVIEW TO:

COMMENTS FROM SECOND REVIEW

Appendix E - Unexpected Child Death Serious Incident Process

Appendix F – Form for notification of unexpected child death to the CCG

FORM FOR NOTIFICATION OF UNEXPECTED CHILD DEATHS TO THE CCG
WARWICKSHIRE NORTH CLINICAL COMMISSIONING GROUP

To be sent by fax to: **or** Secure email to: ……

This form must be forwarded within 1 working day

Information on File:

Name of Child: …… **NHS No**: ……

Date of Birth: …… **Date of Death**: ……

Place of death: ……

……

Place of resuscitation: ……

……

……

Brief description of case (if not on Form A): ……

……

……

……

Has the child been seen in the last week
by a GP or Out of Hours Service? **Y / N** if Yes please provide details:

……

……

……

Details of any recent hospital admissions (in last month): ……

……

……

……

CAE completed? **Y / N**

Notified as **SUI** within provider Trust? **Y / N**

Is an **RCA** being undertaken? **Y / N**

SI FORM FOR NOTIFICATION OF UNEXPECTED CHILD DEATHS TO
WARWICKSHIRE NORTH CLINICAL COMMISSIONING GROUP

Name of Child: ..... **NHS No**: .....

Child Death

Was a Strategy Meeting undertaken?	
Was a Rapid Response required?	
Was rapid response undertaken?	
Which provider did rapid response? UHCW / SWFT / GEH	
Which Paediatrician did rapid response?	
Which Paediatrician for Unexpected Child Death is managing the case?	

Appendix G Equality Impact Assessment

Directorate	Nursing, Quality and Safety	Team	Patient Safety	Name of lead person	Rebecca Bartholomew

Piece of work being assessed	Serious Incident Policy
Aims of this piece of work	To set out the processes for management of serious incidents

Date of EIA	10.06.15	Other partners/stakeholders involved	Arden CSU, Provider Organisations

Who will be affected by this piece of work?	Serious Incidents are reported in line with national framework (2015) and are managed anonymously by WNCCG. The purpose of reporting serious incidents is to identify and share learning to help prevent future occurrences and improve patient safety. The policy does not appear to have any adverse effects on people who share Protected Characteristics. It is intended that the WNCCG population with benefit from the process of continuous learning and quality improvement.

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	Serious Incidents are reported relating for male and female, however it is uncertain whether transgender people can be identified.	Yes
Race	Serious Incidents are reported relating to people of different races. Patients and their families should be informed by the Provider service of all incidents and the resulting actions following investigations. Some people do not have English as a first language and therefore may require translation to fulfil the requirements of Being Open and Duty of Candour.	Yes
Disability	Some Serious Incidents may affect people who have a learning disability, mental health problem, speech and language disability, hearing or visual impairment or other health condition which may affect their ability to be involved and informed during the Serious Incident process. An individual's disability status may or may not be recorded depending upon the nature of the report.	Yes
Religion/ belief	Serious Incidents may affect people who come from a variety of religious backgrounds. An individual's religious belief is not recorded within reports. There is no evidence to suggest that an individual of a particular religious belief may be more or less likely to be affected.	No

Sexual orientation	Serious Incidents may affect people of a variety of sexual orientations. An individual's sexual orientation is not recorded within reports. There is no evidence to suggest that an individual of a particular sexual orientation may be more or less likely to be affected.	No
Age	Serious Incidents may involve all ages within the population. An individual's age is recorded within reports. People of an older age may be more likely to suffer from ill-health however this is not directly linked to reporting/occurrence of a serious incident.	No
Social deprivation	Serious Incidents can involve people from all social demographics. An individual's socio-economic status is not recorded within reports. People from or of a more deprived background may be more likely to suffer from ill-health however this is not directly linked to reporting/occurrence of a serious incident.	No
Carers	Serious Incidents may involve people who are cared for by another person.	No
Human rights	Will this piece of work affect anyone's human rights?	No

Equality Impact Assessment Action Plan

Strand	Issue	Suggested action(s)	How will you measure the outcome/impact	Timescale	Lead
Potential barrier for the patient/relative /carer where English is not the first language	Translation and interpreting services are available at the Provider Service. If a CCG serious incident occurs translation and interpreting services should be available if required. WNCCG will review each RCA investigation to ensure that information has been sought from key people involved in the case ie. patient/relative/carer	Potential barrier for the patient/relative/carer where English is not the first language	Monitor Duty of Candour KPI within the Provider Quality Schedules	Monthly	Patient Safety leads /Contract Managers
Disability	Potential barrier for a patient/relative/carer with sensory, learning or mental health impairments	The Provider Service/CCG reporting the serious incident must ensure that systems and processes are in place for patients, families and carers involved in adverse incidents to comply with Duty of Candour and Being Open. An independent advocate may be used to facilitate the involvement of the individuals in the process. WNCCG will review each RCA investigation to ensure that information has been sought from key people involved in the case ie patient/relative/carer.	Monitor Duty of Candour KPI within the Provider Quality Schedules	Monthly	Patient Safety leads /Contract Managers
Carers	Serious Incidents may involve people who are cared for by another person.	Patients, families and carers involved in Serious Incidents should expect a common culture of openness, transparency and candour which is explicit within the Serious Incident Policy. WNCCG will review each RCA investigation to ensure that information has been sought from key people involved in the case ie patient/relative/carer.	Monitor Duty of Candour KPI within the Provider Quality Schedules	Monthly	Patient Safety leads /Contract Managers