Serious Incident Policy

Document Data			
Document Type:	Policy		
Document Reference:			
Document Status:	Approved		
Document Owner:	Head of Quality (Patient Safety)		
Executive Lead:	Medical Director		
Approval Authority:	Clinical Quality Group		
Review Cycle:	36		
Date Version Effective From:	1st July 2022	**Date Version Effective To:**	30th June 2023

Document Abstract

This policy outlines University Hospitals Bristol and Weston NHS Foundation Trust's (referred to as UHBW/ or the Trust) formal procedures for reporting, investigating, and learning from serious incidents, including patient safety incidents, health and safety incidents, information governance incidents, safeguarding incidents, major outbreaks of communicable diseases, serious IT systems failures, as well as operational and reputational incidents.

It is the Trust's aim to have an entirely open and transparent culture and approach to incident reporting and investigation, seeking to learn lessons and act to reduce risk when things have gone wrong.

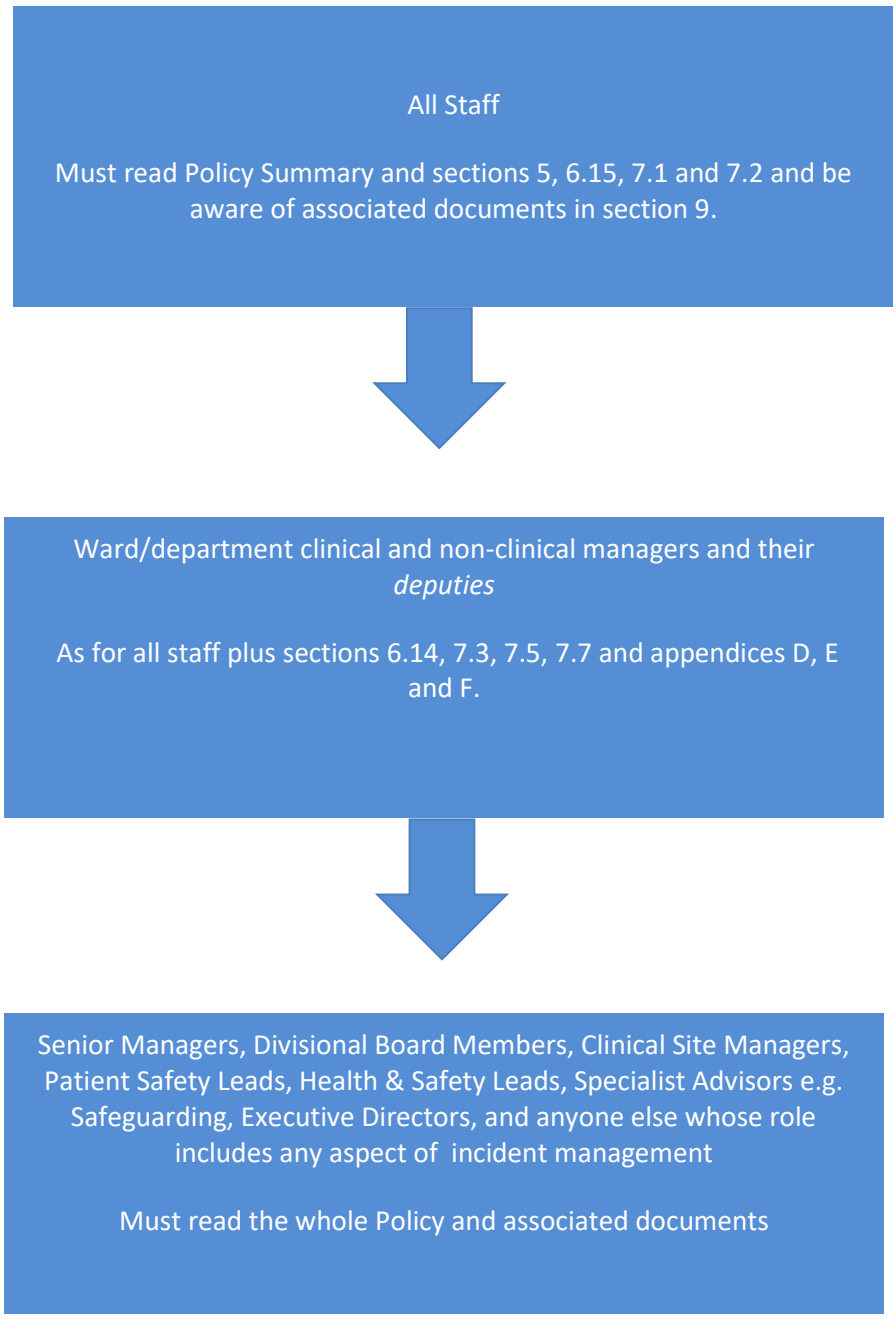
This policy should be read in conjunction with the Trust's Policy for the Management of Incidents and the Staff Support and Being Open Policy, which explicitly describe the process for initial incident management and escalation as a potential serious incident, and the Trust's requirements with regard to its Duty of Candour to inform patients when incidents which affect their care have occurred and where requested, to provide an explanation of what went wrong and what action will be taken to prevent it happening again.

The policy meets the requirements of NHS England's Serious Incident Framework (March 2015).

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
4th May 2017	8.6	[redacted] Head of Quality (Patient Safety) following d/w Incidents and Complaints Working Group	Minor	As above with further minor amends following comments from Clinical Quality Group members. Approved 4th May 2017.
1st December 2018	8.7	[redacted] Head of Quality (Patient Safety)	Minor	Additional clarifications of serious incident definitions (including unexpected deaths) and terms of reference for serious incident investigations. Update of 2018 Never Events list. Inclusion of new processes for maternity incidents: Healthcare Safety Investigation Branch, NHS Resolution Early Notification Scheme and Peri-natal Mortality Review Process.
3rd May 2019	8.8	[redacted] Head of Quality (Patient Safety)	Minor	Amended following feedback from Policy Advisory Group New content on management of cross provider incidents Updated in line with updated Incident Management Policy
13th January 2020	8.9	[redacted] Head of Quality (Patient Safety)	Minor	Changes to executive director sign off process with reconfigured Clinical Quality Group. New process occurs via a separate meeting outside of the Clinical Quality Group. Authority for deciding to report certain serious incidents directly to regulators (CQC, NHSI) New paragraph on conflicts of interest for staff requested to investigate a serious incident. Definition of a draft incident investigation report. Update job title of the Associate Medical Director for Patient Safety to Deputy Medical Director. Minor general update/clarifications
13th March 2020	8.9	[redacted] Head of Quality (Patient Safety)	Name of Trust only	Amended from UH Bristol to University Hospitals Bristol and Weston NHS Foundation Trust

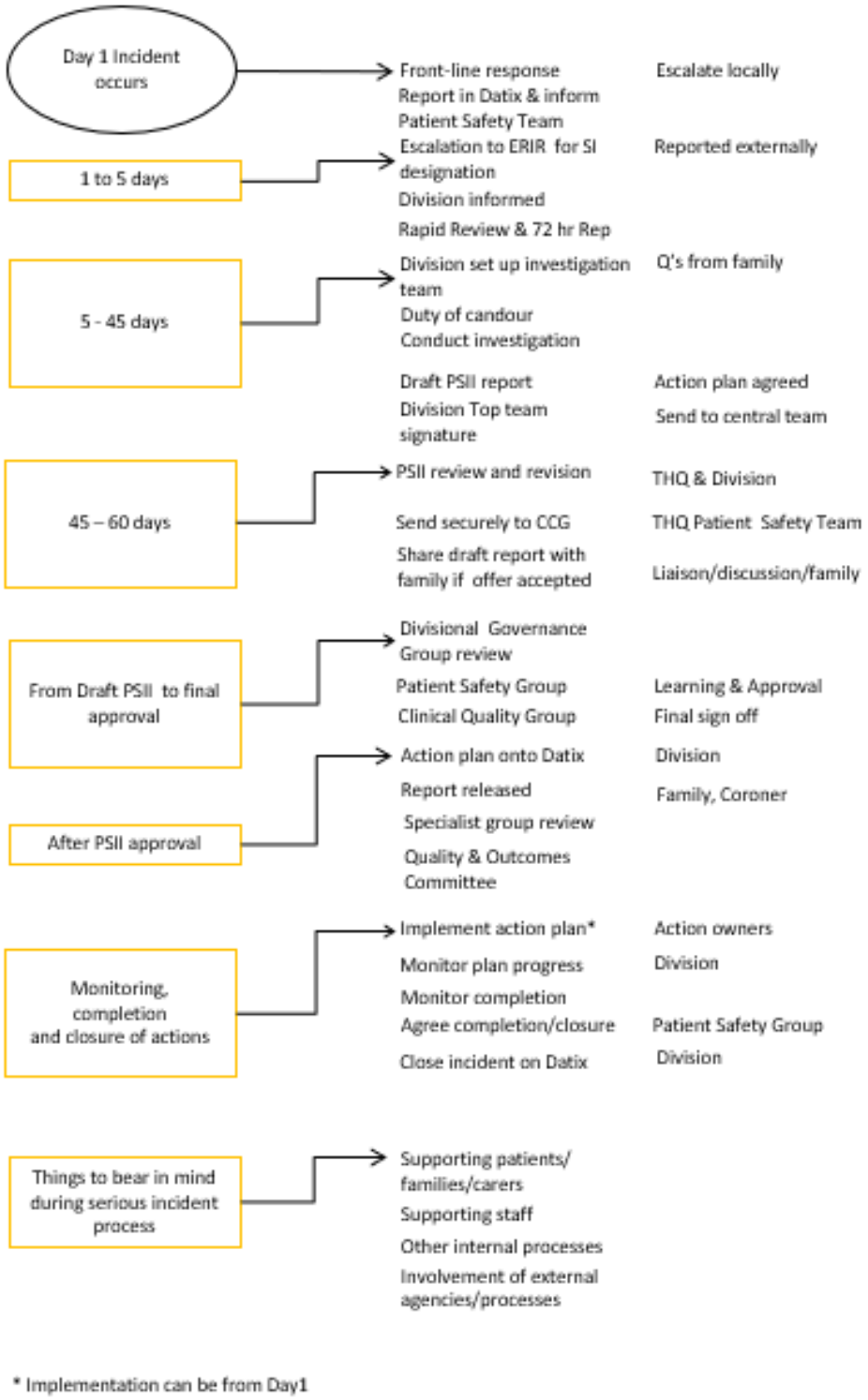
1st July 2021	8.10	[redacted] Head of Quality (Patient Safety)	Minor	Amended to reflect PSII sign off process now with an Executive Director rather than Clinical Quality Group. Amended in response to the Ockenden report: all maternity incidents meeting HSSIB criteria to be reported as serious incidents. Removal of serious incident panels as an additional process. Inclusion of the role of Deputy Head of Patient Safety
31st May 2022	8.11	[redacted] Head of Quality (Patient Safety)	Minor	Interim clarifications in response to Niche review.

1. Do I need to read this policy?



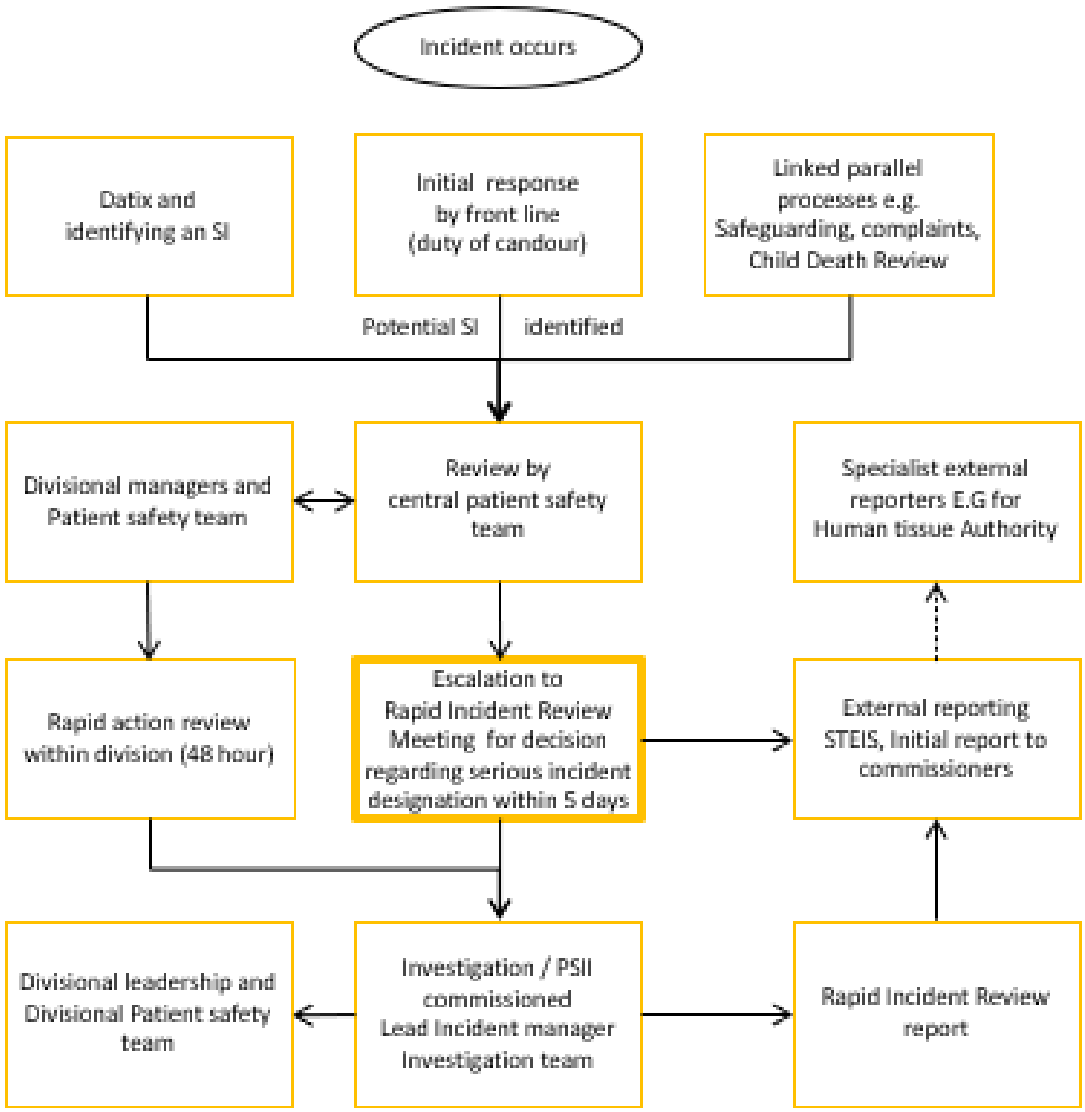
2. Policy Summary

Overview of serious incident process end to end

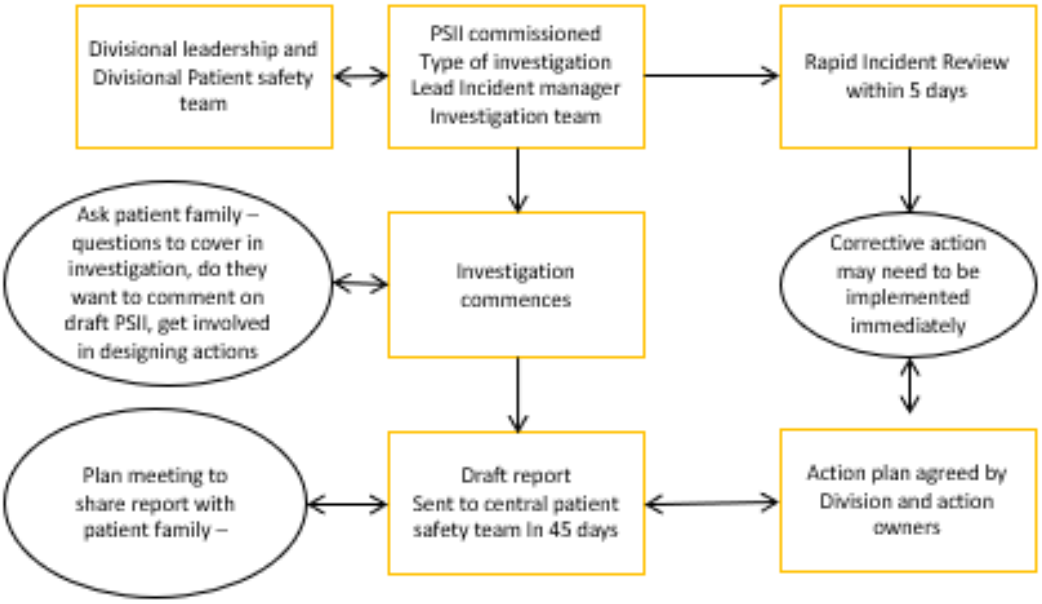


* Implementation can be from Day1

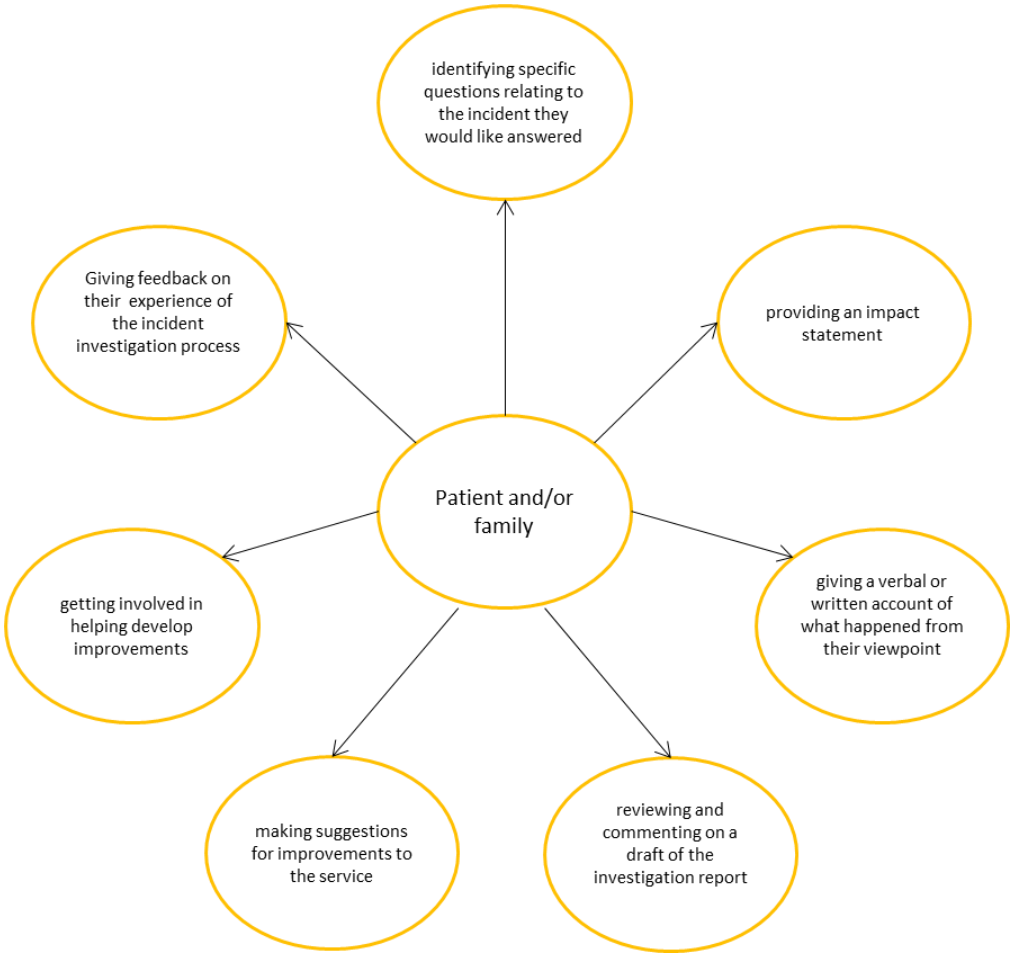
First 5 days


Incident occurs
Datix and identifying an SI
Initial response by front line (duty of candour)
Linked parallel processes e.g. Safeguarding, complaints, Child Death Review
Potential SI identified
Divisional managers and Patient safety team
Review by central patient safety team
Specialist external reporters E.G for Human tissue Authority
Rapid action review within division (48 hour)
Escalation to Rapid Incident Review Meeting for decision regarding serious incident designation within 5 days
External reporting STEIS, Initial report to commissioners
Divisional leadership and Divisional Patient safety team
Investigation / PSII commissioned Lead Incident manager Investigation team
Rapid Incident Review report

5 days to 45 days



How the patient and/or family/carers can be involved if they want to



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3. Introduction

Serious incidents in healthcare are relatively uncommon, but when they do occur, NHS Organisations have a responsibility to ensure that there are systemic measures in place for safeguarding people and property, NHS resources and reputation. This includes the responsibility to learn from these incidents in order to minimise the risk of them happening again.

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.

A serious incident triggers an investigation into a work system's weakness and therefore the potential learning and acting to reduce safety risk. Thus, they require suitable investigation to identify context, situation and factors that contributed towards occurrence. Serious incidents can be isolated, single events or multiple linked or unlinked events.

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.

There are a number of supporting procedures which underpin this policy and are listed in Section 9.

4. Purpose

The purpose of this policy is to set out

(a) What a serious incident is;
(b) What staff must do when a possible serious incident occurs;
(c) What arrangements are in place for managing a serious incident from when it occurs through to learning from it, taking action to prevent recurrence and closure.

5. Scope

This policy applies to all serious incidents and near misses, including patient safety incidents, health and safety incidents, information governance incidents, safeguarding incidents, major outbreaks of communicable diseases, serious IT systems failures, and operational and reputational incidents. It also covers serious incidents relating to national screening programmes, blood transfusion, organ donation and transplant, and post-mortem services.

This policy applies to all staff working in UHBW services and premises including: temporary (locum, bank and agency) staff, contractors, staff on honorary contracts, students and trainees.

The policy does not replace required external reporting arrangements to be followed for incidents involving a range of issues such as safeguarding, deaths required to be notified to HM Coroner, unexpected child deaths, infection outbreaks, incidents required to be notified to professional regulatory bodies, defective medicinal products, buildings, plant, equipment and other supplies. Normal accident and injury reporting arrangements are similarly unaffected by this policy as are the guidelines for involving the police where

criminal activity is suspected or discovered. Details of external bodies to which certain incidents should be reported can be found at Appendix D.

6. Definitions

6.1 Serious Incident

The NHS Improvement Serious Incident Framework defines a serious incident as an incident (whether by commission or omission) which occurred in relation to care resulting in one or more of the following:

(a) An unexpected or avoidable death[1], major or serious harm or injury to one or more patients, staff, visitors, or members of the public. This includes suicide/self-inflicted death or homicide by a person receiving mental health care in the recent past[2];
(b) An unexpected or avoidable injury that caused serious harm;
(c) An unexpected or avoidable injury requiring further treatment to prevent death or serious harm;
(d) Actual or alleged abuse: sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative or organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:

    (i) healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
    (ii) where abuse occurred during the provision of NHS funded care

(e) A "Never event". All never events are serious incidents , although not all never events necessarily result in serious harm or death;
(f) An incident or series of incidents that prevents or threatens to prevent the Trust's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

    (i) Failures in the security, integrity, accuracy or availability of information and information governance related issues;
    (ii) Property damage;
    (iii) Security breach/concern;
    (iv) Incidents in population-wide healthcare activities such as screening and immunisation programmes where potential for harm may extend to a large population;
    (v) Inappropriate enforcement/care under the Mental Health Act (1983), Mental Capacity Act (2005) and Deprivation of Liberty Safeguards;
    (vi) Systematic failure to provide an acceptable standard of safe care;
    (vii) Activation of Major Incident Plan (by provider, commissioner or relevant agency);

(g) Major loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation;

[1] Caused or contributed to by weakness in care/service delivery (including lapses, acts and/or omissions) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.

[2] This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually-it may be appropriate to declare a serious incident for a homicide by a person discharged from mental health care more than 6 months previously

(h) Serious outbreaks of communicable diseases;
(i) A reportable serious incident that occurred in relation to English NHS national screening programmes. Guidance is available: Managing safety incidents in NHS screening programmes - updated interim guidance (Public Health England March 2015);
(j) A reportable serious incident or adverse event as defined in the Human Tissue Authority's guidance on "Reporting an incident or concern";
(k) Suspension of maternity services in accordance with guidance agreed with commissioners;

This list is not exhaustive and staff can refer any incident they think may be a serious incident to the Trust Headquarters Patient Safety Team or an executive director.

6.2 Never Event

"Never events" are, by definition, patient safety incidents that should never happen if all preventive measures have been implemented. Never events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies. Never events are automatically designated as serious incidents. Never Events list 2018 (updated February 2021)

6.3 Serious Harm

Serious harm is defined by the NHS Improvement Serious Incident Framework 2015 as:

(a) Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);
(b) Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or
(c) Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).
(d) Examples of serious harm include

    (i) Avoidable death or serious harm - caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omissions) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.
    (ii) Where the outcome requires lifesaving intervention or major medical/surgical intervention

6.4 Unavoidable death

(a) For the purposes of incident reporting, an unavoidable death is defined as the unexpected death of an individual(s) where there is a less than 50:50 chance the death was attributable to problems in healthcare[3].

[3] Hogal et al: Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis, BMJ 2015;351:h3239

6.5 Avoidable death

(a) An avoidable death is defined as the unexpected death of an individual(s) where there is a greater than 50:50 chance the death was attributable to problems in healthcare. It is important to note that when a death is assessed as avoidable based on a greater than 50:50 chance the death was attributable to problems in healthcare, this does not necessarily mean that individuals were directly to blame nor that all staff involved in the patient's care weren't doing their best for the patient. In the vast majority of cases there is a system error.

6.6 Unexpected death

(a) A death that occurs contrary to the expectations of clinical staff bearing in mind their understanding of the patient's clinical condition and the care they were providing to treat them. Such an occurrence should be reported as an incident and reviewed at a Rapid Incident Review meeting to identify whether this triggers a systems patient safety incident investigation to identify learning an improvement actions. The degree of harm rating of the incident must be updated to reflect the findings of a review or investigation in accordance with either paragraphs 5.16 or 5.17. Other review processes exist for patient deaths, please refer to the SOP "Link between incidents, complaints and other investigatory processes".

6.7 Near Misses

A situation when an incident or serious incident very nearly happens that could have resulted in injury, damage or loss but did not do so due to chance, corrective action and/or timely intervention.

The NHS Improvement Serious Incident Framework 2015 states:

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

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

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

6.8 Draft incident investigation report

(a) A draft incident investigation report is one which the investigation team/lead investigator (see Appendix E) are satisfied is complete and factually accurate and ready to be presented to committees outlined in Appendix H, and the patient/family if so desired, for comments to be considered for inclusion in the final version. If specified in a request, drafts and supporting documentation are normally disclosable under the Freedom of Information Act 2000 unless an exemption can be demonstrated to apply. Advice should be sought from the Information Governance Team if required.

7. Duties, Roles and Responsibilities

7.1 Trust Board of Directors

(a) Ensures that robust systems are in place to identify, manage and learn from serious incidents and that it receives it has sufficient assurance that these systems are working effectively.

7.2 Chief Executive

(a) Has overall responsibility for safety and ensuring that the necessary resources and systems are in place for the effective management of serious incidents

7.3 Executive Directors

The following responsibilities may be delegated to a Deputy. Executive directors are:

(a) Responsible for deciding if an incident is a serious incident, deciding on the nature of the investigation, commissioning the subsequent investigation and facilitating the setting up of a cross-division investigation, informing and consulting with executive colleagues as required.
(b) Responsible for setting out the Terms of Reference for the serious incident investigation.
(c) The commissioning executive director is responsible for acting on any issues escalated to them which are compromising the progress of the investigation.
(d) An executive director must provide interim sign off of a draft PSII
(e) prior to sharing with patient/family/carers for their comments.
(f) The medical director or chief nurse will sign off patient safety serious incident investigations. This means they are satisfied that the investigation of the incident has been sufficiently robust and includes all relevant lead specialist professionals, that the context, situation and system weaknesses have been appropriately identified, that the actions reflect the report content and that plan for sharing lessons learned internally or externally is comprehensive.
(g) Sign-off for early release of serious incident reports to Coroner, Care Quality Commission or family/carers/patient
(h) An executive director must provide interim sign off of a draft Patient Safety Incident Investigation (PSII) prior to sharing with patient/family/carers for their comments.
(i) Final sign off of serious incident investigations after determining that the investigation of the incident has been sufficiently robust and that system weaknesses have been appropriately identified, that the actions reflect the report content and that the lessons learned have been shared internally or external as relevant
(j) The Director of Finance, in liaison with the Trust's counter-fraud service, and in accordance with the Trust's Standing Financial Instructions, is responsible for contacting the police if a serious incident involves fraud or corruption.
(k) A Deputy Medical Director acts as Caldicott Guardian and provides advice relating to serious incidents involving breaches of patient confidentiality or other inappropriate use of patient information.
(l) A Deputy Medical Director chairs the Trust-wide Patient Safety Group.

7.4 Quality and Outcomes Committee (QOC)

(a) Is accountable to the Trust Board of Directors and provides assurance that the governance systems and processes for the management of serious incidents is robust and compliant with local and national policies.
(b) They receive notification of serious incidents including never events and the outcomes of their investigations, including any overdue actions and inform the Trust Board of Directors of any issues requiring escalation.

7.5 Senior Leadership Team (SLT)

(a) Receives regular quarterly reports on numbers and themes of serious incidents, timeliness of reporting and investigation and lessons learned.

7.6 Clinical Quality Group (CQG)

(a) Receives regular quarterly reports on numbers and themes of serious incidents, timeliness of reporting and investigation and lessons learned.
(b) Is responsible for monitoring the delivery of any overdue actions
(c) Receives thematic reviews of serious incidents. These could be routine annual reviews such as for pressure ulcers/falls or adhoc as commissioned by the Chief Nurse/Medical Director
(d) Receives reports from external investigations, such as those national investigations by the Health Services Safety Investigation Body (HSSIB), and receives assurance from the division that actions in response to recommendations are completed

7.7 Patient Safety Group (PSG)

(a) Identifies key learning points from serious incident investigations for wider sharing across divisions and throughout the Trust. It disseminates these through:

    (i) The issue of Safety Bulletins and Rapid Response Bulletins
    (ii) Members of the group feeding back to their divisions
    (iii) Actions to ensure specific messages are communicated to relevant groups and leads

(b) Receives quarterly reports from specialist groups such as the Falls and Tissue Viability Groups which include incident and serious incident analysis.
(c) Reviews the quality, content and completeness of any patient safety-related serious incident investigation reports and requests further investigation, action or revision before they can be submitted for approval at the Clinical Quality Group
(d) Receives assurance on the completion of all serious incident action plans, includes those in response to external investigations, and approves closure of the serious incident
(e) Identifies and assesses organisation-wide risks arising from serious incidents for inclusion on the Trust Services Risk register.

7.8 Specialist Groups such as the Falls and Tissue Viability Groups

(a) Identify key learning points from serious incident investigations relating to their specialist expertise for wider sharing across divisions and throughout the Trust.
(b) Ensure all new actions arising from serious incident investigations are incorporated into their work plan, monitoring their progress and seeking assurance on their implementation.

7.9 Divisional Governance Groups

(a) Agree their serious incident investigation reports and receive those arising from external investigations such as the HSSIB.
(b) Monitor the completion of actions arising from internal and external incident investigations and report exceptions to the Divisional Board.

7.10 Divisional Directors, Clinical Chairs and Heads of Nursing/Midwifery

(a) Are responsible for ensuring that divisional processes are in place in their areas to identify and manage serious incidents effectively and that all their staff are aware of their responsibilities, particularly in relation to the timescales for reporting and investigation of serious incidents.
(b) Designate a lead incident investigator for internal investigations and ensuring the independence of the investigation.
(c) Ensure that a robust and SMART[4] action plan is developed by the division in response to the recommendations of a serious incident investigation, and that this is compiled in consultation with those with the authority and resources to implement the actions required. Ensure that the overall action plan owner and local governance group for monitoring progress is clearly identified.
(d) Sign off serious incident investigation reports within their division.

7.11 Head of Quality and Patient Safety or Deputy Head of Patient Safety

(a) Ensures that potential serious incidents are identified, flagged with the relevant executive, reported and investigated appropriately. This includes ensuring serious incidents are reported externally via the STEIS system, monitoring progress with investigation, reviewing incident investigation outcomes and action plans and submitting quarterly reports to the Patient Safety Group and the Clinical Quality Group.
(b) Provides expert advice to executive directors on the criteria for identifying serious incidents.
(c) Informs Communications Department of serious incidents likely to result in media attention
(d) Authorises proactive contact regarding serious incidents with regulatory bodies such as the Care Quality Commission or NHS Improvement and provides further assurance if required.
(e) Liaises with and provides assurance to commissioners in reporting and learning from serious incidents.
(f) Maintains oversight of the management of serious incidents involving patient pathways and systems across other external providers to ensure investigations are joined up, timely and signed off within UHBW in accordance with this policy.
(g) Ensuring the relevant senior manager reports serious incidents to external bodies as set out in Appendix G.

7.12 Corporate Patient Safety Team

(a) Will provide advice on the reporting and investigation of serious patient safety incidents and, when applicable, lead the investigation of cross-divisional and Trust-wide incidents.
(b) Will identify and escalate potential serious incidents to a Rapid Incident Review Meeting as described in the Policy for the Management of Incidents for decision as to whether a serious incident has occurred, coordinating the gathering of additional information as

[4] SMART-Specific, Measurable, Achievable, Relevant and Time-bound

requested by the executive director and circulating the executive director's decision to the necessary people to ensure the necessary action results.

(c) Reports serious incidents to commissioners via the STEIS system as required by the head of quality (patient safety).

(d) Conducts initial quality assurance reviews of patient safety incident investigation (PSII) reports for serious incidents, and requests clarifications of reports from divisions.

7.13 Head of Health and Safety

(a) Responsible for providing expert advice on the reporting and investigation of health and safety serious incidents and, when applicable, leading the investigation of cross divisional and Trust wide incidents.

7.14 All Managers

(a) Are responsible for ensuring relevant staff are familiar with this policy.

(b) Are responsible for ensuring all incidents that occur or are identified within their department are recorded accurately on the Datix online reporting system within the same day/shift, and are reviewed within 72 hours according to the Trust's Policy for the Management of Incidents.

(c) Are responsible for informing their divisional Patient Safety Manager/Advisor, Trust Headquarters Patient Safety Team, or, out of hours, contact the Clinical Site Manager if they think a serious incident has occurred.

(d) Are responsible for informing their ward or department manager or consultant or, in their absence, another senior manager or consultant if they think a serious incident has occurred.

(e) Are responsible for offering support to their staff following a serious incident as set out in the Staff Support and Being Open Policy.

7.15 All staff

(a) Are responsible for reporting an incident when it occurs in line with the Trust's Incident Management of Incidents via the Trust's online incident reporting system Datix.

(b) If staff are uncertain whether something that has happened is an incident or not they should report it on Datix in any case for onward assessment by divisional/corporate patient safety teams. "If in doubt report".

(c) For the purposes of learning and improvement all staff are expected to share their account of the context, situation and sequence of events relating to any incident under investigation that they witnessed or have information about.

(d) Are responsible for informing their ward or department manager or consultant or, in their absence, another senior manager or consultant if they think a serious incident has occurred.

7.16 Lead Investigator

(a) All serious incidents will have a designated Lead Investigator who will be responsible for ensuring that the incident is managed and investigated accordingly. The appointment is made by the Divisional Director, Clinical Chair or Head of Nursing/Midwifery with the

relevant Divisional Manager, taking advice from Clinical Directors/divisional patient safety leads/managers/advisors and Executive Directors as required.

(b) The lead investigator must not be involved in the direct care of those patients affected nor should they work directly with those involved in the delivery of that care. 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.

(c) The lead investigator will usually be the person identified to keep the patient/family/carers updated on the progress of the investigation except in situations where there are multiple investigations when this will be the case manager as outlined in the Standard Operating Procedure 'Link between serious incidents other investigatory procedures'.

7.17 Case Manager

(a) The case manager will act as a co-ordinator in situations where there are multiple investigations as outlined in the Standard Operating Procedure 'Link between serious incidents other investigatory procedures'.

7.18 Clinical Directors

(a) Take a leadership role in the management of serious incidents in their clinical area.

(b) Support as required effective rapid incident review when an incident is identified, advise on the appointment of investigators, and potentially support investigations as part of an investigation team, supervising an investigator or leading an investigation.

7.19 Clinical Site managers/Supervisor of Midwives

(a) Have out of hours responsibility for initial management of serious incidents in line with this policy, liaising with the on-call manager or on-call executive director as required.

7.20 Divisional Patient Safety Leads/Managers/Advisors

(a) Contact the Trust Headquarters Patient Safety Team and provide information on potential or confirmed serious incidents.

(b) Ensure Duty of Candour is complied with, recorded within the patient's notes and on the Datix system, and the principles of being open adhered to.

(c) Ensure serious incidents are investigated, and investigations are completed on time.

(d) Ensure the dissemination of shared learning within their division, across the organisation and externally where relevant and for divisional compliance the requirements of the Incident Management Policy.

(e) Ensure that risks arising from serious incidents are identified, assessed and reviewed for entry on the appropriate divisional risk register, informing their Divisional Boards and advising on mitigation.

(f) Co-ordinate timely conduct of PSIIs within their division and assure the quality of investigation reports produced as a result, using the checklist provided.

(g) Add any actions from the investigations to the relevant incident on the Datix system so that implementation can be effectively tracked, ensure these are kept up to date with progress and that completed actions are closed within a timely manner.

(h) Overseeing and escalating through reports into their divisional quality and safety governance structure actions which have not been completed within the planned timescale.

(i) Flag any recommendations with Trust-wide implications to the Patient Safety Group for consideration as a clinical risk for onward identification to the Clinical Quality Group.

7.21 Information Governance Team

(a) Advise and support in relation to all aspects of Information Governance related incidents, in line with the criteria provided by the Information Commissioner, including whether information governance incidents meet the threshold for reporting as a serious incident.

(b) Communicate potential information governance serious incidents to the Trust HQ Patient Safety Team on the same day as identified as per Standard Operating Procedure for incident reporting, investigation and management and Information Governance Serious Incidents.

7.22 Trust Legal Team

(a) Provide advice and guidance for any department dealing with serious incident that has or may have legal ramifications.

7.23 Communications Team

(a) In collaboration with the Chief Executive or a nominated director, is responsible for managing media enquiries regarding serious incidents. This will be delegated to the on call communications team member and on call director out of hours.
(b) The Director of Communications will be responsible for the arrangements for managing multiple enquiries from multiple external companies or people, for example by sending out a press release if relevant.

8. Policy Statement and Provisions

8.1 Principles

The Trust works within the seven key principles in the NHS Serious Incident Framework:

(a) Openness and transparency when dealing with those affected or involved;
(b) Prevention: identifying learning from investigations and taking action to reduce the risk of a recurrence;
(c) Objectivity: investigation by staff not involved in the care of patient affected;
(d) Timely and responsive: investigations and report completed within timescales; investigation participants prioritising;
(e) Systems-based: looking at the system in which the incident occurred and using recognised investigative tools such the Systems Engineering Initiative for Patient Safety (SEIPS) framework;
(f) Proportionate: focusing resources where the most learning is to be gained; only applying the necessary resources to any particular investigation;
(g) Collaborative: working effectively with other teams and organisations.

The Trust has long-established principles relating to serious incidents which are outlined below.

(h) Advice should be sought early from the head of quality and patient safety or deputy, a patient safety manager, or other corporate function (e.g. Health and Safety) as to whether an incident should be escalated;

(i) It may be appropriate for a near miss to be classed as a serious incident because the outcome of an incident does not always reflect the potential severity of the harm that could be caused should the incident (or a similar incident) re-occur;
(j) Incidents may only be recognised as a serious incident some time after the event. In such cases the member of staff to whom such evidence becomes available must immediately report the incident as described in this policy to ensure promotion of learning and patient safety;
(k) Patient/family/carers complaints or concerns may include incidents or allegations of harm. These should be managed in accordance with the Standard Operating Procedure for Link between incidents and other investigatory procedures and consideration given for the need for a patient safety incident investigation;
(l) Executive director responsibility for deciding if a serious incident has occurred;
(m) Possibility of multiple incidents investigated together;
(n) All serious incidents are systematically investigated, reported on, and the results reviewed;
(o) Downgrade of incidents which investigation shows not to be serious;
(p) A formal governance process for approving reports;
(q) Consistency with the Trust's Policy for the Management of Incidents;
(r) Where the serious incident is related to other Trust policies e.g. Safeguarding Policy, Health & Safety Policy, the Serious Incident Policy must be followed in parallel with these other policies and the required legislation. This policy will complement and work alongside any local procedures that are in place for dealing with areas of specialist practice;
(s) In the cases of incidents involving clinical matters it is recognised that, on occasions, the divide between genuine failures of services and complications that may arise as the result of inevitable risks of treatment may be small;
(t) The need to support patients, families and staff as set out in the information leaflet: Guidance for patients and families about incidents. This includes providing a seamless and joined up investigation for incidents which occur across more than one division, provider and for incidents which may involve more than one investigatory process e.g. a complaint, inquest, Learning from Deaths review, child or neonatal mortality review.
(u) The Trust is committed to ensuring that staff asked to undertake serious incident investigations are appropriately trained and that sufficient resource will be provided to ensure agreed actions are embedded;
(v) Use of the Communications Team in dealing with the media;
(w) Ensuring the Trust Board of Directors is sighted on media interest;
(x) Where an incident has not taken place but staff wish to raise a concern, the Trust's expectations and guidance for communication of concerns about practice with an adverse impact on safety is available in the Trust's Freedom to Speak Up Policy. Guidance is also available from healthcare professional regulatory bodies e.g. General Medical Council, Nursing and Midwifery Council
(y) Police co-ordination via incident or duty manager will take place where applicable, except with fraud where this responsibility is undertaken by the Counter Fraud Service.
(z) It is important to note that when a death is assessed as avoidable based on a greater than 50:50 chance the death was attributable to problems in healthcare, this does not necessarily mean that individuals were directly to blame nor that all staff involved in the patient's care weren't doing their best for the patient. In the vast majority of cases there is a system error.

8.2 Initial response by front-line staff to a potential serious incident

When a serious incident occurs, staff need to ensure the following:

(a) They meet the immediate needs of those involved and secure the safety of people and the environment. The needs of those affected should be the primary concern of those involved in the response to, and investigation of, serious incidents;
(b) They put in place immediate preventative measures to prevent re-occurrence;
(c) Any documentation, such as a patient's medical records, should be identified and secured. Any medical equipment and associated consumables thought or suspected to have contributed to the incident should be quarantined in the condition it was in when the incident occurred and Clinical Engineering (MEMO) contacted as soon as possible;
(d) The incident must be reported on Datix the same working day or shift and escalated. During working hours this is via line management to the divisional patient safety manager/advisor and Trust Headquarters Patient Safety Team. Out-of-hours, escalation is via the site management team/on-call manager and potentially executive director;
(e) Saying sorry is not an admission of liability and is the right thing to do. The Staff Support and Being Open Policy sets out clear procedures for early, meaningful and sensitive engagement with affected patients and their families/carers from the point at which the serious incident is identified, throughout the investigation, report formulation and subsequent action planning, through to closure of the investigation process;
(f) Early consideration of the Duty of Candour, identifying a single point of contact, support and information for patients, for relatives, staff and others affected by the incident should be given. See the guidance "Supporting and working with families after an unexpected death/serious incident" and Guide for patients and families about incidents on the DMS for further guidance of dealing with families and patients and Duty of Candour Trust web pages for further information on Duty of Candour requirements.
(g) Early consideration for support for staff involved. See the Staff Support and Being Open Policy and Just Culture Guide.

8.3 Datix and the identification of a potential serious incident

(a) Orange and red triaged incidents (See policy summary section of the Incident Management Policy), unexpected deaths very high risk incidents and any other potential serious incidents[5] will be also automatically notified to divisional patient safety manager/advisors and the Trust Headquarters Patient Safety Team through the Datix system.
(b) Unexpected deaths will be recorded as such on the Datix system and undergo an initial rapid incident review and incident triage This will proceed to a full investigation should the initial review be unable to discount any causal or contributory factors as stated in footnote to 3.1 a).
(c) The Trust Headquarters Patient Safety Team will also monitor, daily, all incidents reported through the Datix system to identify potential serious incidents.
(d) Divisional patient safety manager/advisors will also monitor, daily, their own incidents and escalate potential serious incidents to the Trust Headquarters Patient Safety Team.
(e) All maternity incidents meeting HSSIB criteria will be initially reported as serious incidents and a "clock stop" requested of commissioners pending the outcome of the HSSIB investigation. If no care failings are identified commissioners will be requested to downgrade the incident from a serious incident.

[5] Those likely to fulfil this policy and the national Serious Incident Framework definitions

8.4 Escalation of a potential serious incident for decision (identifying a serious incident)

(a) Potential serious incidents will be entered onto the Executive Escalation Checklist form by the Trust Headquarters Patient Safety Team and provided to a suitable executive director for consideration. They will record a decision on the form adding their comments and further action required.

(b) The Trust Headquarters Patient Safety Team will communicate the executive director's decision to the relevant parties (e.g. Divisional Patient Safety Teams, other directors as requested) and, if a serious incident has been identified, log for subsequent monitoring, record the outcome on Datix and attach an electronic copy of the escalation form to the incident on Datix.

8.5 External Reporting

(a) A serious incident will be reported on the STEIS system within 48 hours of identification by the Trust Headquarters Patient Safety Team to alert the commissioner.

(b) When it is not clear if an incident is a serious incident, there should be a discussion with the commissioners to agree the way forward.

(c) If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled – for example there were no acts or omissions in care which caused or contributed towards the outcome, the incident can be downgraded. This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focused on the incidents where problems are identified and learning and action are required.

(d) Where a serious incident necessitates the activation of the Trust's or the commissioner's Major Incident Plan, would cause significant public concern, media concern or be significant to other agencies such as the police, an immediate report on STEIS should be made followed by a telephone call to commissioners. If the Care Quality Commission (CQC) or NHS Improvement is to be directly notified, this will be authorised by an executive director.

(e) Certain serious incidents require additional direct and timely reporting by designated individuals to a regulating body. Examples include the Human Tissue Authority, Care Quality Commission, Information Commissioner's Office, Health and Safety Executive. A full guide can be found in Appendix G.

(f) Where a patient safety incident meets the criteria for reporting to the Health and Safety Executive under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR), this will be undertaken by the Trust's Health and Safety Department. The terms of reference for any PSII for a patient safety incident reportable under RIDDOR should include the requirements for RIDDOR and the single investigation report should serve both Health and Safety and patient safety purposes.

(g) Maternity incidents meeting the criteria for NHS Resolution's Early Notification Scheme will be notified to the Trust's Legal Team as soon as identified.

8.6 Commissioning and setting up a serious incident investigation

(a) The executive director who identified the serious incident will decide on the type of the investigation and set out the terms of reference, including for cross-divisional and independent investigations. The high risk incident checklist will be completed outlining specific terms of reference for the investigation. This will be communicated to the relevant Division(s) by the Trust Headquarters Patient Safety Team (see also appendices E and F.)

(b) The Health Services Safety Investigation Body (HSSIB) will investigate certain maternity and neonatal incidents. This includes:

(i) Intrapartum Stillbirths.
(ii) Early Neonatal Death (0-6 days of life).
(iii) Severe Brian Injury diagnosed within first 7 days of life.
(iv) Maternal Deaths (within 42 days of the end of the pregnancy).

A full description is available at: https://www.hsib.org.uk/maternity/resources/trust-pack/

(c) For the investigation of other serious incidents such as Information Governance, Health and Safety or financial incidents, guidance on formulating the terms of reference will be sought from the relevant director or lead specialist professional.
(d) The scale and scope of the investigation should be proportionate to the incident to ensure resources are effectively used. Incidents which indicate the most significant need for learning to prevent serious harm should be prioritised.
(e) Typically, serious incidents require a comprehensive investigation, but the scale and scope (and required resources) should be considered on a case-by-case-basis. Some incidents may be managed by an individual (with support from others as required) whereas others will require a team effort and this may include members from various organisations and/or experts in certain fields.
(f) Commissioning of the investigation will include, if known at the time, consideration for other parallel statutory or investigatory processes and direction regarding the primary overarching process (depending on the type of investigation required) in which to manage and govern the investigation;
(g) In many cases an internally managed investigation can fulfil the requirements for an effective investigation. In some circumstances (e.g. very complex or catastrophic incidents spanning multiple organisations and/or where the integrity of the investigation would be challenged/ undermined if managed internally) an independent investigation may be required (see Appendix E for further details).
(h) The majority of investigations will be set up by the divisions who will identify a lead incident investigator who will be suitably trained in order to carry out investigations which are evidence-based, robust, proportionate and suitably independent.
(i) To ensure objectivity, lead incident investigators and the investigation team must not be involved in the direct care of the patient, nor should they work directly with those involved in the delivery of that care. However it is important to involve staff with relevant professional expertise in the investigation. More guidance on the investigation team composition, seniority, competencies, skills and experience is available in Appendix F.
(j) There needs to be adequate engagement and the opportunity for all staff involved in the incident to contribute the information they hold to the investigation should be considered at the outset of an investigation.
(k) All staff involved in undertaking investigations should be clear under which policy they are being undertaken and are clear about the purpose of the investigation and the intended audience.
(l) A rapid incident review will take place for all serious incidents as described in Appendix D and a report produced and sent to the Trust Headquarters Patient Safety Team.
(m) The Chief Nurse or Medical Director or a designated deputy should identify specific terms of reference for the incident investigation including objectivity of the investigating team and how the investigation links with other required review processes e.g. Learning from Deaths process, and these should be recorded in the outcome section 2 of the Rapid Incident Review report.
(n) Incident investigations will be systematic and follow accepted PSII methodology, using the relevant template developed by the Trust. There is further guidance on incident investigation available on the patient safety intranet pages.
(o) Investigations are of the following types, with more guidance in Appendix E.

(i) Divisional;
(ii) External to the Division;
(iii) Cross-divisional;
(iv) Independent e.g. by the Healthcare Safety Investigation Branch of NHS Improvement or other externally commissioned organisation.

(p) All serious incident investigations will be completed[6] within 60 working days of the incident being reported on STEIS, except for independent external investigations which will be completed within six months. Exceptions can be requested where there is a valid reason to do so e.g. awaiting a post-mortem result or other external constraint.
(q) Exceptions must be requested as soon as a potential cause of an investigation delay is identified by contacting investigation by the Head of Quality (patient safety).
(r) The PSII is not designed to investigate individual fault. The Just Culture Guide and further information in the Trust's Staff Support and Being Open Policy describes how potential individual culpability should be managed.

8.7 Incidents which are subject to other parallel investigatory processes

(a) It is recognised that sometimes the same issue will be addressed through multiple processes, for example as a complaint, an incident, or a Child Death Review. Where this occurs, the Trust will ensure that these processes work together in a way which patients and their families can understand and which provides a single coordinated point of contact with the Trust

(a) The Standard Operating Procedure Link between incidents, complaints and other investigatory processes describes the Trust's approach to co-ordinating multiple investigatory processes.

8.8 Involvement of patients/families

(a) Involvement begins with a genuine apology. The principles of honesty, openness and transparency (as set out the Trust's Staff Support and Being Open Policy) must be applied.
(b) Detailed guidance is provided in the Trust's "Supporting and working with families after an unexpected death or serious incident" guidance.
(c) An early meeting must be held to explain what action is being taken, how patients and families can be informed, what support processes have been put in place and what they can expect from the investigation. This must set out realistic and achievable timescales and outcomes. See also the Trust's "Guidance for meetings with families to discuss concerns" and the patient information leaflet "Guide for patients and families about patient safety incidents/events".
(d) Those involved are likely to want to know:

(i) What happened?
(ii) Why it happened?
(iii) How it happened?
(iv) What can be done to stop it happening again to someone else?

(e) It is important that appropriate treatment and support is provided for patients and victims and their families and carers. This should be considered on an individual basis.

As a draft for sending to the commissioners.

(f) Depending on the nature of the incident, it may be necessary for several organisations to make contact with those affected. This should be clearly explained to the patients/victims and families/carers as required. A co-ordinated approach should be agreed by the partner agencies in discussion with those affected. See also Standard Operating Procedure "Link between serious incidents and other investigatory procedures".

(g) As part of the initial Duty of Candour discussion or at any point prior to finalising the PSII report, patients and/or families/carers will be offered the opportunity to be involved in the design of actions to help prevent a recurrence of a similar incident (See patient information leaflet: Guides for Patients and Families about Patient Safety Incidents/Events).

8.9 Feedback from patients and/or families/carers regarding their experience of the serious incident process

(a) At the point where patients and/or families/carers receive the final serious incident investigation report (if they have chosen to receive it) they will be asked for feedback regarding their experience of the serious incident process including how this could be improved.

8.10 Involvement of experts

(a) Expert opinions can be sought to assist serious incident investigations in circumstances where the investigating team requires a further opinion in complex or specialised situations. This can be a second opinion from within the Trust (but without the clinical team involved) or commissioned independently.

8.11 The draft investigation report

(a) The lead investigator will complete a draft investigation report and seek comments from the contributors and those involved in the incident. Further guidance on the investigation report is in the Patient Safety Incident Investigation intranet pages. The lead investigator is required to ensure contributions are fairly reflected in the report as supported by evidence established during the investigation, but has final authorship of the report content subject to sign off by the authorised divisional board member and executive director.

(b) An action plan will be developed by the division, in response to the report's recommendations and in consultation, where necessary, with other partners, and added to the draft report. The action plan is a divisional responsibility and will be compiled by, or compiled in consultation with, those with the authority and resources to implement the actions required.

(c) The report will checked within the division against the PSII quality assurance checklist. The report will then be approved and signed by a divisional board member, Clinical Chair, Head of Nursing/Midwifery or Divisional Director.

(d) The draft report will be sent to the Trust Headquarters Patient Safety Team within 45 working days. The central team will review the report and liaise with the division to arrange for clarifications if applicable. The report will then be sent as a final draft within 60 days via secure e-mail by the central team to the commissioners requesting closure. STEIS will be updated with the investigation findings.

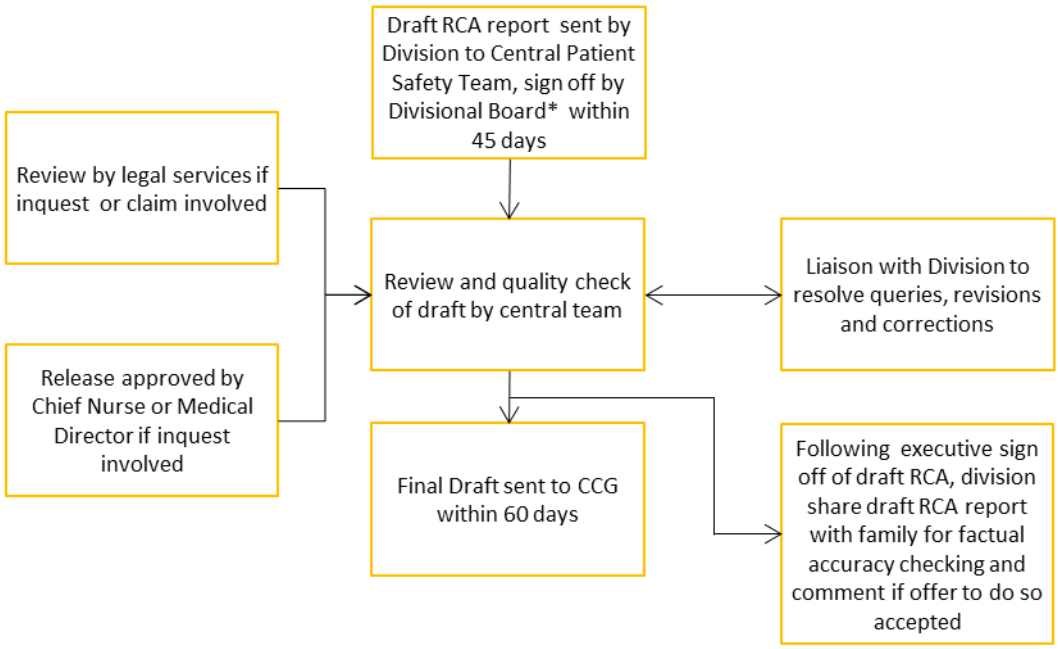
(e) Once the final draft of the PSII is signed off by the division and is ready to send to commissioners the patient and/or family/carers can be provided with the final draft of the report if they so wish for their factual accuracy checking and comments. It must be signed off by an executive director prior to sharing with families. This could take place at a meeting or as part of the ongoing communication by the lead investigator (or case manager in the

situation of multiple investigatory processes) updating the patient or family/carers on the progress of the investigation. Any such meeting or communication would not preclude the normal discussions that would happen along the way with families.

(f) If an inquest is to be held, or the investigation report is to be sent to the Care Quality Commission (CQC), draft PSII reports will be sent to the Trust Legal Team to identify any possible legal issues, and the commissioning executive director before release to external bodies.

(g) The HSSIB will send reports of their external investigations of maternity incidents to contributors and the head of midwifery for factual accuracy checking prior to finalising. For cross divisional incidents these will also be sent to the Head of Quality (Patient Safety) who will ensure other divisions have the opportunity to make factual accuracy checks.

(h) This process is summarised below:



8.12 Further progress of the investigation report from draft to final approval.

(a) All serious incident reports will be reviewed by the relevant Divisional Governance group(s).

(b) Patients and families who wish to comment on the draft report will have the opportunity to do so prior to it being finalised as described in section 7.7.

(c) After a report has been sent to the commissioners it will be reviewed at the Patient Safety Group.

(d) The group may request further information, action or revision before the report is cleared for submission to the Clinical Quality Group for final approval. For details see section 5.1 Roles and Responsibilities of Committees and Groups.

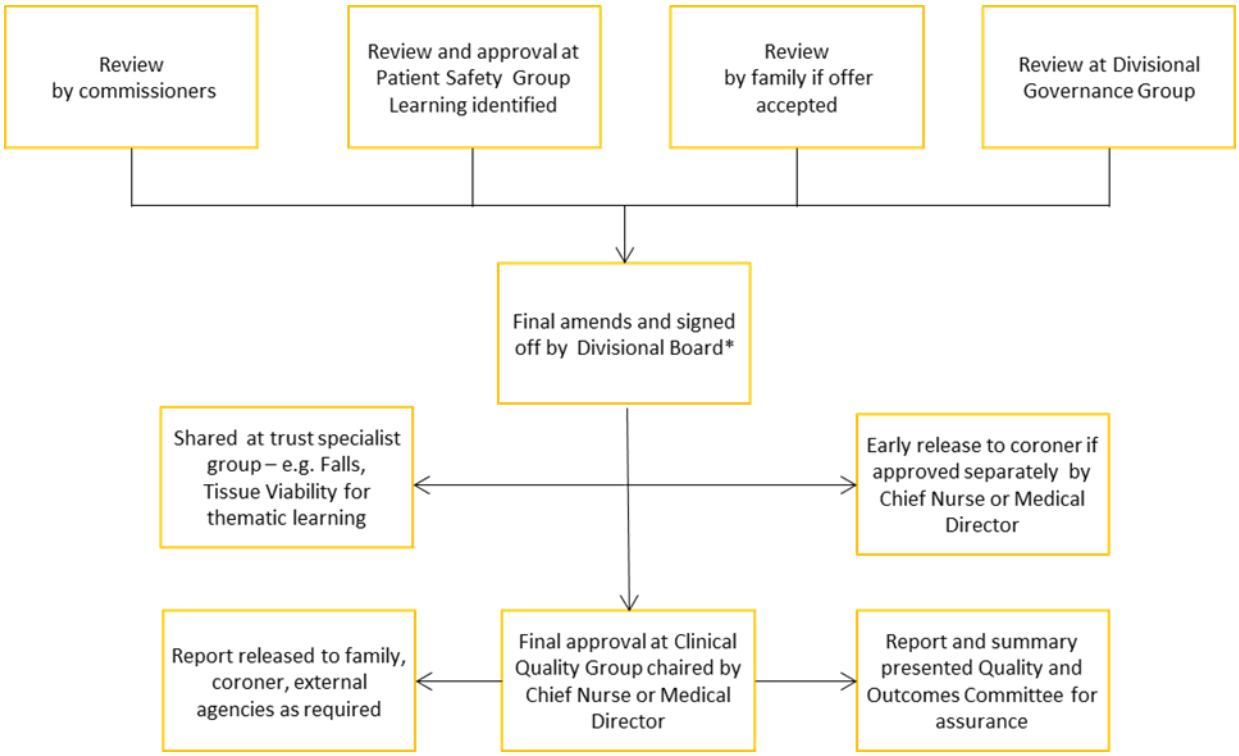
(e) The report will then be presented by the Division to the Trust's Clinical Quality Group for final Trust approval. This will be the final approved version which can be shared without further approval with the family/carer/patient, Coroner or external agencies. This approval can be made without the Clinical Quality Group meeting by the commissioning executive director if required for urgent external release.

(f) Following approval at the Clinical Quality Group, the Division will then enter the agreed action plan on Datix against the original incident.

(g) Following approval at the Clinical Quality Group the PSII report will be presented to the Quality and Outcomes Committee (of the Trust Board).

(h) All investigations conducted by the HSSIB, whether serious incidents or not, will be reported in full to the Clinical Quality Group.

(i) This process is summarised in the diagram below:



8.13 *Incidents which are linked to Coroner's Inquests*

(a) Patient Safety Incident Investigation reports for incidents which are linked to Coroner's Inquests, whether serious incidents or not, should be signed off by an executive director.

8.14 *Managing cross provider incidents*

(a) The Head of Quality (Patient Safety) will, working with divisional patient safety teams, will maintain oversight of the management of serious incidents involving patient pathways and systems across other external providers to ensure investigations are joined up, timely and signed off within UHBW in accordance with this policy.

8.15 *Monitoring of serious incident progress and implementation of the action plan*

(a) It is the Division's responsibility to monitor and ensure the timely implementation of the action plan and record updates of progress on Datix against the relevant incident.

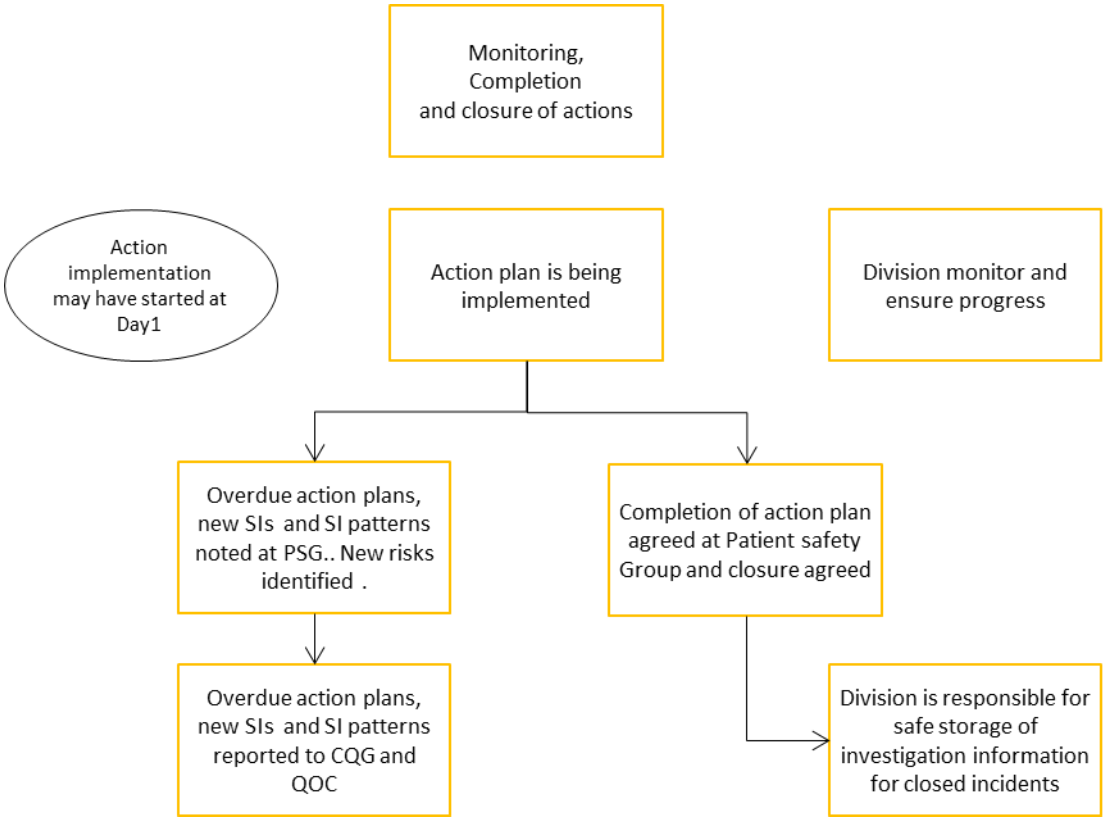
(b) The Patient Safety Group will receive updates on action plans that are due for completion, including those arising from external investigations such as those conducted by the HSSIB.

(c) The Patient Safety Group will review each month the final draft of investigation reports submitted to Commissioners.

(d) Specialist Groups such as the Falls and Tissue Viability groups will conduct thematic reviews of serious incidents and incorporate findings[7] into their work plans. They will report on the implementation of their work plans via updates of their work plans to the Patient Safety Group.

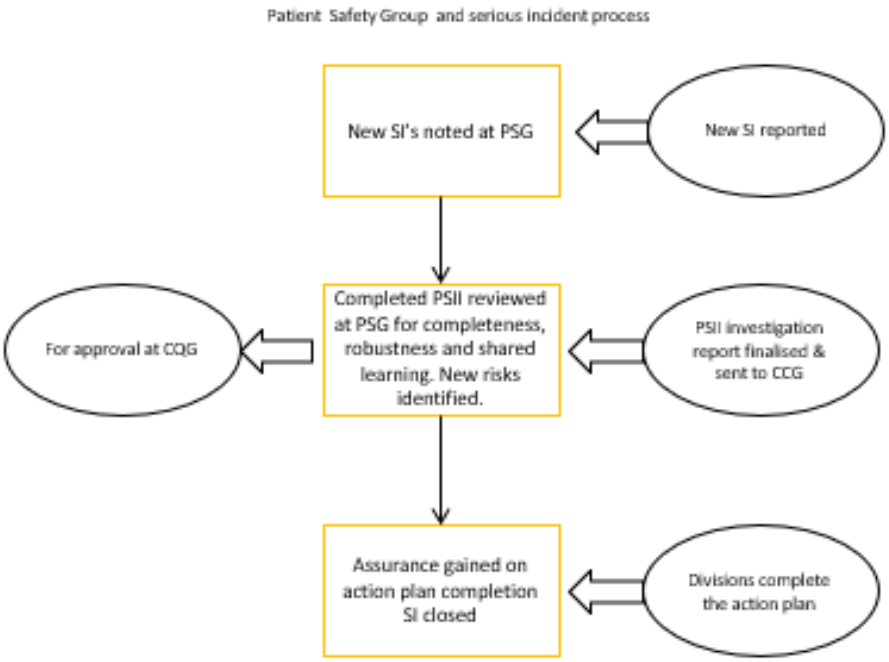
(e) Overdue actions will be monitored monthly at the Patient Safety Group, and escalated to the commissioning executive director via reports into the Clinical Quality Group and the Quality and Outcomes Committee if required.

(f) The Patient Safety Group will record the completion of a serious incident action plan. This means that no further monitoring of the incident or plan is required other than through any audits identified in the investigation report. This process is summarised below:



(g) The diagram below summarises the serious incident process in respect of the Patient Safety Group:

[7] All actions will be incorporated in to work plan, either singly, or as a thematic action reflecting multiple actions.



8.16 Monitoring of trends

The frequency and content of reports to key groups is set out below

Audience	Frequency	Items reported
Patient Safety Group	Monthly	Number of serious incidents reported monthly Reporting and investigation performance Exception reports for the month detailing reasons for delay in reporting or completing investigation Breakdown by type/category of serious incident Details of new serious incidents reported Report of Serious incidents with overdue actions detailing why overdue, action underway to address and estimated completion date
Quality and Outcomes Committee Clinical Quality Group Senior Leadership Team	Quarterly	Numbers of serious incidents reported quarterly Reporting and investigation performance Quarterly exception reports for the detailing reasons for delay in reporting or completing investigation Breakdown by type/category of serious incident Details of new serious incidents reported Report of Serious incidents with overdue actions detailing why overdue, action underway to address and estimated completion date Themes arising from serious incident investigations completed in the quarter

Patient Safety Group (as above plus)	Quarterly	Falls Group and Tissue Viability reports including themes arising from serious incidents and progress of actions in the Group's work plan to minimise the risk of recurrences.

Where relevant, reports will highlight risks identified from serious incidents and provide associated risk assessments, including Trust-wide risk reduction measures in accordance with the Trust's Risk Management Policy.

8.17 Sign-off and Quality Assurance

(a) The arrangements for sign off of draft reports for sending to the commissioners and for formal approval are shown in the Table in Appendix H.

(b) The overall governance process for assuring report quality is summarised in a flowchart shown in Appendix H.

8.18 Audit

(a) As part of the serious incident investigation process, staff should consider whether there is any need to undertake a clinical audit to assess the effectiveness of actions arising from incidents. If audit requirements are identified, these should be listed in the PSII action plan template. Once agreed, projects should be registered with the Clinical Audit & Effectiveness Team who will help advise on and facilitate the process.

9. References

Serious Incident Framework NHS England 2015

Revised Never Events Policy and Framework NHS Improvement February 2018

Never Events List 2018 NHS Improvement February 2018 (updated May 2019)

Early Notification Scheme NHS Resolution

Just Culture Guide NHS Improvement 2018

Managing safety incidents in NHS screening programmes Public Health England 30 October 2015

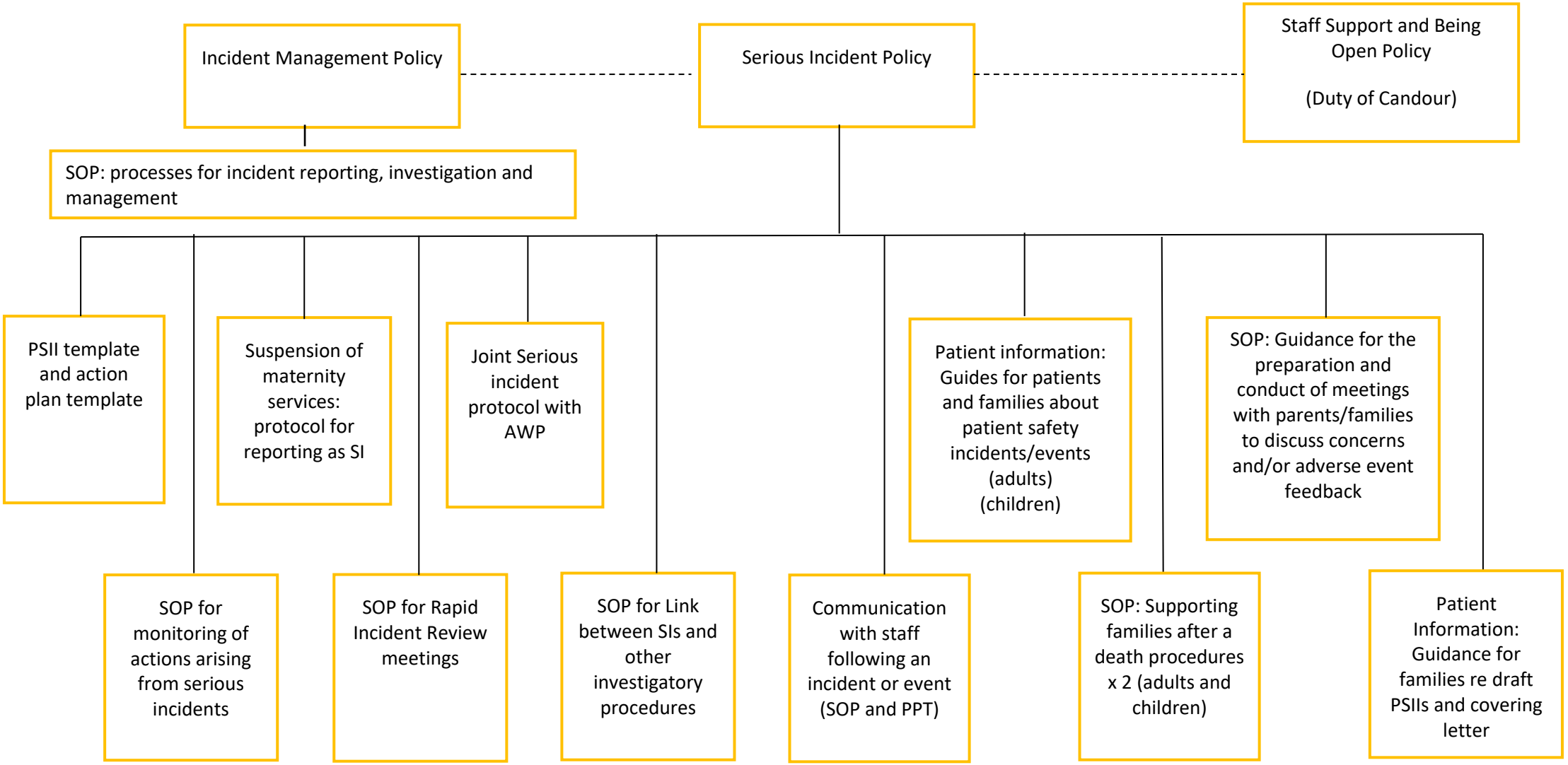
Human Tissue Authority Serious Incident guidance Reporting an incident or concern July 2015

Raising and acting on concerns about patient safety (2012) General Medical Council January 2012

Medicines and Healthcare products Regulatory Agency Medicines and Healthcare products Regulatory Agency

Working Together to Safeguard Children, HM Government Department for Education March 2015

10. Associated Internal Documentation



(a) Also:

Trust Risk Management Strategy

Risk Management Policy

Health and Safety Policy

Freedom to Speak Up Policy

Incident Management Policy

Major Incident Plan

Post Mortem Consent Policy and Procedure

Disciplinary Policy

Information Governance Policy

Standard Operating Procedure: Communication for staff following an incident likely to require further investigation (adult patients)

Freedom of Information SOP

(b) Supporting documents on patient safety intranet pages

Trust PSII template and action plan template

Duty of Candour

Information for staff involved in incidents

11. Appendix A – Monitoring Table for this Policy

Objective	Evidence	Method	Frequency	Responsible	Committee
Serious Incident reporting	Within 48 hours of identification	Monthly compliance reports Board quality dashboard	Monthly	Head of Quality (Patient Safety)	Patient Safety Group, Clinical Quality Group, Quality and Outcomes Committee
Openness and transparency	To comply with Duty of Candour	See Staff Support and Being Open Policy			
Timely investigations	Rapid Incident Review report within 5 days	Monthly compliance reports Board quality dashboard	Monthly	Head of Quality (Patient Safety)	Patient Safety Group, Clinical Quality Group, Quality and Outcomes Committee
	PSII to commissioners within 60 day timescale or agreed extension	Monthly compliance reports Board quality dashboard	Monthly	Head of Quality (Patient Safety)	Patient Safety Group, Clinical Quality Group, Quality and Outcomes Committee
Quality of investigation reports to ensure they are: thorough, objective and systematic	Meeting internal and commissioners quality checklists	QA by commissioners for each PSII	Ad hoc	Commissioners	No reporting
Sharing learning	Monthly Trust message for safety briefs and safety bulletins	Monthly posting of safety bulletins on Connect Ad hoc spot check audit of quality of safety brief	Monthly Ad hoc	Patient Safety Group, Clinical Quality Group	No reporting

Risk reduction measures	Action plans are implemented on time	Monthly overdue actions report	Monthly	Head of Quality (Patient Safety)	Patient Safety Group, Clinical Quality Group, Quality and Outcomes Committee
Governance	All serious incident investigations and reports will comply with the governance approval and sign-off requirement in the policy	Trust Headquarters Patient Safety Team will monitor and record compliance in the Serious Incident log. Decisions will be recorded in the relevant groups / committees	Upon completion	Head of Quality (Patient Safety)	Patient Safety Group, Clinical Quality Group, Quality and Outcomes Committee
Patient/ Family/carer involvement	Patients and/or families are asked for feedback regarding their experience of the serious incident investigation process at the point of sharing the final PSII with them.	Initial audit after 6 months followed by annual thereafter.	Annual	Divisional Patient Safety Managers	Patient Safety Group, Clinical Quality Group

12. Appendix B – Dissemination, Implementation and Training Plan

The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Head of Quality (Patient Safety)
This document replaces existing documentation:	Yes
Existing documentation will be replace by:	
This document is to be disseminated to:	Senior leadership Team, Patient Safety Group, Divisional Directors and Patient Safety Leads, Health and Safety Leads for cascading to all staff
Training is required:	Yes
The Training Lead is:	Patient Safety Managers

Additional Comments
Training will be provided at Trust Induction and Clinical Update training and PSII training days. The consultation process for the policy update has ensured divisional and central patient safety leads/ advisors and managers are already cognisant of the policy content.

13. Appendix C – Equality Impact Assessment (EIA) Screening Tool

Further information and guidance about Equality Impact Assessments is available here:
http://nww.avon.nhs.uk/dms/download.aspx?did=17833

Query	Response
What is the main purpose of the document?	The purpose of this policy is to set out (a) What a serious incident is; (b) What arrangements are in place for managing a serious incident from when it occurs through to learning from it, taking action to prevent recurrence and closure; (c) What staff must do when a possible serious incident occurs.
Who is the target audience of the document? Who is it likely to impact on? (Please tick all that apply.)	Add ☑ or ☒ **Staff ☑ Patients ☑ Visitors ☑ Carers ☑ Others**

Could the document have a significant negative impact on equality in relation to each of these characteristics?	YES	NO	Please explain why, and what evidence supports this assessment in relation to your response.
Age (including younger and older people)		X	This policy will include all people of all areas and follow the same process
Disability (including physical and sensory impairments, learning disabilities, mental health)		X	This policy will ensure disability is always taken into consideration
Gender reassignment		X	This policy will include any gender
Pregnancy and maternity		X	This policy includes information on pregnancy and maternity incidents
Race (includes ethnicity as well as gypsy travelers)		X	This policy will not discriminate against race
Religion and belief (includes non-belief)		X	This policy will ensure all religions are taken into consideration
Sex (male and female)		X	This policy covers all sexes
Sexual Orientation (lesbian, gay, bisexual, other)		X	This policy will ensure sexual orientation is not discriminated against
Groups at risk of stigma or social exclusion (e.g. offenders, homeless people)		X	This policy will include all groups
Human Rights (particularly rights to privacy, dignity, liberty and non-degrading treatment)		X	This policy will investigate all incidents, including any issues of Human Rights violations

Will the document create any problems or barriers to any community or group? ~~YES /~~ NO

Will any group be excluded because of this document? ~~YES /~~ NO

Will the document result in discrimination against any group? ~~YES /~~ NO

If the answer to any of these questions is YES, you must complete a full Equality Impact Assessment.

Could the document have a significant positive impact on inclusion by reducing inequalities?	**YES**	**NO**	**If yes, please explain why, and what evidence supports this assessment.**
Will it promote equal opportunities for people from all groups?	X		This policy will investigate all incidents and ensure equal opportunities are considered throughout the process
Will it help to get rid of discrimination?	X		The policy will investigate all incidents and highlight any discrimination encountered
Will it help to get rid of harassment?	X		The policy will ensure any harassment is highlighted, discussed and removed.
Will it promote good relations between people from all groups?	X		All groups are considered when investigating serious incidents and given equal information
Will it promote and protect human rights?		X	

On the basis of the information/evidence so far, do you believe that the document will have a positive or negative impact on equality? (Please rate by circling the level of impact, below.)

Positive impact				**Negative Impact**		
Significant	Some	Very Little	NONE	Very Little	Some	Significant

Is a full equality impact assessment required? ~~YES /~~ NO

Date assessment completed: 14 December 2018

Person completing the assessment: [redacted]

14. Appendix D – Rapid action review and Rapid Incident Review process

(a) A rapid action review is required for all incidents meeting the criteria in the policy summary section of the Policy for the Management of Incidents and informs the initial management report of the serious incident. Please see SOP for Rapid Incident Review Process

(b) The initial management report is a summary of the facts as known at the time and initial actions taken using the Trust template.

15. Appendix E - Types of serious incident investigations

Introduction

(a) The nature and terms of reference and the depth of investigation will be determined in accordance with the NHS England Serious Incident Framework_ and will be commissioned by the relevant Executive Director as informed by the initial review.

(b) The level of investigation may need to be reviewed and changed as new information or evidence emerges as part of the investigation process.

(c) The recognised system-based method for conducting investigations, commonly known as Patient Safety Incident Investigation (PSII), should be applied to the investigation of serious incidents

(d) Investigations will be carried out or supervised by someone who is trained in PSII investigation

(e) The Health Services Safety Investigation Body (HSSIB) will investigate certain maternity and neonatal incidents.

(f) The level of investigation is determined by the commissioning executive director.

(g) An external independent review of an incident or a second opinion regarding the clinical care provided can be sought to inform any level of incident investigation where the integrity of the investigation is likely to be challenged, or where an additional level of objectivity is required due to the nature of the incident. The need for this will be determined by the manager or director commissioning the investigation (see levels of investigation below) and set out in the terms of reference of the investigation.

(h) Where serious concerns about a death are expressed, a low threshold should be set for commissioning an external investigation.

(i) Levels of investigation:

(i) All potential serious incidents will be subject to an initial Rapid Incident Review (see policy summary section of the Policy for the Management of Incidents)

(ii) Patient Safety Incident Investigation: For serious incidents involving complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable. This could be used for a divisional investigation, one external to the division or a cross-divisional investigation depending on the nature of the incident.

(A) Where there are similar themes arising from incident reporting from Patient Safety Incident Investigation and serious incident investigations, cross-trust, cross- division, or within a department which have resulted in harm to patients.

(B) Where there is evidence that indicates the possibility of sustained poor practice.

(C) Other incidents or circumstances where the Chief Nurse/Medical Director have identified potential themes which raise concerns sufficient to warrant a different level of investigation to that of a serious incident.

(iii) Independent investigation e.g. by the Health Services Safety Investigation Body or NHS Improvement or other externally commissioned organisation. 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

(j) Some incidents may be best incorporated as part of an existing multi-incident PSII investigation and action plan. This would be where the similarity of the incident is such that investigation would not lead to any new learning and where action already planned or underway would address any failures in care. In such cases, with the agreement of the commissioners, a serious incident would be reported, an initial review report would be sent but no further investigation would be undertaken.

Further considerations

(k) The patient and/or family/carers should be given the opportunity to meet with the Incident Lead Investigator to share any concerns or questions they have. These need to be addressed in the investigation. Further information is available in the Trust's Supporting Staff and Being Open Policy

(l) The Lead Incident Manager and the members of the investigation team will need to have the seniority, competencies, skills and experience for the investigation. This is set out in Appendix F.

(m) Where incident investigations are particularly complex or require cross-organisational working, an extension to the investigation timescales can be requested from commissioners. This must be requested at the start or early stages of the investigation by the Head of Quality (Patient Safety)

(n) Where legal matters are raised or court proceedings in relation to the incident have started or are thought likely, advice must be sought from the Legal Team

16. Appendix F - Competencies and Seniority of Investigators and Teams

Seniority, experience and training of Lead Investigators

(a) The lead incident investigator will be suitably trained in order to carry out investigations which are evidence-based, robust, proportionate and suitably independent.

(b) In circumstance where a lead investigator is approached to conduct an investigation and there is a potential conflict of interest or any circumstance that could compromise their objectivity, this should be declared to the executive director commissioning the investigation. Conflicts of interest can include personal, professional and financial relationships outside of trust employment.

(c) A lead investigator will have undergone Patient Safety Incident Investigation training. They will normally have experience in leading or taking part in a PSII investigation. If they lack recent investigatory experience they will be mentored or supervised by a senior colleague recently experienced and trained in PSII investigations

(d) Internal independent and cross division investigators will be at least Matron or Consultant level or equivalent for non-clinical incidents, and be trained and experienced in PSII investigation.

(e) External lead investigators will be respected and well-regarded senior professionals in their own field and be trained and experienced in PSII investigation and may involve the Health Services Safety Investigation Body.

The Investigation team will possess

(f) Knowledge of what constitutes an effective Patient Safety Incident Investigation investigation, and the skills/competencies to lead and deliver this

(g) Skills/competencies in effective report writing and document formulation (if they will be involved in production of the report)

(h) Expertise in facilitating patient/family/carers involvement

(i) Understanding of the specialty involved, most likely with more than one profession represented to ensure investigation balance and credibility

The investigating team must also have access to the following: administrative and IT support; communications and media management support; legal and information governance advice

The team may need proof-reading support and access to appropriate links/mechanisms to share lessons locally and nationally during the investigation as required.

17. Appendix G – Reporting incidents to External Bodies

Incident Topic	External Agency	UHBW reporter and contact for advice
All patient safety incidents	Care Quality Commission via Datix uploads to the National Reporting and Learning System (NRLS)	Trust Headquarters Patient Safety Team
All serious incidents	Commissioners via South West Commissioning Support Unit	Head of Quality (Patient Safety) Trust Headquarters Safety Team
All serious incidents involving welsh patients receiving specialist treatment	Welsh Health Specialised Services Committee	Via BNSSG commissioners as above
All serious incidents	Care Quality Commission via NRLS and STEIS but also proactively in some circumstances e.g. Never Events	Chief Nurse/Medical Director Head of Quality (Patient Safety)
Maternity incidents as described in section 7.6	Healthcare Safety Investigation Branch	Head of Midwifery Patient Safety Manager for maternity services
Maternity/ Neonatal Incidents meeting criteria for Early Notification Scheme	NHS Resolution	Legal Team
Maternal and neonatal deaths	Mother and Babies Reducing Risk through Confidential Enquiries	Women's and Children's Division Quality and Patient Safety Manager, St Michaels Hospital
Information Governance Serious Incidents	Information Commissioner's Office, Department of	Head of Information Governance Information Governance Officer

Incident Topic	External Agency	UHBW reporter and contact for advice
	Health via NHS Digital	
Serious Health and Safety incidents (RIDDOR)	Health and Safety Executive	Head of Health and Safety Services
Incidents which involve medical devices Incidents which involve medicines	Medicines and Healthcare Products Regulatory Agency (MHRA)	Medical Devices: Medical Device Safety Officer Medicines: Medicines Safety Officer
Blood Transfusion incidents	MHRA and Serious Hazards of Transfusion	Transfusion Practitioner or Haematology Department Guidance for what is reportable: Serious Hazards of Transfusion web portal (SHOT) and SABRE – Serious Adverse Blood Reactions and Events
Incidents involving possible criminal activity	Police	Head of Legal Services Local Security Management Specialist Director of Finance & Local Counter Fraud Specialist where fraud is suspected to be involved
Emergency Plan/Major incident invoked	NHS Improvement BNSSG regional team[8]	Resilience Manager
Safeguarding Children & Adults	Local Safeguarding Children Board Commissioners	Chief Nurse Nurse Consultant for Safeguarding
Deaths of patients aged under 18	Child Death Review process	Designated doctor for Child Deaths
Incidents where press enquiries are anticipated	Print, Radio and Television Media	Head of Communications
Incidents where Professional Regulatory or Defence Organisations are	General Medical Council, Nursing and Midwifery Council or Health Professionals	Medical Director or Chief Nurse Divisional Clinical Chair Head of Nursing

[8] Bristol North Somerset South Gloucestershire

Incident Topic	External Agency	UHBW reporter and contact for advice
likely to be involved	Council, General Pharmaceuticals Council Professional Defence Organisations	Supervisor of Midwives Lead Allied Health Professional Director of Pharmacy
Major communicable disease outbreaks and MRSA bacteraemia incidents	Health Protection Agency	Infection Control Team
Serious infection related incidents	Health Protection Agency	Infection Control Team
Other unexpected deaths	Referral to HM Coroner	Legal Services
Incidents likely to form the basis of a negligence claim	NHS Resolution	Legal Services
Radiation incidents involving staff Radiation incidents involving patients	Health and Safety Executive Environment Agency IRMER Inspectorate of the Care Quality Commission	Local Radiation Protection Supervisor and Trust Radiation Protection Advisor
Fraud	NHS Protect	Local Counter Fraud Specialist Local Security Management Specialist
Workforce incidents	Home Office	Director of People
Screening Programmes	Relevant Screening Programme Centre	Public Health England Screening Quality Assurance Service (South) Managing safety incidents in NHS screening programmes (Public Health England 30 October 2015)
Serious adverse event or reaction resulting from the procurement,	Human Tissue Authority within 24 hours	Stem Cell Transplant Quality and Service Manager

Incident Topic	External Agency	UHBW reporter and contact for advice
testing, transport or infusion of stem cells		
Post mortem serious incidents	Human Tissue Authority	Human Tissue Authority Designated Individual (Consultant Senior lecturer Oral and Maxillofacial Pathology) https://www.hta.gov.uk/reporting-incident-or-concern

18. Appendix H– Governance approval of Serious Incident investigations

Governance levels of patient safety incident investigations and authority for sign off of investigation reports and completion of actions.

Level of investigation	**Action plan approval**	**Investigation/ PSII managerial[9] sign off**	**Action plan monitoring by**	**Investigation report Governance approval**	**Action plan sign-off (completion agreed)**	**Report supplied for assurance purposes**
Serious Incident, concise, comprehensive PSII or cross divisional investigation (commissioned from within or outside the division)	Trust Patient Safety Group, Clinical Quality Group	Divisional Director, Clinical Chair or Head of Nursing at local level. Draft PSII must be signed off by an executive director prior to sharing with patient/family. Executive Director sign off of final PSII	Trust Patient Safety Group	Trust Patient Safety Group, Clinical Quality Group	Trust Patient Safety Group	Quality and Outcomes Committee
Cross provider PSII (serious incident) If UHBW is not leading investigation but contributing to investigation.	Head of Quality (Patient Safety) in conjunction with divisional senior manager (Clinical Chair, Head of Nursing /Midwifery or Divisional Director	Head of Quality (Patient Safety)	Trust Patient Safety Group	Trust Patient Safety Group. Trust Clinical Quality Group for information.	Trust Patient Safety Group	Trust Patient Safety Group

[9] Managerial sign-off is for the purpose of the release of a final draft report to send to the commissioners. All final sign off of serious incident investigations is completed by an executive director.

Level of investigation	Action plan approval	Investigation/ PSII managerial[9] sign off	Action plan monitoring by	Investigation report Governance approval	Action plan sign-off (completion agreed)	Report supplied for assurance purposes
If UHBW leading investigation, as for all serious incidents below.						
Serious Incident, concise, comprehensive PSII or cross divisional investigation (commissioned from within or outside the division)	Trust Patient Safety Group, Clinical Quality Group	Divisional Director, Clinical Chair or Head of Nursing at local level. Draft PSII must be signed off by an executive director prior to sharing with patient/family. Executive Director sign off of final PSII usually at the Clinical Quality Group.	Trust Patient Safety Group	Trust Patient Safety Group, Clinical Quality Group	Trust Patient Safety Group	Quality and Outcomes Committee
Independent investigation including HSSIB	Trust Patient Safety Group, Clinical Quality Group	N/A	Trust patient Safety Clinical Quality Group	N/A	Clinical Quality Group	Quality and Outcomes Committee