ST CATHERINE'S HOSPICE

Incident Management Policy (including accidents, near misses and serious incidents)

Document Control Table

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Document Ref:	POL 28
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SMT sponsor:	Giles Tomsett, Chief Executive
Members of stakeholder group:	SMT
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Amendment History

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HS01.01 Accidents, incidents and near misses policy (Oct 2014)	May 2016	Karen Anderson, Hear of HR	Full review/revision to ensure comprehensive enough and to take account of introduction of Datix. HS01.01 superseded by POL 28 May 2016
POL 28 vs1	May 2017	J Abbott & P Brayden	Scheduled review. No material changes (small changes made to correct typos and other minor amendments to improved clarity)

Associated Documents

H&S Policies
Raising a Serious Concern at Work Policy
Safeguarding Adults Policy
Safeguarding Children Policy
Duty of Candour Policy
IG Policy
Business Continuity Plan
Media policy

Risk Management Policy

References

1. Health & Safety at Work Act 1974
2. Management of Health and Safety at Work Regulations 1992
3. The Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (HSE 1999) http://www.hse.gov.uk/pubns/hsis1.pdf [accessed 5/5/16]
4. Health and Social Care Act 2008 (regulated Activities); Regulations 2014 http://www.cqc.org.uk/content/regulations-service-providers-and-managers [accessed 5/5/16]
5. NHS England Serious Incident Framework. 2015 https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf [accessed 5/5/16]
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8. Health & Social Care Information Centre. Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation. 2105 https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf

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Contents

1. Purpose

St Catherine's Hospice (StCH) aims to deliver all its services and carry out all its activities to a consistently high standard. As with all health and social care provision in the UK, StCH has a duty to investigate all untoward occurrences, including incidents and complaints in a proportional and consistent manner. In addition, it has a statutory obligation to report and fully investigate serious incidents (SIs).

The collation and analysis of all data on incidents of all types and near misses, and all associated investigations, is an intrinsic part of risk management as it provides valuable opportunities to learn and improve. This policy describes St Catherine's Hospice (StCH) arrangements for reporting incidents of all types and of any significance, and the actions expected to manage investigations and to ensure all necessary follow-up is completed.

It should be recognised that as an organisation committed to continuous improvement learning from incidents is an invaluable opportunity to develop our care, our services and standards.

2. Scope of policy

This policy applies to all Hospice services and activities and to all Hospice-employed staff, staff working in related/seconded teams, volunteers, patients, visitors and others who may be affected by incidents, accidents or near misses that occur in connection with the Hospice's activities.

For the purpose of this policy, 'incidents' will be used to refer collectively to incidents, accidents and near misses.

3. Definitions

Accident	An unplanned event that results in personal injury, damage, loss or all three
Incident	Any occurrence that is inconsistent with routine operation of organisation (eg: electrical failure, gas incident, ICT failure, unplanned fire evacuation)
Near miss	An unplanned event or situation that **could have resulted** in injury, illness, damage, loss, but did not do so due to chance, corrective actions and/or timely intervention
Serious incident (SI) [NHS England definition of 'serious incident' in healthcare]	Serious Incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services.
Reportable incident	An incident which should be reported to a relevant external regulator (eg RIDDOR, CQC, Safeguarding). Each regulator will have its own criteria - see Appendix 3 Reportable Incidents

Never events	Serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented by the healthcare provider.
Major incident	An unexpected event which overwhelms normal resources and which requires special measures (ie implementation of the Hospice's Business Continuity Plan)
RIDDOR	The Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (HSE 1999). RIDDOR defines the type of incidents, diseases and occurrences that must be reported to the Health and Safety Executive to comply with statutory requirements.
CQC	Care Quality Commission, the independent regulator of health and adult social care in England

4. Policy statement & aims

StCH acknowledges and accepts its responsibilities to report and investigate incidents and events of all severity relating to its staff, volunteers, services and activities. The Hospice will implement robust procedures for the investigation of incidents, and will use the outcomes and recommendations from investigations to learn lessons; in order to improve staff, volunteer and service user safety and welfare, and to improve services.

StCH is committed to supporting its staff, volunteers and others affected by its activities in the event of an incident or investigation. This commitment is underpinned by the Hospice's desire to support and embed a positive reporting culture within the organisation to enable the organisation to learn when things have gone wrong.

Aims of the policy:

1. To create and maintain a positive reporting culture:

- All staff and volunteers and all those connected with the Hospice are assured that StCH maintains an open and just environment, where no-one will be treated unfairly as a result of reporting an incident
- All staff understand their responsibility to report incidents that they have identified/witnessed
- All incidents are reported and all relevant external agencies and regulatory bodies are notified.

2. All incidents are managed in a timely and organised way:

- All managers understand their responsibilities in relation to incident management
- All incidents are investigated within agreed timeframe, with outcomes and recommendations identified, implemented and reported appropriately.
- Robust records of all incidents are created and maintained.

3. Incidents are used to identify and implement improvements

- In every case, the root cause of the incident is identified
- Lessons are learned from reported incidents, and appropriate action taken to prevent recurrence, including making changes to practice and/or the environment to improve patient and staff/volunteer safety where appropriate.
- Appropriate levels of debrief from lessons learned take place following incidents
- Themes are identified and addressed at team/department/organisation level as appropriate.

5. Accountability and responsibility

5.1 Chief Executive and CQC Responsible Individual

The chief executive is

- **accountable** for the implementation of this policy.
- S/he is ultimately **responsible** for the management of all incidents and internal and external reporting arrangements and for
- ensuring investigations are undertaken in an appropriate manner and within appropriate timescales. This includes
- ensuring that there is an appropriate framework for the reporting, investigation of all serious incidents (see *Appendix 2 - Procedure for management of serious incidents*) in accordance with NHS England Serious Incident Framework and with the hospice's Business Continuity Plan.
- The post holder is also responsible for ensuring lessons learned from investigations are implemented within the Hospice.

5.2 Senior Management Team (SMT)

SMT members are responsible for

- ensuring incident reporting arrangements and investigation processes are implemented within their service areas in accordance with this policy. This includes
- monitoring, review, sharing of lessons learned and follow up of reported incidents, and for ensuring actions are taken in response to individual incidents or trends identified.
- When delegating responsibility for handling incidents to members of their team they are responsible for ensuring that those individuals have had access to appropriate training and resources.
- SMT is responsible for providing assurance to the Board (via the Board Quality Committee) that incidents are reported and handled proportionately and that appropriate action and learning takes place in accordance with StCH culture of continuous improvement.

In addition, specific SMT members or individuals have delegated responsibility for specific areas of incident reporting/investigation handling as follows:

5.3 Director of Care Services (Registered Manager & Accountable Officer for Controlled Drugs)

The StCH Registered Manager (as reported to the Care Quality Commission) is

- the allocated 'Incident Approver' responsible for final sign off of all clinical related incidents.
- S/he has delegated responsibility for ensuring that statutory notifications are made in accordance with CQC regulations and with the regulations on controlled drugs.

5.4 Head of Human Resources (lead for Health, Safety and Welfare)

The Head of HR is

- the allocated 'Incident Approver' responsible for final sign off of all non clinical related incidents.
- S/he has delegated responsibility for reporting incidents to the Health and Safety Executive in accordance with The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR).
- S/he also has delegated responsibility for ensuring that appropriate support arrangements are in place for staff or volunteers involved in incidents, in particular where they may have been victims of violence and aggression or where an incident

results in a regulatory body or criminal investigation or action being pursued against employees or volunteers.

5.5 The Senior Information Risk Owner and Information Governance Lead (Director of Finance and Site Services)

The Senior Information Risk Owner (SIRO) has:

- delegated responsibility for ensuring appropriate reporting, investigation and management of all information governance (IG) incidents. This includes
- responsibility for reporting all IG serious incidents requiring investigation (SIRIs) and cyber-SIRIs via the NHS IG toolkit incident reporting tool.
- S/he is ultimately responsible for signing off of all IG incidents, involving the Caldicott Guardian as appropriate.

5.6 Caldicott Guardian (Medical Director)

The Caldicott Guardian is responsible for

- ensuring that appropriate action is taken following incidents relating to failure to protect patient and service user information or failure to ensure appropriate sharing of patient and service user information.

5.7 Director of Fundraising and Marketing

The Director of Fundraising and Marketing is responsible for

- ensuring appropriate proactive and appropriate communication (internal and external) about incidents where relevant.

5.8 Managers (general)

Managers at all levels (including senior managers) within StCH are responsible for the following:

- Encouraging a positive reporting culture within their service areas
- Ensuring this policy is implemented in their service areas and that all their direct reports are aware of how to report incidents electronically via StCH Datix system.
- Taking immediate action following incidents within the scope of their remit to prevent recurrence and/or eliminate or reduce any identified risks and to provide immediate support to staff
- Acting as incident handlers of incidents reported within their area of responsibility. This will include
- assessing the severity of an incident and escalating the handling to an SMT member in the case of all serious incidents (see *Appendix 2 - Procedure for management of serious incidents*)
- Investigating incidents or nominating investigators or contributing to investigations undertaken by others.
- Conducting risk assessment following incidents and notifying their manager (or other appropriate person) if risks highlighted by an incident cannot be reduced to an acceptable level.
- Using information from investigated incidents to inform the undertaking and review of risk assessments for their service areas.
- Ensuring (in conjunction with the HR department if necessary) arrangements for debriefing and providing ongoing support to staff within their service areas where required
- Providing, arranging the provision of, or highlighting the need for staff education or training identified as result of incident investigation
- Providing feedback to the person who reported the incident on actions taken following the event where appropriate
- Nominating an individual(s) within their service area or a suitable colleague(s) to handle incidents in their absence

- Ensuring that any volunteers or contractors working within their service areas are briefed on how to report any incidents to an appropriate member of the StCH team.

5.9 Managers (specific)
In addition, some managers have specific delegated responsibility or hold specific roles related to particular aspects of incident management or the management of certain types of incident as follows:

5.9.1 Quality and Information Manager
The Quality and Information Manager is the nominated manager responsible for:

- the maintenance of the StCH Datix information system and for ensuring that the electronic incident reporting system is accessible as far as reasonably practicable.
- ensuring that suitable business continuity arrangements are in place should electronic incident reporting function become unavailable
- co-ordinating the analysis of incident data to produce performance, management and assurance reports
- administration and management of files and records relating to current and historic serious incidents investigations.
- auditing of incident reporting and management to ensure adherence to this policy.

5.9.2 Adult safeguarding lead and deputy / child safeguarding lead and deputy

- The adult safeguarding lead and deputy are responsible for co-ordinating the StCH response to incidents regarding the safeguarding of vulnerable adults and of children as appropriate (see policies on Adult and Child safeguarding).

5.9.3 Marketing and Communications Manager
The Marketing and Communications Manager is responsible for:

- in liaison with the appropriate Director(s) facilitating and coordinating any communications with the media, including social media.

5.9.4 Research lead
The research lead is the manager responsible for

- co-ordinating the investigation of all incidents relating to research undertaken at StCH
- reporting, or ensuring that the principal investigator reports, any incidents related to the conduct of research in line with local and individual study guidelines.

5.9.5 Contracts Officer
The contracts manager is responsible for

- ensuring that all external contractors are aware of the need to report any incidents occurring on StCH premises, to StCH property or staff or at StCH run or sponsored events to an appropriate member of StCH staff without delay.

5.10 All staff and volunteers
All staff and volunteers are responsible for:

- ensuring they understand their individual roles and responsibilities in relation to incident reporting and management
- reporting all incidents in a timely way via the Datix system, ensuring that reports are factually accurate and complete

- seeking advice from their own or any available manager as soon as possible if they are unsure about whether an episode constitutes an incident requiring reporting or if they are unsure about how to report an incident
- cooperating fully with any incident investigations
- identifying any individual learning needs which arise out of any incidents which they report or in which they are involved and taking steps to meet these needs.

5.11 Contractors

All contractors or supporters identifying incidents are responsible for

- reporting them to an appropriate member of the StCH team.

5.12 Governance groups overseeing and scrutinising the reporting and management of incidents

Each governance group has a role in reviewing incidents relevant to their specific remit, including identification of trends and actions required to address vulnerabilities and to manage risk. See Section 7 for more details.

6. Procedure for management of incidents, accidents and near misses *(See Appendix I - process flowchart)*

6.1 Reporting an incident

6.1.1 What to report

Please refer to *Section 3 Definitions* for definitions of the types of event that should be reported as an incident. If staff are in any doubt about whether or not a witnessed/identified event should be reported, they should seek advice as soon as possible from an appropriate manager.

All staff are able to raise concerns about issues that affect staff or patient safety (or that have the potential to damage the organisation) either directly with their line manager, director or through Human Resources. All staff at StCH are able to raise concerns without recrimination; see Raising a Serious Concern Policy.

6.1.2 How to report

- All incidents must be reported via the Datix electronic reporting system. All staff have access to this via the StCH intranet.
- Contractors, visitors, volunteers and patients are expected to report any incident to a member of staff who will then implement the incident reporting procedure using Datix. The incident report is to be completed by the member of staff who is first to know about the incident.
- All incidents must be logged on Datix within 2 working days of being identified; in cases where this will not be possible (eg due to shift patterns), a verbal report must be made to an appropriate manager within this timeframe.
- Staff reporting an incident via Datix must follow all online instructions/guidance and complete all mandatory fields in order to submit the report (reporters will receive acknowledgement via Datix when a report has been submitted).
- In the event that the Datix system is unavailable, staff identifying an incident must inform a member of the Quality Team as soon as possible, providing all relevant details about the incident; the Quality Team will create a temporary hard copy of the report which will be uploaded to Datix as soon as the system is available (the hard copy will be destroyed appropriately).

6.1.3 Reportable and serious incidents

*** See Appendix 2 for detailed procedure for managing serious incidents***

- A reportable incident is an incident which should be reported to a relevant external regulator (eg CQC, RIDDOR). The broad definition of a reportable incident is any situation or event:
  - that led to an unexpected death
  - where a person came to harm (specified injuries)
  - where a person could have come to harm
  - which disrupts the normal running of the service.
- StCH definition of a serious incident is one that is graded amber or red. See *6.3 and Appendix 4 Risk Grading Matrix*.
- It is the responsibility of the director who has been designated 'final approver' of any given incident to ensure that the required notification has been sent to the relevant agency and has been made in line with each agency's protocol (and also, where appropriate, to inform the relevant commissioner). See *Section 5 Accountability & Responsibility*
- It is also the responsibility of the relevant director to inform trustees and the Communications Manager of any reportable or serious incident.

(*See Appendix 3 Reportable Incidents* for guidance on which incidents should be reported to which agency)

6.2 Immediate action to take following an incident

Immediate action will depend on the individual circumstances of the incident. On identifying an incident, the safety of those involved is the first priority and if the incident has caused an injury to an individual (other than patient) a first aider should be called, and in the case of a patient the senior duty nurse should be informed.

Wherever possible, action should address any faults or defects that expose staff, patients or others to imminent harm, for example defective equipment or machinery is to be removed from service immediately.

6.3 Investigation

Each reported incident will be forwarded (via Datix) to the appropriate manager for review and investigation. The manager assigned to do this is known as the 'incident handler'. It is the handler's responsibility to ensure that the incident is managed to satisfactory closure.

The key steps the handler must take:

6.3.1 Review incident report
- confirm appropriate manager has been assigned as handler (and reassign if necessary)
- ensure that all required information has been provided by the reporter, requesting any missing information as necessary.

6.3.2 Assign risk grading to incident
- if graded green or yellow handler carries out investigation
- if graded amber or red handler escalates incident to relevant director who will assume responsibility for leading the investigation
(see Appendix 4 Risk Grading Matrix)

6.3.3 Carry out investigation
- investigations should be both proportionate and sufficiently thorough with all relevant details documented and uploaded to Datix, ensuring the Datix record provides a complete audit trail of the steps taken, discussions/meetings held and decisions made.
- the handler may appoint additional investigators as appropriate
- investigations should aim to provide clear factual accounts of what happened
- investigations will focus on issues and solutions, not personalities or emotions
- interviews should be conducted with all relevant staff, and a written report of each made
- in the case of serious or complex cases it may also be necessary to ask staff to provide written statements
- the investigation will consist of three key phases: gathering and mapping information; analysing information; and production of report with findings and recommendations (see 6.3.4)

6.3.4 Identify outcomes and recommendations
- using a root cause analysis approach, identify outcomes, lessons learned and recommendations
- ensure recommendations are as specific as possible (what action, by whom, by when)
- report outcomes, lessons learned and recommendations to relevant directors/managers/teams

- provide summary of outcome of investigation to reporter of incident.

If Datix is unavailable, incident handlers must keep paper copies of all relevant documents (storing them securely to maintain confidentiality) and forwarding them to the Quality Team for uploading as soon as Datix is available. All paper copies must then be destroyed appropriately.

6.4 Staff support following an incident

In the first instance, it is the manager's responsibility to offer immediate support to staff who have witnessed or who have been involved in an incident. The manager will inform HR Department if the staff member is likely to need further support; any follow-up/ongoing support will be offered and coordinated by the HR Department.

6.5 Managing contact with the media

The StCH Communications Manager will be informed of any reported SIs or other incidents which might attract media attention by the relevant director. All contact (whether reactive or proactive) with the media in relation to an incident will be handled by the StCH Communications Manager, under the direction of the Fundraising and Communications Director, in line with the plan agreed by SMT.

6.6 Requests to provide witness statements in relation to external investigations or inquests

Any request received by a member of staff directly from HM Coroner, Coroner's Officer or Police to provide information relating to an external investigation or inquest is to be directed immediately, without responding, to the StCH Caldicott Guardian who will manage the enquiry.

7. Outcomes, learning and action

Within StCH, emphasis is placed on identifying learning from incidents to alleviate risks to service users, staff and the public, and in the promotion of changes in practice based on individual and aggregated analysis of incidents. To ensure outcomes are shared, lessons are learned and recommendations are implemented the following will happen.

At local level (ie following individual incidents):

- the outcome and recommendations from each investigation will be shared by the incident handler with the relevant managers/leads of work teams
- it is the responsibility of relevant managers/leads to share and discuss investigation outcomes with their teams, highlighting lessons learned, drawing up and monitoring action plans as appropriate. Action plans will include timescale for completion and leads for each action.
- in the case of SIs, summary investigation reports will be shared with SMT and relevant directors will report on progress with implementation of recommendations to SMT.

At organisation level:

- data from reported incidents will be analysed for trends or patterns, and shared with SMT and relevant Board committees according to an agreed schedule
- Q&I Manager will carry out regular audits to monitor reporting of incidents and implementation of recommended actions/improvements, following up with relevant managers as required, and reporting findings to SMT.

- SMT will be expected to provide evidence and/or comment on how actions have addressed systematic and organisational issues.
- information from incidents will be used to inform the identification, assessment and management of risk (in accordance with StCH Risk Management Policy).
- StCH is committed to learning from incidents. The SMT is responsible for monitoring the effectiveness of how StCH ensures both local and organisational learning from incidents, complaints and claims.

Collation and Review

The StCH clinical governance framework and risk management framework outlines the hospice governance structure and the various governance groups and work teams which are responsible for

- regularly reviewing particular types of incident, identifying trends, managing risks identified and escalating any risks which cannot be managed to the SMT
- making regular reports of collated incidents and exception reports of serious/high risk incidents to the SMT.

These governance groups are as follows:

- Medicines management group - reviews all medicines related incidents
- Patient safety group - reviews all patient safety incidents (eg infection control, falls, equipment related incidents)
- Health and safety group - reviews all incidents related to health and safety at work or the working environment
- Information governance group - reviews all IG incidents
- Research group - reviews all incidents related to research being conducted at StCH.

In addition, the following groups have a role in ensuring that appropriate action is taken as a result of incidents:

- Quality through audit group - is responsible for supporting governance groups in the implementation of their agreed audit programmes, including those audits that are recommended to take place following incidents.[1]
- Learning and development group - is responsible for coordinating appropriate learning for the whole organisation or for specific staff groups where widespread gaps in knowledge or understanding have contributed to incidents.

8. Monitoring and review of policy

This policy and its associated procedures will be reviewed every two years. The review will focus on:

- results from audits of action plans
- analysis of types and levels of incidents reported, who by and which areas/functions of the hospice they focus on
- the quality of incident reports and incident investigations (including specificity of recommendations).

[1] The Quality through Audit Group will operate in this capacity during 2017, build capacity of each governance group in relation to audit, and then be disbanded by end 2017

Policy Impact Assessment

The impact assessment is used to ensure:

- we do not inadvertently discriminate as a service provider or as an employer
- that the information governance implications of any changes in the way we work, implicit in any new policies or revisions to existing policies, are considered and addressed appropriately.

To be completed and attached to all policies when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Equality Impact**		
a.	Does the policy affect one group more or less favourably than another on the basis of - race - ethnic origins - nationality - gender - culture - religion or belief - sexual orientation (including lesbian, gay & bisexual people) - age - disability (eg physical, sensory or learning) - mental health	**N**	
b.	If potential discrimination has been highlighted, are any exceptions valid, legal and/or justifiable?	**N/A**	
c.	Is the impact of the policy likely to be negative? If so, can the impact be avoided or reduced?	**N**	
2.	**Information Governance Impact**		
a.	Is the policy (or any of its associated procedures) likely to have an adverse impact on: - information quality - information security - confidentiality - data protection requirements	**N**	
b.	If so, have these issues already been raised with the Information Governance Group? What action has been agreed?	**N/A**	

Appendices

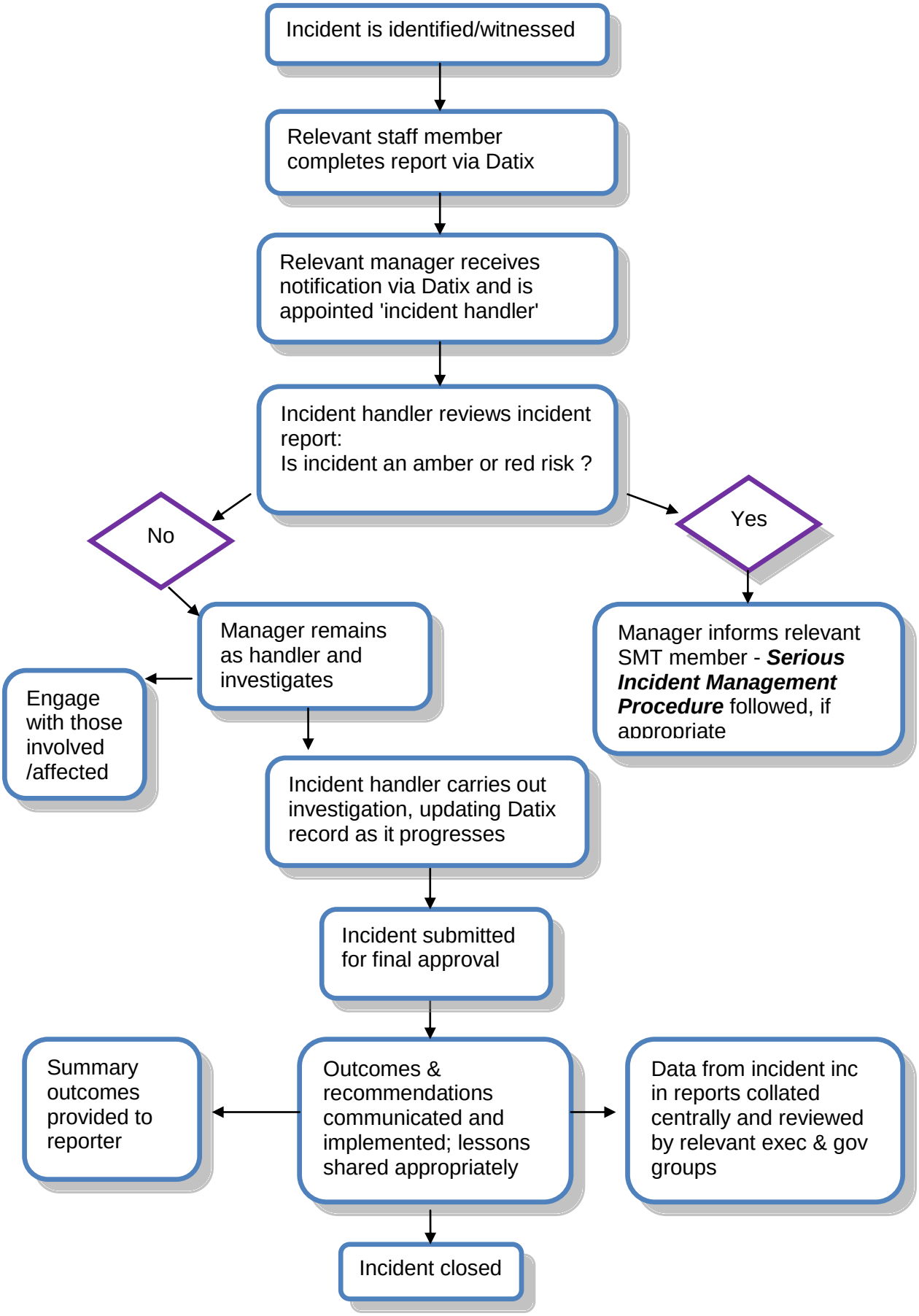
Appendix 1 - Incident management flowchart

Appendix 2 - *Serious* incident management procedure

Appendix 3 - Reportable incidents

Appendix 4 - Risk grading matrix

Appendix 1 - incident management flowchart



Appendix 2 - Serious Incident Management Procedure

Serious incident reporting and investigation procedure

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Document Control Table

Document title:	Serious incident reporting and investigation procedure
Document ref:	POL 28 (Appendix 2)
Author (name and job title):	Dr Patricia Brayden, Medical Director / Jane Abbott, Quality and Information Manager
Sponsor (SMT/Service Lead): - name - job title	Giles Tomsett, Chief Executive
Associated policy: - title - doc ref	Incident Management Policy (including accidents, near misses and serious untoward incidents)
Members of stakeholder group	SMT
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POL 28 vs1 (May 2016)	May 2017	P Brayden & J Abbott	Scheduled review. No material changes made

Associated Documents

Incident Policy
Duty of Candour Policy
Business Continuity Policy
Safeguarding Adults Policy
Safeguarding Children Policy
Duty of Candour Policy
Information Governance Policy
Media policy
Risk Management Policy

References

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Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 http://www.cqc.org.uk/content/regulations-service-providers-and-managers
Incident Decision Tree. National Patient Safety Agency. 2004 http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/human-factors-patient-safety-culture/?entryid45=59900

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Contents

1. Purpose

StCH has an Incident Policy which covers the reporting of all incidents. The majority of incidents which occur are relatively minor in terms of their consequences to service users, staff or the hospice. These incidents can usually be investigated and managed within departments. However in some circumstances, more serious incidents (**SIs**) can occur. These require a proportionately greater response. This greater response is often required at the time and in the immediate aftermath of the incident and is **always** required afterwards to ensure that lessons are learnt and implemented in order to prevent recurrences.

NHS England, in the document *Serious Incident Framework - supporting learning to prevent recurrence*, describes serious incidents in health care as 'adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified.' This NHS document describes the circumstances in which such a response may be required and outlines the process and procedures for achieving it, to ensure that Serious Incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again.

The purpose of this StCH procedure, which is based on the NHS Framework, is to ensure that StCH, as a commissioned provider of NHS healthcare, and as a registered charity, meets all statutory and regulatory requirements with respect to recognising, reporting, investigating and responding to serious incidents and for arranging and resourcing investigations.

It aims to emphasise the key principles and to provide a framework outlining the key steps involved in serious incident management at StCH. As in the NHS Framework, it

- defines the roles and responsibilities of those involved in the management of serious incidents;
- highlights the importance of working in an open, honest and transparent way where service user and others affected are put at the centre of the process
- promotes the principles of investigation best practice and in particular ensuring thorough but proportionate investigation and
- focuses attention on the identification and implementation of improvements that will prevent recurrence of serious incidents, rather than simply the completion of a series of tasks.

2. Scope

This procedure provides a guide on the handling of serious incidents and suspected serious incidents at StCH and outlines the principles which STCH will adhere to in investigating and handling such incidents.

Although based on the NHS framework, it is applicable **not just to clinical and support services but to *all* areas of hospice activity, including income generating activities such as fund-raising and trading.** This is because a SI in any area could have an effect on the reputation of the organisation and a subsequent loss of confidence would threaten its ability to continue as a charity.

It cannot cover the detailed management of every potential SI or the detailed reporting mechanisms for each particular type of SI, but rather it **outlines the steps that may be necessary when a serious incident occurs** and clarifies who is responsible for taking those steps. It must be therefore be read in conjunction with the business continuity plan and with more detailed procedures for specific types of incident (e.g. controlled drugs incidents, RIDDOR etc).

3. Definitions/Glossary

Accident	An unplanned event that results in personal injury, damage, loss or all three
Incident	Any occurrence that is inconsistent with routine operation of organisation (eg: electrical failure, gas incident, ICT failure, unplanned fire evacuation)
Near miss	An unplanned event or situation that **could have resulted** in injury, illness, damage, loss, but did not do so due to chance, corrective actions and/or timely intervention
Serious incident (NHS England definition of 'serious incident' in healthcare)	Serious Incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services.
Significant or high risk incident (StCH definition)	Incident or near miss with an amber or red rating on the StCH risk grading matrix. All such incidents should be escalated to an SMT member who will conduct an initial investigation to decide whether the incident should be treated as a serious incident
Reportable incident	An incident which should be reported to a relevant external regulator (eg RIDDOR, CQC, Safeguarding). Each regulator will have its own criteria - see *Appendix 3 Reportable Incidents*
Never events	Serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented by the healthcare provider.
Major incident	An unexpected event which overwhelms normal resources and which requires special measures (ie implementation of the Hospice's Business Continuity Plan)
RIDDOR	The Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (HSE 1999). RIDDOR defines the type of incidents, diseases and occurrences that must be reported to the Health and Safety Executive to comply with statutory requirements.
CQC	Care Quality Commission, the independent regulator of health and adult social care in England
Working days	Days which do not include weekends or public holidays

4. Responsibilities and Duties

The responsibilities and duties are as in the accompanying Incident Management Policy see - sections 5.1-5.10

In addition:

All staff are responsible for
- reporting suspected serious incidents without delay
- cooperating with incident investigations.

Managers are responsible for
- immediate management of serious incidents as directed by the chief executive or SMT member on call. This includes taking immediate steps to assure safety of all concerned, preserving evidence and identifying witnesses and people affected
- co-operating with and contributing to incident management and investigation teams as directed by the chief investigator
- escalating high risk (amber or red) incidents to senior managers when they identify them as part of the incident handling process.

Quality and Information manager
- supporting SMT in reviews to establish whether SI has taken place and proposing level of investigation
- support to chief investigators and ensuring rigour and consistency of serious investigation handling.

Senior Managers (SMT members) are responsible for
- declaring significant incidents
- external reporting of significant incidents (see Appendix B)
- with the Q&I manager, conducting immediate reviews of SIs or suspected SIs to recommend the level of investigation required
- acting as chief investigators of SIs and leading investigation teams if appropriate
- acting with delegated authority to direct particular aspects of incident handling appropriate to their roles
- ensuring implementation and monitoring of action plans.

Chief Executive
- has overall responsibility for ensuring that StCH meets all statutory and regulatory requirements with respect to recognising, reporting, investigating and responding to serious incidents and for arranging and resourcing investigations.
- has overall responsibility for liaising on behalf of the hospice with the media and other external stakeholders, usually delegating the formulation of a post incident communication strategy to the Director of Fundraising and Marketing
- provides assurance to the Board of Trustees that, following any SI, an action plan to prevent recurrence is implemented in an appropriate timescale.

5. Procedure

Principles of incident management
There are 7 key principles of incident management which must be adhered to. A brief summary is given here and further details are available in the NHS framework.

1. Openness and transparency: the needs of those affected should be the primary concern in the response to and the investigation of serious incidents. The principles of openness and honesty as outlined in the NHS Being Open guidance and the NHS contractual Duty of Candour must be applied in discussions with those involved.

2. Preventative. Investigations of serious incidents are undertaken to ensure that weaknesses in a system and/or process are identified and analysed to understand what went wrong, how it went wrong and what can be done to prevent similar incidents occurring again. Investigations carried out under this Framework are conducted for the purposes of learning to prevent recurrence. They are not enquiries into how people died or conducted to hold individuals or organisations to account. Other processes exist for that purpose e.g. criminal or civil proceedings, disciplinary procedures, employment law and systems of service and professional regulation.

3. Objective. Those involved in the investigation process must not be involved in the direct care of those patients affected nor should they work directly with those involved. Those working within the same team may have a shared perception of appropriate/safe care that is influenced by the culture and environment in which they work. As a result, they may fail to challenge the 'status quo' which is critical for identifying system weaknesses and opportunities for learning.

4. Timely and responsive. Serious incidents must be reported without delay and no longer than 2 working days after the incident is identified. Every case is unique and those managing serious incidents must be able to recognise and respond appropriately to the needs of each individual case.

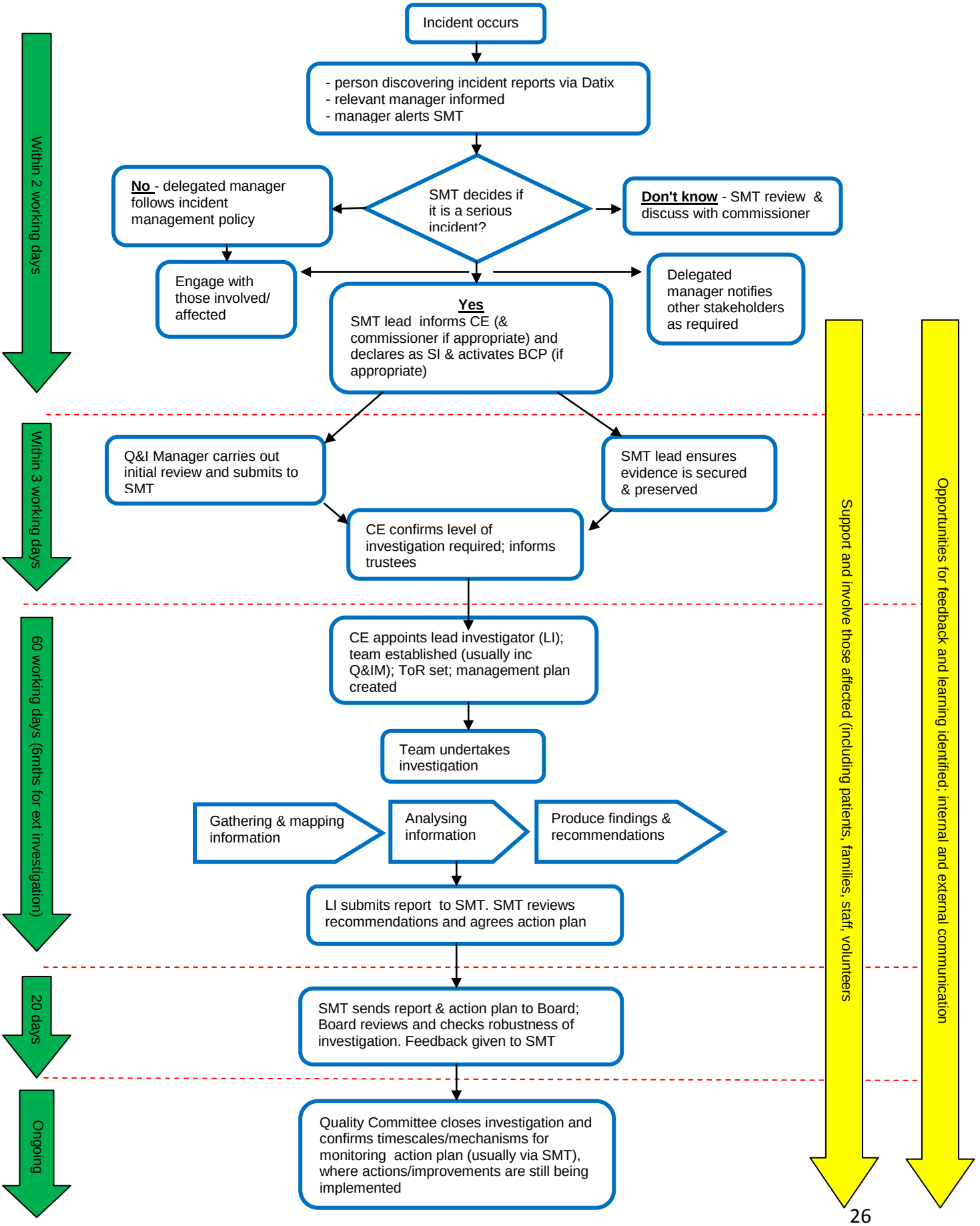
5. Systems-based. The investigation must be conducted using a recognised systems-based investigation methodology that identifies:
o The problems (the what?)
o The contributory factors that led to the problems (the how?) taking into account the environmental and human factors; and
o The fundamental issues/root cause (the why?) that need to be addressed.
The investigation must be undertaken by those with appropriate skills, training and capacity.

6. Proportionate. The scale and scope of the investigation should be proportionate to the incident to ensure resources are effectively used and should be considered on a case by case basis. Incidents which indicate the most significant need for learning to prevent serious harm should be prioritised. Some incidents may be managed by an individual (with support from others as required) whereas others will require a team effort.

7. Collaborative. Serious incidents often involve several organisations. When other organisations are involved, StCH will work in partnership to ensure effective management of the incident.

The flowchart on the next page gives an overview of the serious incident management process at StCH.

Serious Incident Management Process



5.1 Identifying and reporting incidents

The first step is to identify that a serious incident has - or might have - taken place. Sometimes it is immediately obvious that an SI has taken place, but identification of SIs is not always straightforward. Whilst many SIs will be identified internally via the StCH local incident reporting and risk management frameworks, they can also be identified as a result of external allegations, reports, reviews or complaints.

In identifying whether an SI may have taken place staff should refer to the following definition adapted for StCH from the NHS Serious Incident framework.

'In broad terms, a serious incident at StCH is an event where the potential for learning is so great, or the consequences to patients, families and carers, staff or the hospice is so significant, that it warrants using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect service users patients directly and include incidents which may indirectly impact service user or public safety or the hospice's ability to continue to meet its charitable objectives.
The occurrence of a serious incident demonstrates 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 or members of the public, future incidents of abuse to patients staff or the public, or future significant reputational damage to the hospice.'

They should also refer to the more detailed guidance on assessing whether an incident is a serious incident within Chapter 1 of the NHS Serious Incident framework. It is important to note that there is no definitive list of events/incidents that constitute a serious incident and NHS guidance is that lists should not be created locally as this can lead to inconsistent or inappropriate management. However, the NHS does set out circumstances in which a serious incident **must** be declared. These are briefly summarised as the following:

*Serious Incidents include **acts or omissions in care** that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, **incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern** resulting in a loss of confidence in healthcare services.*

These are documented in further detail in Part 1 Chapter 1 'What is a serious incident?' of the NHS Serious Incident Framework and are reproduced for convenience in Appendix A of this document.

Staff responsible for deciding whether a SI has taken place should refer to these circumstances and decide whether they apply or might apply. If there is any doubt about whether an incident constitutes a SI, it should be treated as if it is an SI; it can always be downgraded later. For this reason, any incident which is rated **as an amber or red risk** on the StCH risk grading system should be considered and treated as a potential SI. Even if the incident does not qualify as an SI in NHS terminology, it may still be a significant or serious event *for the hospice* and as such, will require an enhanced level of investigation or response.

5.1.1 Declaration of the SI and immediate action

Any member of staff who identifies that a serious incident (or possible serious incident) has taken place should report this immediately to their manager or to the manager on call for the service area in question. If there is no manager available they should escalate the reporting to the SMT member on call.

Unless the manager is confident that it is NOT an SI, they should report it immediately (face to face or by phone) to the SMT member for the department concerned who will declare it internally as an SI / suspected SI and notify the Chief Executive promptly. If the incident occurs outside normal working hours the SMT member on call is responsible for this. S/he is also responsible for invoking the major incident / business continuity procedure if appropriate.

A senior manager / senior clinician(s) (eg consultant on call) should be identified by the chief executive, (or out of hours by the SMT member on call), to undertake the following:

- Obtain all relevant physical, scientific and documentary evidence, and make sure it is secure and preserved. This is important for the overall integrity of the investigation process
- Identify witnesses, including staff, and other service users, to ensure they receive effective support.
- Identify an appropriate person to conduct an initial incident review (characteristically termed the 72-hour review) and produce a brief written report to confirm whether a serious incident has occurred and if applicable, the level of investigation required and to outline immediate action taken (including where other organisations/partners have been informed)
- Identify which commissioners and other relevant internal and external parties (for example, police, Safeguarding Professionals, the Information Commissioner's Office see *Appendix 3 Reportable Incidents*) should be informed and oversee arrangements for such reporting*
- Agree who will make the initial contact with those involved or harmed, or their family/carer(s). Those involved should have a single point of contact within the hospice.
- Arrange appropriate meeting(s) with key stakeholders, including patients/victims and their families/carers as required.

*If it is unclear whether an incident constitutes a serious incident or not, the CE or other members of the SMT should still report it to the commissioners and other relevant external bodies and engage in open and honest discussions to agree the appropriate and proportionate response. Any downgrading must be agreed with the relevant commissioner on a case by case basis.

Incidents that are found at any point not to meet the threshold of a serious incident must be managed in line with the hospice's incident reporting policy.

5.1.2. Reporting

The incident should be reported internally via the local incident reporting system (Datix). Within StCH the following should usually be informed of any SI at the earliest opportunity:

- SMT members
- Quality and information manager
- Communication and marketing manager
- Manager of the service area involved

Any decision not to inform these individuals will be at he discretion of the Chief Executive, who will also be responsible for informing the chair of trustees.

All SIs as defined by the NHS Serious Incident Framework must be reported by the hospice to its commissioners without delay and no later than 2 working days after the incident is identified. Incidents falling into any of the serious incident categories listed below should be

reported immediately to the relevant commissioning organisation upon identification. This should be done by telephone as well as electronically:

- Incidents which activate the hospice 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 or other external agencies.

For SIs meeting NHS criteria for an SI, as StCH does not have access to the NHS serious incident management system (STEIS), it should report the incident to the commissioners who will log it on the STEIS system, (or its successor system) on the hospice's behalf. The serious incident report must not contain any patient or staff names and the description should be clear and concise. A template for reporting is available in appendix 6 of the NHS Serious Incident Framework.

Other regulatory, statutory, advisory and professional bodies should be informed about serious incidents depending on the nature and circumstances of the incident. Serious incident reports must clearly state which other relevant bodies have been informed. See *Appendix 3 Reportable Incidents* for a list of other organisations that must be considered. In general, it is the SMT member for the department or area of responsibility concerned who will be responsible for ensuring these external reports in a timely way.

In some circumstances, where a serious incident or multiple serious incidents raise profound concerns about the quality of care being provided, the NHS recommends that organisations should consider calling a Risk Summit, which provides a mechanism for key stakeholders in the health economy to come together to collectively share and review information. Most serious incidents of the type anticipated at StCH will not warrant this level of response however.

5.1.3 Initial review

An initial review of any SI or suspected SI (characteristically termed a '72 hour review') should be undertaken and shared with the SMT and the commissioner). This will usually be completed by the Q&I manager in liaison with an appropriate member of SMT should be completed within 3 working days of the incident being identified. The aim of the initial review is to:

- Identify and provide assurance that any necessary immediate action to ensure the safety of staff, patients and the public is in place;
- Assess the incident in more detail (and to confirm if the incident does still meet the criteria for a serious incident and does therefore require a full investigation); and
- Propose the appropriate level of investigation and investigators to ensure objectivity.

The information submitted as part of the initial review should be reviewed by the appropriate stakeholders (usually the SMT) and the investigation team (once in operation) in order to inform the subsequent investigation.

The Chief Executive will inform the chair of Trustees at this point if s/he has not already done so.

5.1.4 Escalation and information sharing

The NHS framework for serious incident management makes reference to the need to alert 'the wider healthcare system' where a serious incident indicates an issue/problem that has (or may have) significant implications for the wider system, or may cause widespread public concern. This is a judgement call depending on the nature of the incident, although the scale of the incident and likelihood of national media attention will be a significant factor in

deciding to share information. Further guidance on this is available within the NHS framework document.

In practice, it is unlikely that an incident occurring at the hospice is likely to fall into this category. However the SMT should still consider the need to share information more widely, for example with other hospices, national bodies such as Hospice UK or the National Council for Palliative Care and should decide whether to make any proactive media statements, as well as preparing reactive media statements and making a plan for directing any media enquiries appropriately. This communication strategy will be led by the CE and Director of Fundraising and Marketing and no such communications should take place unless authorised by these individuals.

5.2 Procedure for investigation of SIs

Different types of SI will require different types of investigation, but the same principles and steps are likely to apply.

5.2.1 Appointing the investigating team

An investigating team should be set up, led by a lead investigator (ie the assigned 'handler' on Datix) who will be a member of the SMT and supported by the Q&I manager. It is essential that the team is constituted to ensure objectivity and that team members keep the SMT and others fully briefed about the incident and actions being taken. In particular, the investigation team is responsible for identifying learning. This should be shared at any stage of the investigation process and the team should not wait for the investigation to be completed to highlight system weaknesses/ share valuable learning which may prevent future harm.

5.2.2 Involving and supporting those affected

The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. It is important that affected patients, family members staff, or others are involved and supported throughout the investigation.

People (service users/ family members /carers / members of public) affected

The team will identify the appropriate person to support people affected. This person can be a clinician involved in the incident but this not always appropriate. Involvement begins with a genuine apology. Staff responsible for liaising with and supporting bereaved and distressed people must explain what went wrong promptly, fully and compassionately, applying the principles of honesty, openness and transparency.

An early meeting should be held to explain what action is being taken, how they can be informed, what support processes have been put in place and what they can expect from the investigation. This should be followed up in writing.

Those affected should have the opportunity to express concerns and questions, inform the terms of reference of the investigation, know how they will contribute to the investigation, be given access to the findings of the investigation and be given an opportunity to respond to and comment on the findings and recommendations outlined in the final report. They should also be offered media advice should the media make enquiries.

Further guidance on the support to be offered to those involved is available within the NHS framework and the team should refer to this document to ensure that they have considered all needs. They should also consider the needs of other patients and service users.

Staff who were involved or who may have witnessed the incident
Serious incidents can have a significant impact on staff who were involved or who may have witnessed the incident. They will want to know what happened and why and what will be done to prevent similar incidents happening again.

The investigator or investigating team should involve the HR department to ensure that staff involved in the investigation process are given the opportunity to access professional advice from their relevant professional body or union, staff counselling services and occupational health services. They should also be provided with information about the stages of the investigation and how they will be expected to contribute to the process.

The team conducting the incident investigation should be clear that **this investigation is separate to any other legal and/or disciplinary process**. Whilst StCH will advocate justifiable accountability there must be zero tolerance for inappropriate blame and those involved must not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration by virtue of involvement in the investigation process.

The Incident Decision Tree or a similar framework should be used to promote fair and consistent staff treatment. In the very rare circumstances where a member of staff has committed a criminal or malicious act, the organisation should advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation.

5.3 Agreeing the level/type of investigation (within 3 working days of incident)
There will be 3 levels of investigation, mirroring the NHS framework:

Level 1: concise internal investigation: less complex incident, within one service area, can often be investigated by one individual
Level 2: comprehensive internal investigation: more complex incident; needs team of investigators with specialist subject areas
Level 3: external investigation. This may be imposed by a commissioner or the CE may decide to appoint an external investigation because in house resources are inadequate or do not guarantee a sufficient level of objectivity.

For most SIs a level 2 (comprehensive internal investigation) will be appropriate, but for some incidents a more concise investigation will be sufficient and occasionally a level 3 investigation will be imposed or required. The Chief executive makes the ultimate decision about what level of investigation is required.

5.4 Production of final report
The investigation concludes with an investigation report and action plan. This needs to be written as soon as possible and in a way that is accessible and understandable to all readers.

Guidance from NHS England is available on report writing, and templates are available in the appendices (*Appendix C*) and online[2].

The report should:

- Be simple and easy to read;
- Have an executive summary, index and contents page and clear headings;
- include the title of the document and state whether it is a draft or the final version;

[2] templates http://www.nrls.npsa.nhs.uk/resources/?entryid45=75419

- Include the version date, reference initials, document name, computer file path and page number in the footer;
- Disclose only relevant confidential personal information for which consent has been obtained, or if patient confidentiality should be overridden in the public interest. This should however be considered by the Caldicott Guardian and where required confirmed by legal advice;
- Include evidence and details of the methodology used for an investigation (for example timelines/cause and effect charts, brainstorming/brain writing, nominal group technique, use of a contributory factor Framework and fishbone diagrams, five whys and barrier analysis);
- Identify root causes and recommendations;
- Ensure that conclusions are evidenced and reasoned, and that recommendations are implementable;
- Include a description of how patients/victims and families have been engaged in the process;
- Include a description of the support provided to patients/victims/families and staff following the incident.

5.5 Action plan (to be produced within 60 working days of incident)

The report recommendations will be reviewed by SMT who will draw up the action plan.

NHS England recommends use of the NPSA Action Plan template available online[3]:

The minimum requirements for an action plan include the following:

- Action plans must be formulated by those who have responsibility for implementation, delivery and financial aspects of any actions (not an investigator who has nothing to do with the service although clearly their recommendations must inform the action plan);
- Every recommendation must have a clearly articulated action that follows logically from the findings of the investigation;
- Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. It must target the weaknesses in the system (i.e. the 'root causes' /most significant influencing factors) which resulted in the lapses/acts/omissions in care and treatment identified as causing or contributing towards the incident;
- A responsible person (job title only) must be identified for implementation of each action point;
- There are clear deadlines for completion of actions;
- There must be a description of the form of evidence that will be available to confirm completion and also to demonstrate the impact implementation has had on reducing the risk of recurrence.

A SMART approach to action planning is essential. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound. To ensure that the most effective actions/solutions are taken forward, it is recommended that an option appraisal of the potential actions/solutions is undertaken before the final action plan is developed and agreed.

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

5.6. Quality assurance and closure

The report and action plan will be submitted to the Board of Trustees or the appropriate board sub-committee for assurance. The Board will review the final report and action plan and ensures it meets the requirements of robust investigation. Feedback will be given to SMT. At this point the investigation is declared closed and confirms timescales/mechanisms for monitoring (usually via SMT) action plan where actions/improvements are still being implemented.

5.7 Next steps and monitoring of actions

Ongoing monitoring of actions will take place.

6. Dissemination

This procedure will be launched alongside the Incident Management Policy at a managers' update - or via face to face communications to managers. It will be followed up by an email to all staff. New staff should be made aware of this procedure at induction.

7. Monitoring and review

This procedure will be reviewed every 2 years together with the associated incident management policy.

Appendix A

How to identify a serious incident (from NHS England Serious Incident Framework)

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 ongoing healthcare.

The occurrence of a serious incident demonstrates 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. 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, 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.

Appendix B - Notification of interested bodies - who and what? (see Appendix 2 of NHS framework)

Serious incidents must be notified without delay (or within specified timescales) to all relevant bodies via the appropriate routes. Guidance produced by specific bodies should be referred to in order to ensure compliance with their requirements. Commissioners should be notified of serious incidents no later than 2 working days after the incident is identified.

CQC - registered manager
http://www.cqc.org.uk/content/notifications

Controlled Drugs - RM/CDAO
Serious incidents relating to controlled drugs must be reported to the provider's Accountable Officer/CD LIN

Coroner - medical director
An unexpected death (where natural causes are not suspected) and all deaths of detained patients must be reported to the Coroner by the treating clinician. This should be done immediately. It is recognised that, following an unexpected death, a serious incident may not be identified until the issuing of the coroner's report.

Coroners make two sorts of referral to the police:

- For an investigation under the Coroner's Act where the Coroner expects a police officer to investigate the death and prepare a file for the inquest by obtaining witness statements and other evidence.
- For a criminal investigation where the Coroner is concerned that the circumstances of the death may involve criminal liability.

Investigating police officers should be clear with the NHS and other organisations when they are acting on behalf of the Coroner to establish the cause of death, rather than investigating a crime. If the matter becomes a criminal investigation, the investigating officer should make it clear to the NHS organisation and others that the status of the investigation and their role in it has changed.

Defects and Failures - Registered manager
Where incidents relate to a defect or failure involving engineering plants, infrastructure and/or non-medical devices, a defect and failure report should also be submitted by the organisation to the Department of Health via the defect and failure reporting portal
http://efm.hscic.gov.uk/

Health and Safety Executive (HSE) - Head of HR/H&S lead
The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 (HSWA) and ensuring that "risks to people's health and safety from work activities are properly controlled". Serious incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The trigger point for RIDDOR reporting is over 7days' incapacitation (not counting the day on which the accident happened). Further information on reporting is available at http://www.hse.gov.uk/riddor/report.htm.
Incidents involving work-related deaths (or cases where the victim suffers injuries in such an incident that are so serious that there is a clear indication, according to medical opinion, of a

strong likelihood of death) should be reported under RIDDOR and managed in accordance with the Work-Related Deaths Protocol. In the first instance the incident should be reported within the organisation in the normal way and to the commissioning organisation.

Health Education England - Medical Director
Directors of Education and Quality (DEQ) in Health Education England (HEE) and its Local Education and Training Boards are responsible for the quality of the education and training provided to medical, nursing, dental and Allied Health Professionals (AHP) students and others, and training grade doctors. These students may be involved in serious incidents and HEE have a duty of care to them. Also they are an excellent source of feedback on the standard of patient care experienced in their placement.

HEE DEQs should therefore be informed about serious incidents where trainees are involved. The provider should ensure that the responsible DEQ is made aware of the incident as soon as possible. This does not, however, alter the serious incident management process which should be undertaken in line with national serious incident Framework.

Care must be taken to ensure all parties understand that notification of serious incidents involving trainees is focussed on supporting those trainees and ensuring the standards of training are appropriate. It is very rare that serious incidents are the result of individual failings and notifications sent to DEQs are not intended as a comment or judgement on the capability of trainees.

Information governance serious incidents, Caldicott and data protection - Medical Director/Caldicott Guardian
When reporting serious incidents, providers must comply with Caldicott, data protection and information governance requirements. Where incidents relate to information governance issues they should be reported within the IG Toolkit, in line with the Health and Social Care Information Centre guidance HSCIC Checklist (see *Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation and subsequent guidance*
https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf).

The severity of the incident must be assessed using the scale and severity factors outlined within the HSCIC guidance. All incidents which reach the threshold for a level 2 IG related serious incidents are reported publicly via the IG toolkit and should be reported and investigated as serious incidents under this Framework. Serious incidents relating to information governance have to be reported to commissioner so they can report on STEIS or successor.

Local Authorities - safeguarding lead
Local Authorities also have a particular role to play in safeguarding adults and children and young people in vulnerable circumstances. Providers and commissioners must ensure that information about abuse or potential abuse is shared with Local Authority safeguarding teams.
The interface between the serious incident process and local safeguarding procedures must therefore be articulated in the local multi-agency safeguarding protocol and policies. Providers and commissioners must liaise regularly with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating safeguarding concerns, which is agreed by relevant partners.

Medicines and Healthcare products Regulatory Agency (MHRA) - Director of Care Services

The MHRA is the UK's regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness. The MHRA requires that suspected problems ('adverse incidents') with a medicine or medical device are reported as soon as possible, eg if:

- a medicine causes side effects
- someone's injured (or almost injured) by a medical device, either because its labeling or instructions aren't clear, it's broken or has been misused
- a patient's treatment is interrupted because of a faulty device
- someone receives the wrong diagnosis because of a medical device
- a medicine doesn't work properly
- a medicine is of a poor quality
- a medicine or medical device is suspected of being fake or counterfeit

https://www.gov.uk/report-problem-medicine-medical-device

Police - relevant SMT member

The police are likely to investigate incidents where there is;

- evidence or suspicion that the actions leading to harm (including acts of omission) were reckless, grossly negligent or wilfully neglectful;
- evidence or suspicion that harm/adverse consequences were intended

In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body. Referral to the police should be undertaken by a senior member of staff in the reporting organisation.

Professional regulators and professional misconduct - relevant SMT member

The vast majority of serious incidents are caused by the failure of systems and not the actions of individuals and this must be recognised by the team handling the investigation. Serious incident management process should be followed and progressed in line with the national Serious Incident Framework even if grounds arise to suggest that a serious incident may have occurred as a result of 'professional misconduct'. If grounds for professional misconduct are suggested it is important that the appropriate lead (e.g. the Responsible Officer/Medical or Nursing Director) within the provider organisation is alerted (within 2 days) to ensure that appropriate action is taken as and when required. Appropriate action includes the investigation and/or HR team taking time to carefully assess or refer on to experts the actions or omissions in question, within the context of the incident, to identify whether these are considered reckless or malicious, as opposed to slips, lapses, or a situation where there are others routinely taking the same route or in need of similar levels of support, supervision or training. Systems failures are most likely to be at the core of the problem and, the most effective place to target improvements/solution to prevent recurrence.

The Incident Decision Tree should be used to determine if action is required in relation to individuals

Information relating to all Statutory Regulators and the process for managing professional misconduct can be found in the statutory regulators directory
http://www.professionalstandards.org.uk/regulators/statutory-regulators-directory

Public Health England - Medical Director

PHE also has a broader role in supporting the management of serious incidents that occur within other NHS services, where there is a potential for the incident to have adversely affected the health of a wider population. Such incidents may include decontamination failures; inadvertent contact on NHS premises of patients and staff with someone with a transmissible infectious disease such as measles or TB; outbreaks of health care associated infections; the finding of a Health Care Worker infected with a blood borne virus; failure of microbiological laboratory practice; release/widespread exposure to harmful chemicals or a source of radiation.

Where the potential exists for the health of a wider group of people to be adversely affected by an incident in the NHS, the responsible NHS provider must contact the relevant Public Health England Centre through their Health Protection Team and involve PHE as part of the local incident control team. Commissioners must work with the providers of services which they directly commission to ensure this is the case. Public Health England will provide expert input to the assessment of population risk and advice on the management of public health aspects of the incident. The local team will draw on regional and national expertise within PHE as necessary.

Serious Adverse Blood Reactions and Incidents (SABRE) - Director of Care Services

The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require that serious adverse incidents and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety. This information is vital to the work that the Serious Hazards of Transfusion (SHOT) uses to compile its reports. Further details on reporting can be found at:
https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open

Appendix C - Investigation report templates

1. Concise report template

Concise **Investigation Report Template**

- save the document with the chosen file name. Always include a version number in the filename.

Template can be found here: \\SCHCRAFSS01\Public\Forms & Templates\Incident investigation report templates\Concise investigation report template .dotx

2. Comprehensive report template

Comprehensive and Independent **Investigation Report Template**

- save the document with the chosen file name. Always include a version number in the filename.

Template can be found here:
\\SCHCRAFSS01\Public\Forms & Templates\Incident investigation report templates\Comprehensive investigation report template.dotx

Appendix 3 - Reportable incidents

Agency	Incidents to be reported	StCH responsible officer
Care Quality Commission (CQC)	- serious injury to person using service - abuse or allegation of abuse - events that stop service running safely and properly - incidents reported to or investigated by police See link for more details https://www.cqc.org.uk/content/notifications	Registered Manager (Director of Care Services)
CDAO of relevant CCG	See link for details: http://www.legislation.gov.uk/uksi/2013/373/regulation/11/made	Accountable Officer for Controlled Drugs (Director of Care Services)
Health & Safety Executive	RIDDOR - see link for details http://www.hse.gov.uk/pubns/hsis1.pdf	Head of HR (as lead for H&S and Welfare)
Information Commissioner's Office (via NHS IG Toolkit)	IG Serious Incidents Requiring Investigation (SIRIs) - see link below for details https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf	Director of Finance & Site Services (as SIRO & IG Lead)
Medicines and Health Care Products Regulatory Agency (MHRA)	Incidents involving medical equipment - see link for details www.mhra.gov.uk/index.htm	Registered Manager (Director of Care Services)
Relevant local authority	Incidents related to safeguarding of vulnerable adults and children. See StCH Safeguarding Policy for guidance.	Safeguarding Lead
Coroner	See link below for details http://www.manchester.gov.uk/info/626/coroners/5532/when_death_occurs/2	Medical Director
Police	Serious incidents only - Chief Executive to decide	Chief Executive

Appendix 4 - Risk Grading Matrix

	Consequence				
Likelihood	Negligible 1	Minor 2	Moderate 3	Major 4	Extreme 5
V unlikely 1	1	2	3	4	5
Unlikely 2	2	4	6	8	10
Possible 3	3	6	9	12	15
Likely 4	4	8	12	16	20
Certain 5	5	10	15	20	25

0-4	Negligible risk
5-10	Moderate risk
11-15	Significant risk
16-25	High risk

The tables overleaf provide guidance on how to determine the appropriate level/score for risk consequence and risk likelihood

Guidance on assessing risk consequence severity

Level/score	Examples of actual or potential consequence on persons	Examples of actual or potential consequences on organisation
Negligible **1**	•Minor first aid treatment or no obvious harm	• No disruption to operational activities. • Financial implications - litigation/costs up to £2k
Minor **2**	• Minor injury or illness requiring minor intervention • Time off work (≤ 3 days) • Increased length of patient stay • No permanent harm	• Short-term business interruptions to specific elements of StCH's core business • Financial implications - litigation/costs less than £30k • Some loss of reputation, minor adverse publicity • Increased level of care
Moderate **3**	• Moderate injury requiring professional intervention • Time off work (4-14 days) • RIDDOR/agency reportable incident • Increased length of stay	• Moderate/long term disruption to small number of functions/staff • Financial implications - litigation/costs £30k-£50k • Local adverse publicity, loss to reputation • Implications for StCH's registration with regulatory bodies
Major **4**	• Major injury leading to long-term incapacity/ disability • Requiring time off work (>14 days) • Increase in length of stay • Mismanagement of patient care with long-term effects	• Long term disruption to a number of aspects of StCH's core activity; viability of service area(s) affected • Financial implications - litigation/costs £250k-£1 million • Regional/national adverse publicity, major loss to reputation, loss of public confidence • Damage to StCH's registration status with regulatory bodies
Extreme **5**	• Single or multiple deaths involving any persons	• Extended service closure • Financial implications - litigation/costs over £1m • National adverse publicity, extreme loss to reputation, loss of public confidence • Major impact on future development or sustainability • Removal of StCH's registration with regulatory bodies

Guidance on assessing risk likelihood

Score/level	**Broad descriptor of frequency** *(How often might it/does it happen)*	**Probability descriptor** *(Will it happen or not?)*
Very unlikely **1**	This will probably never happen/recur	Less than a 1-in-1000 chance of happening
Unlikely **2**	Do not expect it to happen/recur but it is possible it may do so	Between 1-in-1000 and 1-in-100 chance of happening
Possible **3**	Might happen or recur occasionally	Between 1-in-100 and 10-in-100 chance of happening
Likely **4**	Will probably happen/recur, but it is not a persisting issue/circumstance	Between 1-in-10 and 5-in-10 chance of happening
Almost certain **5**	Will undoubtedly happen/recur, possibly frequently	More than a 1-in-2 chance of happening