Incident/Near-Miss Reporting and Investigation Policy (Includes Serious Incidents)

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Policy includes (Management of Incidents and Root Cause Analysis Management)

Document Type	Corporate Policy
Unique Identifier	CL-147
Document Purpose	This policy will set out the process for reporting and learning from adverse incidents, including Near Misses and Serious Incidents. It also incorporates reporting and management of incidents and RCA management
Document Author	▓▓▓▓▓▓▓▓
Target Audience	All members of staff
Responsible Group	Quality and Safety Committee
Date Ratified	27th January 2016
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VERSION HISTORY/ CONSULTATION

Version	Circulation Date	Job Title of Person/Name of Group circulated to	Brief Summary of Change
V1	20.10.15	Chief Executive	
V1	20.10.15	Director of Quality and Executive Nurse	
V1	20.10.15	Interim Medical Director	
V1	20.10.15	Director of Operations	
V3	28.01.16	Company Secretary	
V1	20.10.15	Deputy Director of Nursing	
V1	20.10.15	Deputy Medical Director	
V1	20.10.15	SDU Lead, Community Care North	
V1	20.10.15	SDU Lead Community Care South	
V1	20.10.15	SDU lead, AMH	
V1	20.10.15	Deputy Managing Director, Forward Thinking Birmingham	
V1	20.10.15	SDU lead, LD	
V1	20.10.15	Quality Lead Offender Health	Amendments 7,8,910,11,12,15,1825,27,28
V1	20.10.15	Compliance Manager	
V1	20.10.15	Quality Lead, Community Care South	Amendments page 7
V1	20.10.15	Quality Lead, Community Care North	
V1	20.10.15	Interim Quality Lead, Wyre Forest	
V1&V2	20.10.15 06.11.15	Quality Lead AMH	Amendments 7,9, 10,11,14,18,24,29
V1	20.10.15	Clinical Lead – AMH	
V2	20.10.15 06.11.15	Quality Lead CYPF, Sexual Health and Dentistry	Amendments page 8, 26, comments page 9,24
V1	20.10.15	Quality Lead, LD	
V1	20.10.15	AMH- Consultant Psychiatrist	
V1	20.10.15	Sexual Health, Clinical Director	
V1	20.10.15	Consultant Palliative Care Medicine	
V1	20.10.15	CC- Consultant Psychiatrist	
V1	20.10.15	AMH, Consultant Psychiatrist	

V1	20.10.15	AMH, Consultant Psychiatrist	
V1	20.10.15	Dental Services Clinical Director	
V1	20.10.15	LD, Clinical Lead Consultant	
V1	20.10.15	Patient Safety Co-ordinator	
V1	20.10.15	Health and Safety Manager	Amendments to job title
V1	20.10.15	Risk and Security Manager	
V1	20.10.15	Head of Corporate Nursing and Education	Title change, non inclusion of individual names, training section
V1	20.10.15	Nurse Consultant, OAMH	
V1	20.10.15	Chief Pharmacist	Added, all incidents or concerns involving the safe use and management of Controlled Drugs must be reported to the Trust Controlled Drugs Accountable Officer
V1	20.10.15	Head Of Information Governance	
V1	20.10.15	Safeguarding Service Manager	Amendments 10, 12&17
V1	20.10.15	Nurse Consultant Infection Control	
V1	20.10.15	Nurse Consultant- Tissue Viability	
V1	20.10.15	Patient Safety Administrator	IO appointment amended
V1	20.10.15	Patient Safety Manager	Amendments 6,7, 8,9,10,27
V1	20.10.15	Head of Quality Governance	Complete policy review
V1	20.10.15	Quality and Safety Co-ordinators	
V1	20.10.15	Patient Relations Team Lead	Page 17 amend title of policy
V1	6.11.15	Clinical Audit, Effectiveness& Research Manager	Job title change
V2	27.04.16	Clinical Policies Administrator	Addition of Management of suspected serious incidents relating to medication appendix

CONTENTS

Accessibility

Interpreting and Translation services are provided for Worcestershire Health and Care NHS Trust including:

- Face to face interpreting;
- Instant telephone interpreting;
- Document translation; and
- British Sign Language interpreting.

Please refer to the intranet page: http://nww.hacw.nhs.uk/a-z/services/translation-services/ for full details of the service, how to book and associated costs.

Training and Development

Worcestershire Health and Care NHS Trust recognises the importance of ensuring that its workforce has every opportunity to access relevant training. The Trust is committed to the provision of training and development opportunities that are in support of service needs and meet responsibilities for the provision of mandatory and statutory training.

All staff employed by the Trust are required to attend the mandatory and statutory training that is relevant to their role and to ensure they meet their own continuous professional development.

Co-production of Health and Care – Statement of Intent

The Trust expects that all healthcare professionals will provide clinical care in line with best practice. In offering and delivering that care, healthcare professionals are expected to respect the individual needs, views and wishes of the patients they care for, and recognise and work with the essential knowledge that patients bring. It is expected that they will work in partnership with patients, agreeing a plan of care that utilises the abilities and resources of patients and that builds upon these strengths. It is important that patients are offered information on the treatment options being proposed in a way that suits their individual needs, and that the health care professional acts as a facilitator to empower patients to make decisions and choices that are right for themselves. It is also important that the healthcare professional recognises and utilises the resources available through colleagues and other organisations that can support patient health.

1. Introduction

Worcestershire Health and Care NHS Trust is committed to ensuring that our approach to reporting, investigating and learning from adverse incidents reflects the principles of good incident and risk management.

It actively supports the promotion of a positive and fair blame approach to incidents and near miss reporting in a culture of openness and learning which is fundamental to effective risk management.

We will make sure that we share the learning from incidents both internally and externally where appropriate.

Involving patients and their families in investigations - Being open/ Duty of Candour

The level of patient/family involvement clearly depends on the nature of the incident and the Trust's Being Open and Duty of Candour Policy should be read in conjunction with this policy.

If a patient or family wishes to be involved, unless there are specific indications to the contrary or the patient/their family request other arrangements, these issues should be covered in a series of on-going open discussions. The Trust fully supports the 'Being open' principles of openness, honesty and transparency and the "Being Open and Duty of Candour "gives information on the processes to involve the patient and their family.

2. Policy scope

This policy applies to all staff working within the Trust, all patients treated and all visitors, contractors, volunteers and members of the public visiting the premises.

3. Aim of policy

This policy outlines how the Trust will report, manage, analyse and learn from all clinical and non-clinical incidents, near misses and Serious Incidents (SI's) to reduce the risk of harm to patients, staff and other users of Trust premises through improving safety, quality of services and the environment by providing an effective incident reporting and investigation system.

This includes Patient Safety Incidents, which come under the remit of the Patient Safety Team, Health, Safety and Security Incidents, which come under the remit of the Health and Safety Team, and Information Governance Incidents, which come under the remit of the Information Governance Team.

It also includes incident reporting and management of RCA's

4. Duties - roles and responsibilities Trust Board

Trust Board has overall responsibility for effective risk management, the safety of patients, staff and visitors within the Trust and to ensure the Trust complies with its statutory obligations.

a) **Chief Executive** - The Chief Executive has ultimate responsibility for safe care, including risk management, and delegates this responsibility to the Director of Quality and Executive Nurse and the Medical Director.

b) **Director of Quality and Executive Nurse** - The Director of Quality and Executive Nurse is responsible for ensuring that there is an incident/near miss reporting and investigating policy in place ensuring all serious incidents are investigated thoroughly.

c) **Head of Quality Governance** - The Head of Quality Governance is responsible for the development, implementation and maintenance of a robust Trust-wide incident reporting and investigation system and for the operational delivery of this policy

d) **Patient Safety Team** - The Patient Safety team includes the Quality and Safety Co-ordinator, Senior Information Lead, Patient Safety Manager, Patient Safety Information Officer and the Patient Safety Administrator who manage patient safety information including the Ulysses incident reporting system

e) **Investigating Officers** - Investigating Officers (IO's) are identified within the Service Delivery Units (SDU's) IO's are responsible for investigating incidents fully in accordance with this policy , SDU's are responsible for the development and follow up of action plans. All IO's must have undertaken Root Cause Analysis Training

f) **Specialist Advisers** - Specialist advisers e.g. Information Governance Manager, Infection Prevention Control Consultant Nurse, Health and Safety Manager are automatically notified of specific incidents within their sphere of knowledge. They are responsible for reviewing the incident and either giving advice about the investigation of the incident or investigating and reporting on it themselves depending on the level of harm/level of risk. An update is required on the safeguard system following a review of the incident.

g) **Risk and Security Manager** - The Risk and Security Manager is responsible for overseeing that all Health & Safety incidents are investigated and RIDDOR reportable incidents are investigated fully and reported to the Health and Safety Executive timescales.

h) **Service Delivery Unit Leads (SDU leads)** - SDU leads are responsible for promoting effective risk management; ensuring operational systems are in place to meet the requirements of this policy. They have a responsibility to make sure that all incidents within their SDU are reported in accordance with this policy

i) The SDU lead will also be responsible for ensuring that responses are developed within the agreed time scales, and that appropriate actions are taken as a result of any investigations.

j) **SDU Quality Leads or other nominated lead for the management incidents** - Quality Leads are responsible for the effective and efficient management of the incident reporting process within their SDU

The Quality Lead will also be responsible for disseminating relevant learning across the SDU and monitoring actions within the SDU

This includes the responsibility of identifying an Investigating Officer for serious incidents, and additional support where necessary to ensure that timescales are adhered to, and that appropriate actions are taken as a result of the investigation.

It is the responsibility of the Quality Lead to ensure that a detailed investigation report is submitted to the Serious Incident Forum (SI) for approval and that this is submitted within the timescale

It is the responsibility of the Quality Lead or other nominated lead to agree the wording used to describe the incident when reporting on the NHS Strategic Executive Information System. (STEIS). The serious incident report must not contain any patient or staff names and the description should be clear and concise

There may be occasions when the commissioner requires additional information within 72 hours of the first STEIS notification. If this is required, the Quality and Safety team will inform the Quality Lead who will then be responsible for completing the update with the relevant

manager **(See Appendix 3)**. This should be submitted to the patient safety team. A copy of the 72 hour update report must be kept securely within the SDU and in addition stored in the corporate quality and safety teams Serious Incident database.

k)   **All managers** - Managers are responsible for promoting effective risk management; ensuring operational systems are in place to meet the requirements of this policy. This includes making sure that incidents (including near misses) are investigated in accordance with this policy. In addition, managers have a responsibility, to make sure that their staff receive appropriate risk management training by attending induction, mandatory training and other appropriate events.

l)   **All staff** - All staff should be aware of what is an incident, near miss or serious incident and the process for reporting and management of such incidents as part of their own accountability to safe care

m)   **Quality and Safety Committee (Q&SC)** - The roles and responsibilities of the Q&S are determined by the Trust board. The Q&SC is the committee with overarching responsibility for risk management (excluding financial risk) in the Trust.

n)   **Clinical Governance Sub -Committee** – The roles and responsibilities of the CGSC are included in the Terms of Reference and this committee reports to the Q&SC

o)   **Serious Incident Forum (SIF)** - The panel co-ordinates the investigation and reporting of serious incidents and near misses and ensures organisational lessons are learnt and that appropriate external reporting in completed. The Terms of Reference of the SIF are attached at *Appendix 1*

p)   **Health and Safety Committee** – A forum for promoting co operation between management and staff in the identification of Health, Safety and Security Management concerns, in the workplace, and for the determination of measures required to address those concerns

5.   Definitions

a)   **Incident:** an event or circumstances involving patients, visitors or staff that could have or did lead to unintended or unexpected harm, loss or damage. This harm can be identified as physical or psychological

b)   **Harm:** Harm is defined as injury, suffering, disability or death. **(See Appendix 2 for Levels of Harm)**

c)   **Serious Incident (SI):** An incident or near miss occurring on health service premises or in relation to health services provided, resulting in death, serious injury or harm to patients, staff or the public, significant loss or damage to property or the environment or otherwise likely to be significant public concern. This shall include 'near misses' or low impact incidents which have the potential to contribute to serious harm. The definition also applies to any incident involving the actual or potential loss of personal information that could lead to identity fraud or have significant impact on individuals.

d)   **Security incident:** A security incident is one in which there is fraud, theft, deception, criminal damage, car crime, including all property belonging to the Trust. Patients absconding from the Trust or becoming 'missing' are also included in this category. This can also be an SI

e) **Near miss**: a situation in which an event or omission, or a sequence of events omissions, fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient, visitor or member of staff.

f) **RIDDOR reportable incidents**: It is a statutory requirement that all RIDDOR (Reporting of injuries, diseases and dangerous occurrences regulations) reports are submitted to the Health and Safety Executive (HSE) within15 days of the event. An incident is RIDDOR reportable if:

- An accident connected with work results in death or major injury;
- A member of the public is killed or taken to hospital;
- An accident connected with work results in an injury which requires more than 7 consecutive days absence from work;
- Work related disease; or
- Dangerous occurrence

The Trust is required to keep a record of an incident if a worker has been incapacitated for more than three consecutive days. Any queries must be directed to the Risk and Security Management Team

g) **Root Cause Analysis (RCA)**: the process by which the underlying cause(s) of an incident are established. This is often a multi-disciplinary meeting of the individuals who were involved, chaired by an individual who was not involved in the incident.

A timeline must be completed and any recommendations made arising from an RCA must be detailed within an action plan, followed up and is signed off and approved at SI Forum (**See Appendix 4 – RCA Closure Checklist**)

6. Incident/near miss reporting and investigation process

6.1 How to report an incident including timescales

When a member of staff witnesses an incident they should:

- Take all necessary action to attend to the needs of the person(s) affected by the incident and minimise the risk of further harm.
- Where an item of equipment is involved, label and quarantine the item (documenting asset, batch and lot) and retain all evidence where possible.
- Where the level of harm is moderate, severe or death and could therefore, constitute a "Serious Incident" must be reported verbally (by the reporter) to the person in charge/senior manager or the nominated investigator for immediate action. That person will initiate the "Serious Incident" process, alongside the Duty of Candour.
- Complete a Ulysses incident report form (which is accessed through the staff intranet under "Ulysses") immediately if possible, but within a period of 48 hours from the time of witnessing the event. (to include being notified of the incident)

However, where there are exceptional circumstances incidents must be reported out of this timescale rather than not being reported at all.

When completing the Ulysses incident report form the reporter should:

- Include only facts (not opinion)
- Include type of incident, what happened, where did it happen (date and time)
- Who was involved (i.e. The person potentially or actually affected and witnesses)
- Whether a further investigation is required

- Any injury sustained and treatment given / recommended
- What immediate action was taken after the incident
- All questions on the incident form must be recorded and completed
- The following should be noted when completing incident reports

  - Record facts

  - Ensure you describe the incident clearly

  - Do not use patient or staff identifiers in the description box of the form

  - Any equipment involved in the incident should be retained, untouched and in safe keeping for examination

  - If a patient is "found on the floor" record these words: do not assume the patient has fallen. Record, whether witnessed or not, and describe the footwear worn
- Write in lower case / sentence case– not write in block capitals
- The reporter must choose the correct category to ensure the correct staff receive the notification
- If the incident involves a doctor in training this must be added. This is to inform the Medical Director and the Lead Clinical Tutor of any incidents involving medical trainees so that the trainee's supervisor has a timely meeting with them to discuss the learning points and also to inform the revalidation process.

It is the responsibility of the person completing the incident form to alert the head of department or line manager at the first opportunity that an incident form has been completed and appropriate action has been taken.

6.2 Review and Investigation of Incidents including Serious Incidents

When a responsible manager receives notification of an incident they must open and review the incident.

- It is the responsibility of the nominated manager to review the incident

The correct person will review the details of the incident including the accuracy of the level of harm and all other coding making amendments if necessary. The person responsible will also assess and enter the risk grading.

- Where an incident is identified as a "Serious Incident" it is reported immediately to the Quality Lead, relevant managers, Directors and SDU leads by the patient safety administrator

The procedure for Serious Incidents will then be initiated. The SDU is responsible for confirming the name of the RCA investigator for a serious incident

(See Appendix 5 Overview of the Serious Incident Management Process)

- All individual C-Diff, MSSA, MRSA, bacteraemia incidents require an RCA within a set timescale including pressure damage RCAs
- All medication errors are reviewed by the pharmacy team in partnership with the SDU and corporate quality and safety team who assess level of harm

(SI's to be dealt with through the SI procedure)

All incidents or concerns involving the safe use and management of Controlled Drugs must be reported to the Trust Controlled Drugs Accountable Officer

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- Certain incidents are notified to specialist advisers e.g. health & safety advisor, tissue viability nurse, Information Governance Officer automatically through the electronic incident system depending on the coding. Every incident notified to specialist advisers will be reviewed by them within 2 calendar days of notification.
- This includes the Integrated safeguarding team where an incident constitutes a safeguarding concern where staff must follow the Safeguarding Adult/ Safeguarding Children Policy
- Where an incident involves another organisation e.g. the ambulance service then that service should be involved in the investigation and the commissioners informed of the incident by the Patient Safety Manager. This is shared via commissioner/ provider quality review meetings
- For Information Governance incidents and incidents in the National screening Programmes the specialist advisers will be involved in ensuring that the national guidance is implemented where necessary.
- Following investigation all associated documents must be attached to the Ulysses incident report and ensure completion of the action plan within the agreed timescale and give feedback in the SDU Governance meetings on the outcome in addition to the reporter of the incident.
- All members of staff should be identified on an incident as per IG process including involvement with medics

If there are any actions, which cannot be completed for any reason e.g. financial pressures then these should be risk assessed and if necessary included in the risk register

Care of the Person Affected

The immediate concern should be the welfare of the person who is adversely affected by the incident and appropriate action should be taken to treat any injury sustained. Where the incident affects a patient, treatment may be by the clinician immediately involved or depending on the nature of the injury, it may be more appropriate to ask another clinician.

Ensure Environment Safe

If the incident has arisen because of an unsafe environment, immediate action must be taken to make the environment safe and/ or to cease any activity that is highly likely to result in a similar incident. Where necessary, relevant staff should be called in to ensure safety is restored; this may involve external agencies

Leadership of Incidents

To ensure effective leadership management of an incident, the person in charge of the ward/department at the time of the incident will accept initial responsibility for ensuring prompt reaction to the incident.

It is the responsibility of the Quality Lead to ensure that incidents within their respective Service Delivery Units are reviewed, monitored and managed.

Advice can be sought from the Corporate Quality and Safety Team

Take Notes

All staff involved must be advised to make notes of their involvement so that if they are asked to write a statement at a later date, they will not have to rely on purely memory. They should note times, people involved, what happened, concentrating on facts etc..

6.3 Serious incidents and never events

Serious incidents and never events will be reported and investigated in accordance with the **"Serious Incident" procedure as detailed in Appendix 5 and additional information section on page 18**

Actions from Serious Incidents are placed on the SI database and it is the responsibility of the Quality Leads to ensure that all actions are monitored and managed, providing evidence on the data base.

Review of Incidents - If appropriate, the Quality Lead or appropriate nominated senior person(s) may re-grade the incident in terms of level of harm as further facts and issues emerge during a review. Alterations must be clearly identified and reporter informed of change to grade. Any queries must be directed to the corporate patient safety officer.

Significant Events

These are incidents which are reviewed as per SI process, and through this process lessons are learnt and preventative measures will be identified and must be implemented.

6.4 Raising concerns

Sometimes staff may find it difficult to report an incident/near miss perhaps due to the sensitive nature of the circumstances in which the incident happened. In these situations members of staff are encouraged to refer to Raising Concerns at Work Policy and follow the reporting routes outlined within the policy.

Informing Patients and/ or relatives (Duty of Candour)

The Trust actively encourages staff to be open and honest and to provide an early apology where patients are unhappy. All healthcare organisations are under a legal duty to be open and honest with patients when things don't go right. This duty is known as the Duty of candour. As part of any investigation into a reported incident the legal duty of candour should be considered.

Additional support can be offered via the Corporate Quality and safety Team

Media attention

If an Executive Director believes the incident is likely to attract adverse media attention, they will report the matter to the Chief Executive and a report will be made to the Communications Department

External reporting

All patient safety incidents are reported to the National Reporting Learning System. The NRLS and CQC statutory reporting requirements require that incidents graded death or severe harm must be reported to the NRLS within two working days (48 hours) of the incident occurring. Reporting of incidents to the NRLS and CQC should not be delayed by local investigation procedures, following the completion of local investigations. There are specific requirements for external notification of a variety of incidents for example incidents relating to blood transfusions, information governance incidents, screening incidents. This is managed centrally by the Corporate Quality and Safety Team. **(See Appendix 7)**

6.5 Levels of investigation

This endorses three levels of investigation – **(See Appendix 6 for Levels of Investigation)**

- Concise investigations -suited to less complex incidents which can be managed by individuals or a small group of individuals at a local level 2) comprehensive investigations - suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators 3) independent investigations - suited to incidents where the integrity of the internal 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. The level of investigation should be proportionate to the individual incident.
- Concise and comprehensive investigations should be completed within a set period and independent investigations should be completed within a set timescale of being commissioned.
- Serious Incidents should be closed by the relevant commissioner when they are satisfied that the investigation report and action plan meets the required standard. Incidents can be closed before all actions are complete but there must be mechanisms in place for monitoring on-going implementation. This ensures that the fundamental purpose of investigation (i.e. to ensure that lessons can be learnt to prevent similar incidents recurring) is realised.
- Safeguarding investigations may run alongside internal investigations completed and additional advice must be sought from the Integrated Safeguarding Team

7. Training

7.1 Training on the requirements of this policy

Through the SADR process training will be identified for certain job roles and staff are required to undertake training as part of their role.

7.2 Root Cause Analysis (RCA) Training

There is an on-going programme of Root Cause Analysis training for those staff members expected to investigate incidents and near misses. This training consists of a one day programme based on the Root Cause Analysis methodology.

The objectives of the course are to:

- Increase the understanding of the theory underpinning RCA
- Provide candidates with an overview of the RCA process
- Provide skills in some of the RCA Tools
- Demonstrate the advantages of using a systems based approach to patient safety incidents

To ensure the learning from investigations, learning is shared across the Trust's Serious About Safety Bulletin and Directorate Governance meetings.

7.3 Ulysses training

Training on the use of the Ulysses incident reporting module is provided by the Corporate Quality and Safety Team

8. **Equality and diversity**

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their safe individual needs and does not discriminate against individuals or groups on the grounds of any protected characteristic (Equality Act 2010). An equality analysis has been undertaken for this policy, in accordance with the Equality Act (2010).

9. **Process for monitoring compliance with this policy**

Standard/process/ issue	Monitoring and audit			
	Method	By	Committee	Frequency
All incident reporting	Monthly summarised Quality Safety Reports will be produced will be monitored by the Clinical Governance-Sub Committee (CGSC)	Head of Quality/ Governance	Q&S CGSC	Monthly
Non clinical incidents and near misses	Trends will be highlighted within the reports and the Quality and Safety Committee will take responsibility for initiating actions to address these Trends. Any resulting action plans will be monitored by the Health & Safety Committee	Health & Safety Team	Health& Safety Committee	4 monthly
Levels of investigation and process for following up relevant action plans	Audit of compliance with different levels of investigation appropriate to the level of severity of the event(s) and process for following up action plans Any resulting action plans will be monitored by the SDU's and managed via the Serious Incident Database	SDU Leads / Quality Leads	SDU Governance meetings	Monthly

In addition, The Clinical Governance Sub Committee (CGSC) and Quality and Safety Committee Q&SC will monitor and analyse incident reporting trends, subsequent investigations and root cause analysis.

10. Consultation and review

This policy has been reviewed by members of the Clinical Governance Sub Committee and Quality and Safety Committee with comments sought from a variety of staff across the Trust including SDU Leads, Quality Leads, Senior Clinicians (Medical/ Nursing), Directors ,Clinical leads , Specialist staff including complaints and PALS, Compliance Manager to ensure CQC/ Monitor compliance

11. Implementation of policy

This policy will be implemented in accordance with Quality Governance Strategy for the development, management and authorisation of policies and procedures. The policy link will also be made available and included in mandatory training, the staff handbook and relevant staff education/training events.

12. References

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

https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf

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

Royal Colleague of Surgeons (2014) Building a culture of candour: A review of the threshold for the duty of candour and of the incentives for care organisations to be candid. Available online https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf

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

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

Maria Dineen (2011) *Six Steps to Root Cause Analysis* (third edition) ISBN: 978-0-9544328-2-9

NHS England (2014) Principles for managing quality in specialised commissioning(including RASCI template) available at: https://nhsengland.sharepoint.com/TeamCentre/Operations/_layouts/15/WopiFrame.aspx?sourced oc={1CAE2D20-BB4F-47A3-BFB6-3371A4D7AE6A}&file=Principles%20for%20managing%20quality%20in%20specialised%20commi ssioning%20including%20RASCI%20template.docx&action=default

NPSA, RCA toolkit, available at: https://report.nrls.nhs.uk/rcatoolkit/course/iindex.htm

Work related deaths: A protocol for liaison (England and Wales). Available at: http://www.hse.gov.uk/pubns/wrdp1.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%20Chec klist%20Guidance.pdf

Independent Schools Inspectorate (ISI) 2012- Integrated Handbook-framework

Home Office Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews (2013)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209020/DHR_Guidance_refresh_HO_final_WEB.pdf

Department of Health, No Secrets, available at
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008486

13. Associated documentation

It is important that other appropriate policies are read in conjunction with this policy and all Trust policies are relevant.

Specifically the following policies are of prime importance:

- Ulysses user guides
- Quality and Governance Strategy
- Health and Safety Policy
- Complaints, PALs and Professional Enquiries Policy
- Claims management
- Being Open Policy
- Supporting staff involved in an incident complaint or claim
- Raising concerns at work
- Mental Capacity Act 2005
- Safeguarding children and young people policy
- Adult safeguarding policy
- Police/Health & Safety (HSE) Investigations protocol

Additional Information

Serious Incidents and Never Events

Definitions and procedures

In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver on-going healthcare.

The occurrence of a serious incident can demonstrate weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system. .

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

The definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved

Serious Incidents 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. 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

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death.

- 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, 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)

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

In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again.

Equality Analysis

Title of Policy/Function *(Function ,Includes: Services; Projects; Strategy; Processes; Systems; Practices; Procedures; Protocols; Guidelines; Care Pathways etc..)* Policy for the Reporting of and Learning from adverse incidents including Serious Incidents and near misses	New	Existing/Revised **Revised**
Short description of Policy/Function (aims and objectives, is the policy/function aimed at a particular group if so what is the intended benefit): Advises staff on what to report as an incident, how, and why. Advises re action to be taken including information being given to patients, carers and relatives. Advises staff regarding where different types. Advises staff on different levels of investigation and time scales, also development of action plans and sign off arrangements. Identifies mechanisms for learning at different levels within the Trust and nationally. ' The impact of this policy has been assessed as **LOW.**		

Name of Lead/Author(s)	Job Title	Contact details
██████████	Deputy Head of Governance/ Quality	██████████

When the policy/function involves patients/staff/partners/stakeholders etc. please where possible include them in the Equality Analysis to demonstrate openness, transparency and inclusion and particularly by those who this policy/function is most likely to have impact.

Does this Policy/Function have any potential or actual impact that is positive(+), neutral (N) or negative (-) impact on the following protected characteristics please indicate:				
	+	**N**	**-**	**Please provide a rational/justification for <u>each</u> of the following regardless of impact**
Age		X		This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents)
Disability			X	There may be a potential for staff with visual impairment to have difficulties regarding reporting as it is via a personal computer, and arrangements should be in place to support the member of staff to complete reporting if required
Gender Reassignment		X		This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents)
Pregnancy & Maternity		X		This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents) The reporting and learning from an incident would be the same regardless of a woman being pregnant or not. Learning from such incidents should be shared with those returning from maternity leave to ensure they are current in their practice
Race		X		This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents)

			The policy will be applied in the same way regardless of race, there are no known negative impacts on any group of people to any lessor or further degree than other groups
Religion & Belief		X	This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents) and is unlikely to have a negative impact on any individual or religious or belief grounds. Meetings should be avoided on religious days. Health and safety takes precedence
Sex		X	This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents) regardless of gender
Sexual orientation			This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents) regardless of sexual orientation
Marriage & Civil Partnership			This policy is for all staff and relates to Incident/Near Miss Reporting and Investigation Policy (Including Serious Incidents) It is unlikely that any difference would occur as a result of marital status

Other Groups who could experience inequality, e.g. carers, homeless, travelling communities, unemployed, people resident within deprived areas, different socio/economic groups e.g. low income families, asylum seekers/refugees, prisoners, people confined to closed institutions or community offenders, people with different work patterns e.g. part-time, full-time, job-share, short-term contractors or shift workers - *Access, location and choice of venue, timings of events and activities. Support with caring responsibilities*
This policy relates to the Trusts' vision and values

	Name	Job Title
1	███████	Head of Quality Governance
2	███████	Deputy Head of Quality Governance

Reference/Version: v1	Date Equality Analysis completed:	D	D	M	M	Y	Y
		3	0	0	9	1	5

If you have identified a potential discriminatory impact on the policy/function please refer it to the author together with suggestions to avoid or reduce the impact.

A copy of the completed Equality Analysis must be attached to the policy/function and a copy sent to:

███████████

Equality Inclusion Practitioner

Isaac Maddox House, Shrub Hill Road, Worcester, WR4 9RW

Tel: ███████████

████████████████

Appendix 1 | Terms of Reference of Serious Incident Forum (SIF)

1. Purpose

The SIF is a sub-group of the Clinical Governance Sub Committee CGSC and is the designated forum with responsibility for reviewing, evaluating and critiquing all Serious Incidents (SI) (including Never Events) investigation reports.

The purpose of the Group is to:

- Confirm and challenge each final SI investigation report received to ensure that a thorough investigation has taken place to identify the root causes, appropriate recommendations and actions to minimise reoccurrence
- Identify lessons learnt and how the learning have been or will be shared.

2. Scope

The Group is responsible for providing patients and carers, Trust staff, Trust Board, and our commissioners with assurance that SIs occurring within WHCT are robustly investigated, lessons are learnt and that national standards are met.

3. Terms of Reference

The Group will:

- Evaluate SI investigation reports and action plans submitted
- Defer sign-off and request further information or assurance if necessary
- Sign-off and close SI investigations in the Trust ready for submission to the commissioners

4. Accountability

The SIF is accountable to the CGSC. The SIF Chair will escalate any concerns to the CGSC

5. Membership

The SIF consists of the following members:

- Director of Nursing- Chair
- Deputy Director of Nursing- Vice Chair
- Head of Clinical Governance (Vice Chair)
- Deputy Head of Quality/ Governance
- Clinical Lead (members)
- Subject Matter Expert: as and when required (i.e. infection control, safeguarding leads, medicines management lead, IG manager)
- Patient Safety Manager
- Patient Safety Administrator

- Quality Leads in Service Delivery Units
- Investigating Officers (IO) whom have completed the RCA
- Health and Safety Manager/ Risk and Security Manager

6. Quorum

The Group will be quorate by the attendance of at least two of the following members

- Director of Nursing / Deputy Director of Nursing/ Head Of Governance
- Patient Safety Manager or Deputy Head of Quality Governance
- Quality Lead or nominated deputy
- Tissue Viability Lead

Data analysis information from the SIF will be fed into monthly governance reporting.

7. Frequency of Meetings

A SIF meeting will take place weekly every Monday morning 10-12 to evaluate and critique all SI investigation reports. An extraordinary SIF meeting may be convened by the Chair if deemed appropriate. If urgent action is required a virtual meeting may be convened.

The IO, Quality Lead or a nominated representative by the SDU must attend to report on their SDU RCA.

8. Confidentiality

The SIF will be held in private due to the confidential nature of SIs. Confidentiality will be maintained by all members.

9. Support

The Group will be supported by the Patient Safety administrator and the Patient Safety Manager.

Date agreed: July 2015 – Review annually – V2.08.15

Appendix 2 | Levels of Harm

No harm:

Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.

Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.

Low: Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.

Moderate: Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

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

Death: Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care including recently discharge patients (for queries please contact the patient safety manager)

Appendix 3 |

Incident Review Report

*note- RMO and care coordinator relevant in MH services only

Report Author Details:			
Name:	Title:	Authors Contact Details:	Date of Report:

Incident Details and Immediate Corrective actions taken:

Incident ID:	Incident date:	Incident Type:	Service Area:	
Patient Name:		Patient DOB:	Severity of the Incident:	Actual effect on patient:
Patient RMO:		Patient Care Co-Coordinator:		Patient Key worker/Named Nurse:

Incident Description

Immediate Action taken

Chronology (timeline) of Events (please include at least the last 5 patient contacts where possible)

Date	Outcome	Problem Identified

Findings:

Care and Service delivery problems:

Contributory factors:

Conclusions:

Evaluation:(what we did well)

Recommendations: (what we could have done better)

Debriefing / Post-Incident Support	Yes	No	Comments
Have all involved individuals been offered post-incident debriefing?			
Has a written record been kept to verify that these individuals have been offered post-incident debriefing?			
Has support been offered to staff/other patients if required			

Duty of Candour		
Patient's Next of Kin Name:	Next of Kin Contact details:	Have the Next of Kin been informed of the incident:

Further Information:

Appendix 4 | RCA Closure Checklist

◎ Serious Incident RCA Checklist

Save and New   E-mail   Print   Close

Please enter STIES No: [_____]

This checklist provides an assessment of the investigation into the Serious Incident. Please tick if it applies for each RCA.

Is the Lead Investigator appropriately RCA trained:	▣

Was there a pre-incident risk assessment: ▣

Did the core investigation team consist of more than 1 person: ▣

Were local, national, standard NHS investigation guidance and process used: ▣

Was the appropriate evidence used (where it 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 effected (Including patients/staff/victims/perpertrators and their families) were involved and supported appropriatly:

Is a timeline of events produced:

Are good practice guidance and protocols referenced to determine what should have happened:

Are care and servcice delivery problems identified: (This includes what happend that shouldn't have have, and what didn't happen that should have. There should be a mix of care (human error) an dservice (organisational) delivery problems)   ▣

Name of Person Completing this checklist:

[_____]

Is it clear that the individuals have not been unfairly blamed   ▣
(Disciplinary action is only appropriate for acts of wilful harm or wilful neglect):

Is there evidence that the contributory factors for each problem have been explored: ▣

Have strong (effective) and targeted recommendations and solutions (targeted towards root causes) been developed: ▣

Are actions assigned appropriatley: ▣

Is there clear evidence that those affected have been appropriately involved and supported: ▣

Is there a clear plan to support implementation of change and improvement and method for monitoring: ▣

If you have not ticked any of the above, please explain if there was robust rationale that prevents this affecting the quality of the investigation.   ▣ ▣

[_____]

*Word version of RCA checklist included with investigations submitted to Serious Incident Forum

45 day timescale for completion

Corporate Quality and Safety Team →

Within 2 working days

Incident occurs

Report on LRMS/NRLS and to other bodies such as safeguarding lead as applicable

No — Is it a serious incident — **Unknown**

Manage in line with local risk management policy

Review and discuss with commissioner

Yes

Engage with those involved/affected

Report/notify other stakeholders as required e.g. safeguarding, CQC, TDA etc..

Report on STEIS

If requested , complete initial review and submit to Quality and Safety Team

Confirm level of investigation required

Service Delivery Units

Lead investigator identified by SDU Quality lead. Team established. Terms of reference set. Management plan established

Undertake the investigation

Gathering and mapping information → Analysing information → Generating solution

Submit final report and action plan to Quality and Safety Team for SI Forum

Quality & Safety Team

Commissioner (with relevant stakeholders) undertakes a review of the final report and action plan and ensures it meets requirements for a robust investigation. Feedback given to provider

Commissioner closes investigation and confirms timescales/mechanism for monitoring the action plan where actions/improvements are still being implemented

Support and involve those affected (including patients, victims and their families and staff)

Opportunities for feedback and learning identified and information shared via Serious Incident Forum
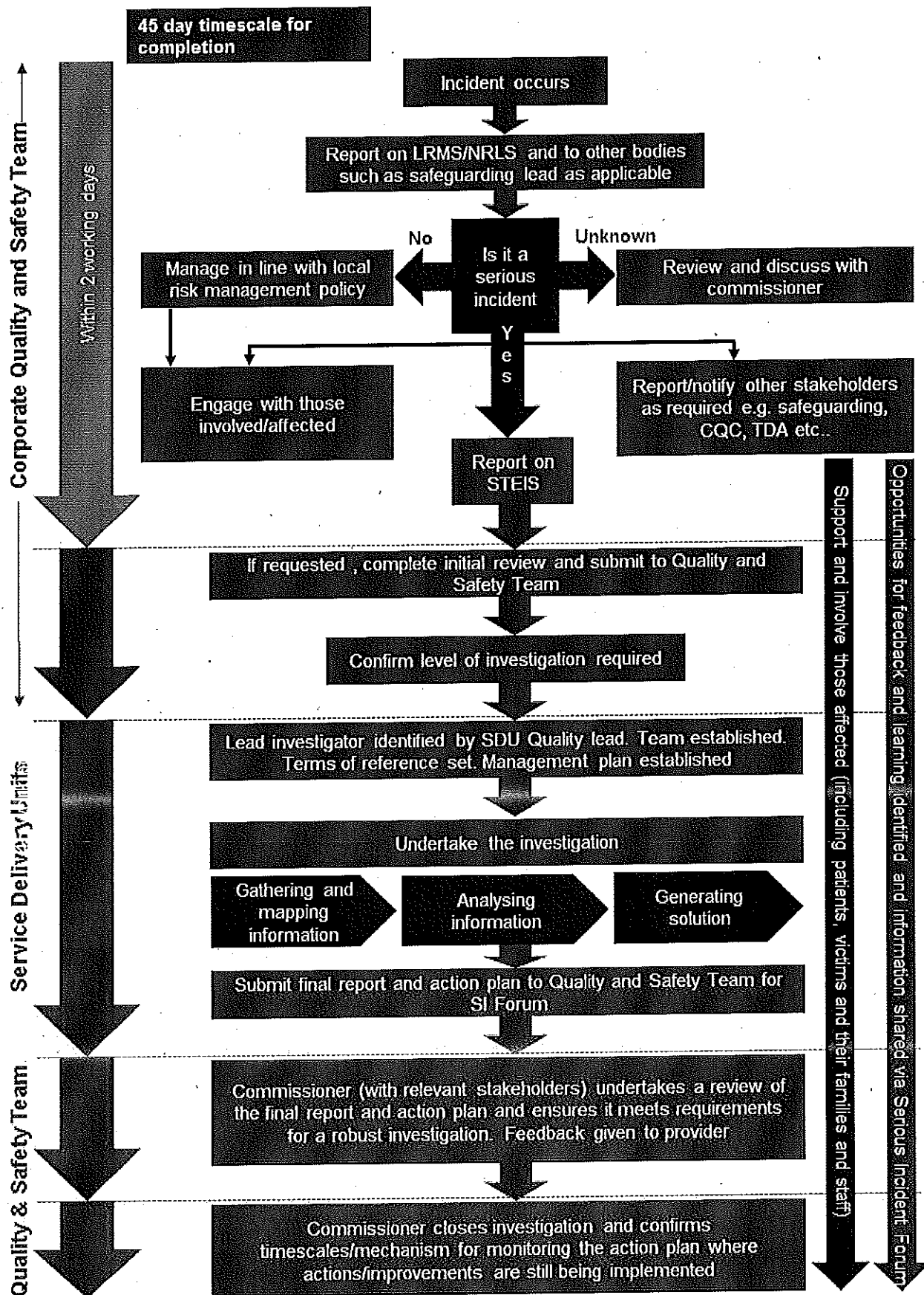
Appendix 6 | Levels of Investigation

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. Resources to support systems-based investigation in the NHS are available online from: http://www.england.nhs.uk/ourwork/patientsafety/root-cause/				
Level	**Application**	**Product/ outcome**	**Owner**	**Timescale for completion**
Level 1 **Concise internal investigation**	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 45 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 **Comprehensive internal investigation** (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	Internal investigations, whether concise or comprehensive must be completed within 45 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan

Level 3 Independent investigation	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 all 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.	6 months from the date the investigation is commissioned
National reporting templates should be used unless agreed that adaptions are required. National templates are reviewed on a continuous basis.				

Incident or 'Near Miss' occurs

Specific sections should be completed depending on the type of incident:

- MEDICATION – for all medication errors
- INTERVENTION – for all incidents requiring MAPA
- SAFEGUARDING – for all incidents involving safeguarding concerns/events
- MISSING PERSON – for all AWOLs or absconds
- POLICE – for all incidents requiring contact with Police

The reporter should complete a **Ulysses** form online and inform the person in charge / Line manager at the time of the incident.
Report all incidents within 48 hours.

Serious Incidents (SI's) should be reported to the line manager and manager on call immediately and on Ulysses.

In the case of Unexpected deaths reported by District Nursing Teams – please contact the Corporate Patient Safety Team in the first instance

DUTY OF CANDOUR – this section should be filled in for all incidents which require DOC process

Line manager must enter, on Ulysses manager's form, all of the actions taken to reduce the risk of this incident occurring again, initiate any additional notifications and check the risk score. The Feedback section should also be completed to inform the reporter.

RIDDOR: Where assaults, accidents or injuries require reporting to the Health & Safety Executive under RIDDOR, Line manager to complete RIDDOR form and email to Health & Safety Manager for onward submission to HSE

The Line Manager should close the incident within 20 working days.

All staff and managers

PLEASE NOTE: It remains the Line Manager's responsibility to take action and prevent or minimise a recurrence of any accidents/incidents to staff, patients and visitors

Root Cause Analysis for all Serious Incidents:

- Quality Lead allocates investigating officer. Directorate Manager allocates support/Terms of Reference set by Quality and Safety Lead.
- RCA document to Patient Safety Team for inclusion on SI Forum agenda (deadline of 20 working days)
- Final RCA approved by SI forum within 40 working days
- Final version of RCA to be stored on SI Database
- Approved RCA to be forwarded to Commissioners by Quality Governance Department
- Include DOC requirements in the RCA.

Serious Incidents will be reported on STEIS by the Patient Safety Team and logged on the SI Database. SI alert email issued

Corporate | Quality Governance Department

Suspected Serious Incident, reported via Ulysses system. This includes incidents where the reporter has not coded it as medication, including incidents relating to falls, patient self-harm and all incidents relating to Controlled Drugs

'Additional Notify' incident report to be sent to Medication Safety Officer (MSO). If incident relates to Controlled Drugs, the additional notify must also be sent to the Trust CD Accountable Officer (CDAO). CDAO to determine if Police to be informed. MSO to review incident and determine if a Serious Incident based on level of harm (Moderate or Severe harm). MSO to liaise with Patient Safety Manager **

Yes - Graded as an SI

No – Not graded as an SI

Governance team to initiate Serious Incident Process as per Trust policy. Quality Lead to oversee SI process and appoint investigating officer to undertake RCA.

Document outcome onto original Ulysses incident report. Add additional information in relation the incident/ associated actions to be taken

Quality Lead to Inform Director of Nursing and Medical Director

** Review of incident to be sent via email to generic pharmacy email address and patient safety email address to cover any absence in teams. Email accounts must be checked daily by team admin staff.

Pharmacy Team WHCNHS.medicines@nhs.net

Patient Safety Team WHCNHS.Ulysses@nhs.net

Inform Local Security Management Specialist if police involvement is anticipated or if there has been a breach in security control measures.

Serious cause for concern in relation to medication stock loss:

- Large quantities missing
- Frequent balance discrepancies
- Discrepancy/ rarely used items
- Staff concerns (ensure Whistle Blowing policies are followed).