Patient Safety Incident Response Policy

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Storage & Version Control

Version 1 of this policy is stored and available through the SHSC intranet/internet and the public facing webpages. This version of the policy supersedes the MD 023 - Incident Management Policy and Procedure (Including Serious Incidents) Any copies of the previous policy held separately should be destroyed and replaced with this version.

Version Control and Amendment Log

Version No.	Type of Change	Date	Description of change(s)
0.1	New draft policy created	01/11/2023	New policy based on changes to the national framework.

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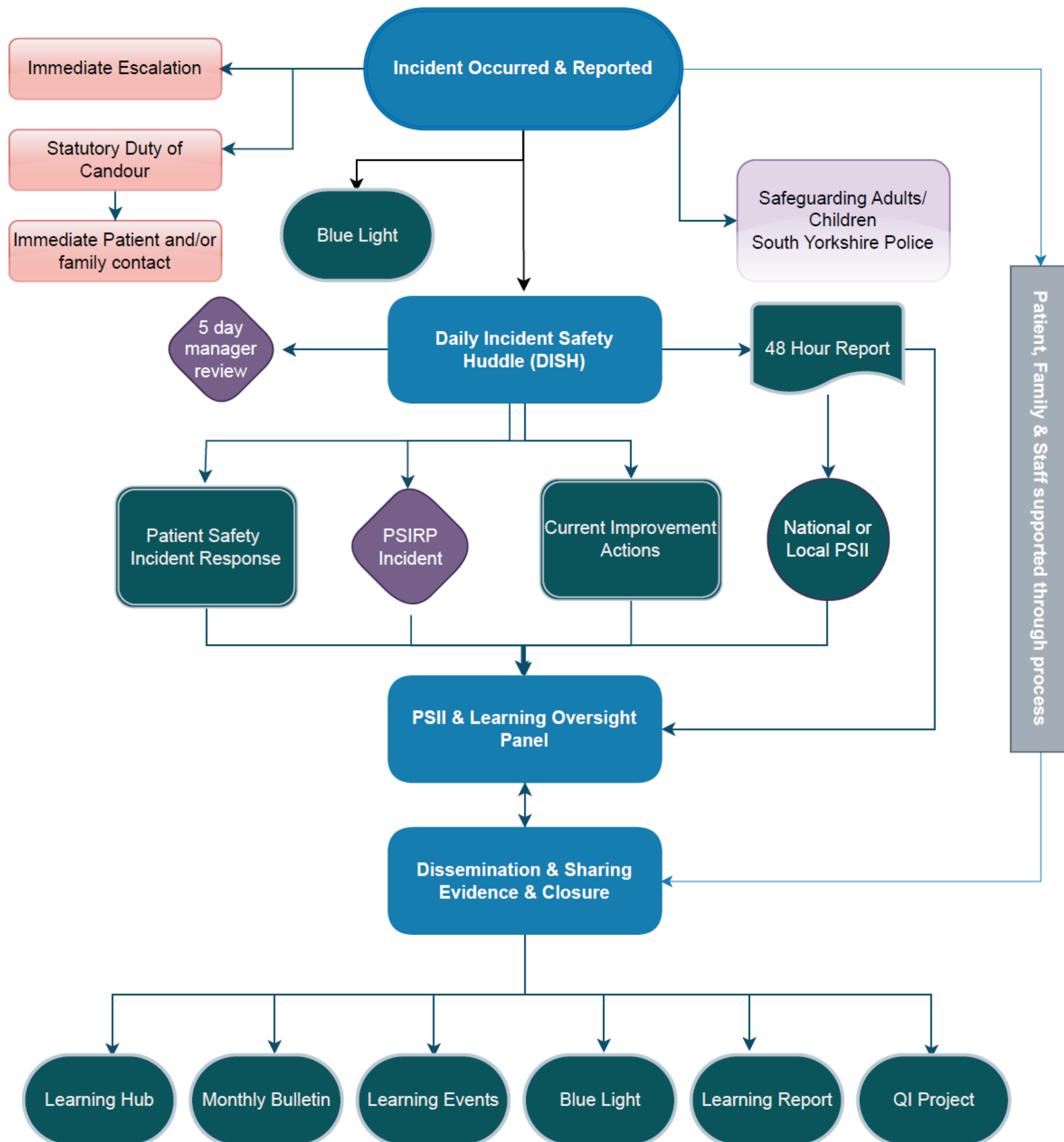
Flowchart



Purpose

The following policy is based on [NHS England's Patient Safety Incident Response Framework (PSIRF).]

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out the **Sheffield Health and Social Care, NHS, Foundation Trust**

(SHSC) approach to developing and maintaining effective systems and processes for reporting and responding to patient safety incidents for the purpose of learning and improving patient safety.

The framework that this policy is built on advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident responses within a wider system of improvement and promotes a significant cultural shift towards systematic patient safety management.

SHSC places the health, safety and welfare of its service users, staff and visitors high amongst its priorities and will ensure it maintains safe and secure conditions throughout the organisation. It will work closely with partner organisations, where the health, safety and welfare are a shared responsibility, to ensure collaborative learning at all levels.

Successful patient safety incident management is underpinned by the development of a proactive learning culture whereby effective incident reporting, investigation and learning from incidents take place and reduces the likelihood of incidents reoccurring. The reporting culture contributes to improved service user safety and service provision and makes the SHSC a safer place to work and visit, for staff, service users and the public.

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF:

- compassionate engagement and involvement of those affected by patient safety incidents.
- application of a range of system-based approaches to learning from patient safety incidents.
- considered and proportionate responses to patient safety incidents and safety issues.
- supportive oversight focused on strengthening response system functioning and improvement.

Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all SHSC services.

Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property (part of a bigger system) of the healthcare system: that is, safety is provided by interactions between components and not from a single component. Responses do not take a ‘person-focused’ approach where the actions or inactions of people, or ‘human error’, are stated as the cause of an incident.

There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. Other processes, such as claims handling, safeguarding investigations, human resources investigations into employment concerns, professional standards investigations, coronial inquests and criminal investigations, exist for that purpose. The principle aims of each of these responses differ from those of a patient safety response and are outside the scope of this policy.

Information from a patient safety response process can be shared with those leading other types of responses, but other processes will not influence the remit of a patient safety incident response.

Our patient safety culture

A culture of open reporting of incidents (including near misses and 'errors') is positively encouraged by SHSC as an opportunity to learn and to improve safety, systems and services. In order to reinforce the fact that the prime concern of SHSC, with regard to the reporting of patient safety incidents, is to ensure that learning takes place, SHSC will implement the principles of the Just Culture guidance, NHS England » A just culture guide, which aims to promote fair and consistent staff treatment within and between healthcare organisations.

The Just Culture guide will not be used routinely. It will only be used when there is already suspicion that a member of staff requires some support or management to work safely, or as part of an individual practitioner performance/case investigation. Any investigation will be moved into an individual practitioner performance investigation when it is suggested a single individual needs support to work safely (including training, supervision, reflective practice, or disciplinary action), as opposed to where a whole cohort of staff has been identified, which would be examined as part of a safety investigation.

The Just Culture guide does not replace the need for patient safety investigation and will not be used as a routine or integral part of a patient safety investigation. This is because the aim of those investigations is system learning and improvement. As a result, decisions on avoidability, blame, or the management of individual staff are **excluded** from safety investigations to limit the adverse effect this can have on opportunities for system learning and improvement.

Identifying contributory systems failures is crucial to successful patient safety management. In order for an effective patient safety culture to operate, employees must be supported to report incidents that have occurred due to human error. SHSC will not sanction or take disciplinary action against staff that freely report mistakes related to human error. Staff will also be supported through the Whistleblowing Policy and Procedure (Freedom to speak up), Speaking Up - Freedom to Speak Up Raising Concerns (Whistleblowing) Policy (HR 015 V6 April 23) | JARVIS (shsc.nhs.uk) and the Statutory Duty of Candour/Being Open Policy, Duty of Candour and Being Open Policy (MD 010 V5 Dec 2021) | JARVIS (shsc.nhs.uk)

SHSC has developed 6 Critical Success Factors (CSF) relative to our patient safety culture which are to:

- Deliver an easy to use, clear, and objective process that encompasses all patient safety incident types.
- Deliver measurable improvements in service user and staff safety.
- Deliver a process that staff, service users and their families/carers, and all other stakeholders trust and have faith in.

- Deliver a collective shared purpose and shared ownership of learning and improvement across the whole of SHSC.
- Deliver reliability (and therefore consistency) in approach, regardless of the directorate or investigator.
- Be able to evidence that each team, service, Directorate, and SHSC as a whole, learns, improves, and sustains the improvements as a consequence of learning from all patient safety incidents and near misses it experiences (i.e., lapses in care and practice standards occur less and systems are better designed).

SHSC will ensure that all patient safety incidents are appropriately managed and investigated based on the potential to learn and improve. Qualitative and quantitative data analysis will be used to highlight trends which may be occurring and uncover any further need for intervention.

It is essential, that all incidents, irrespective of whether they have caused actual harm, or were a near miss, are reported in a timely manner. This will help to mature and develop our risk profile and inform our learning and improvement plan.

Patient safety partners

Patient Safety Partners (PSPs) can be patients, carers, family members or other lay people (including NHS staff from another organisation working in a lay capacity) who are recruited to work in partnership with staff to influence and improve the governance and leadership of safety within SHSC. As such, they perform a very different role from that of the traditional NHS volunteer who acts as, for example, a hospital guide or befriends and supports patients.

Patient Safety Partners (PSP's) have been actively working to support SHSC in preparing for the transition over to PSIRF. Over the next 18 months SHSC will strengthen its commitment to developing these roles across the patient safety systems and processes including:

- Membership of safety and quality committees whose responsibilities include the review and analysis of safety data.
- Involvement in patient safety improvement projects.
- Co-designing and producing the quarterly Learning and Safety report and the bi-monthly Learning Bulletin
- Working with the Patient Safety Specialist and associates to consider how to improve safety.
- Involvement in our staff patient safety training.
- Participation in PSII and Learning Oversight Panel.

The introduction of PSPs is the start of a journey that will significantly change the way SHSC approach's patient involvement. It requires power sharing, a commitment to openness and transparency between staff and patients, as well as good leadership; it will not be tokenistic.

During 2023/24 we are aiming to have trained and appropriately supported PSPs to be involved in all relevant strategic patient safety activity within SHSC.

Addressing health inequalities

SHSC's patient safety incident response processes will support health equality and reduce inequality. We will take a more flexible approach and use data intelligently to help identify any disproportionate risk to patients with specific characteristics, and this information will inform patient safety incident responses.
Inequalities affect patients and their safety. It is important to treat people as individuals and not associate everything about a person with their diagnosis, for example if they have a learning disability or autism. SHSC staff understand that people with a protected characteristic can face inequalities in terms of their care and safety and having more than one protected characteristic may accentuate that inequality.

The Patient and Carer Race Equality Framework (PCREF), which aims to help mental health trusts work with ethnic minority communities to achieve practical change will be implemented to ensure SHSC is responding to learning associated with ethnic minority groups.

A patient and carers feedback mechanism, to embed the patient and carer voice at the heart of the planning, and learning cycle will be implemented and a post learning response questionnaire will be issued to patients and/or their families affected by patient safety incidents.

SHSC will explore and respond to issues related to health inequalities as part of the development and maintenance of our patient safety incident response policy and plans.

The tools we use to respond to patient safety incidents will prompt consideration of inequalities, including when we develop safety actions.

We will engage and involve patients, families and staff following a patient safety incident with consideration of their different needs, including but not limited to:

- Black and minority ethnic groups
- People with a learning disability and autistic people
- People with dementia
- People who need accessible communication including Deaf people and people who do not speak English.
- Lesbian, gay, bisexual and transgender people.

SHSC will uphold a system-based approach (not a 'person focused' approach) and ensure staff have the relevant training and skill development to support this approach. This will support the development of a just culture and reduce the ethnicity disparity in rates of disciplinary action across SHSC's workforce.

Engaging and involving patients, families and staff following a patient safety incident

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

Guidance on engaging patients, family and staff can be found at, Engaging and involving patients, families and staff following a patient safety incidents guidance, patient safety incident response standards and the PSIRF preparation guide

In accordance with the SHSC's Duty of Candour policy, investigators will involve the service user and/or their carers/family or significant other in the investigation process unless there is an identified and documented reason not to do so. In all cases, service users, carers/family or significant others will be informed that SHSC is undertaking an investigation into the incident.

When a learning response takes place, those affected should be involved in a meaningful way. The following standards are endorsed for all learning responses but they must be upheld where a patient safety incident investigation is undertaken.

Those affected by patient safety incidents should be:

- Provided with a named main contact within SHSC with whom to liaise about any learning response and support.
- Communicated with in a way that takes account of their needs.
- Fully informed about what happened.
- Given the opportunity to provide their perspective on what happened.
- Given an opportunity to raise questions about what happened and to have these answered openly and honestly.
- Helped to access counselling or therapy where needed.
- Given the opportunity to receive information from the outset on whether there will be a specific learning investigation and what to expect from the process.

- Signposted to where they can obtain specialist advice and/or advocacy and/or support from independent organisations regarding learning response processes.
- Allowed to bring a friend, family member or advocate of their choice with them to any meeting that is part of the learning response process they are involved in.
- Informed who will conduct any learning investigation and of any changes to that arrangement.
- Given the opportunity to input to the terms of reference for the investigation, including being given the opportunity to request the addition of any questions especially important to them (note this does not mean that their requests must be met, but they must have any decision not to meet their request explained to them).
- Given the opportunity to agree a realistic timeframe for any investigation.
- Informed in a timely fashion of any delays with the investigation and the reasons for them.
- Updated at specific milestones in the investigation should they wish to be.
- Given the opportunity to review the learning report with a member of the investigation team while it is still in draft and there is a realistic possibility that their suggestions may lead to amendments. Note this does not mean that their suggestions must be incorporated but any decision not to incorporate their suggestions must be explained to them.
- Invited to contribute to the development of safety actions resulting from the learning report.
- Given the opportunity to feedback on their experience of the learning response and report (e.g. timeliness, fairness, and transparency).

The line manager/person in charge of the shift must ensure all staff and service users involved in a traumatic/stressful incident are offered support following an incident.

Staff may suffer high levels of stress and distress immediately after an incident and throughout the investigation and learning period. It is imperative, to maintain both staff wellbeing and service user safety and to ensure that staff are well supported throughout the process.

In the first instance a debrief session should be held as soon after the event as possible to allow staff the opportunity to reflect on the situation and explore how it has made them feel. This would usually be organised and facilitated by the ward/team manager. The exact nature of the support mechanisms used will be

dependent on the type of incident and the needs of the individual(s) involved and will always follow the principles of 'being open' as detailed in the Statutory Duty of Candour/Being Open Policy.

The manager/person in charge should consider actions to protect the individual(s) wellbeing at this time. As appropriate, staff will be offered reasonable access to:

- Immediate medical treatment if required.
- Advice/counselling from Workplace Wellbeing.
- Chaplaincy Service.
- Occupational Health Services.
- Advice from Human Resources.
- Legal advice (at the discretion of SHSC).
- Time away from work (nature of leave to be agreed on a case-by-case basis).
- Time out to consult with their Union and/or professional body.

Subsequently managers should ensure staff can access on-going peer support within and/or external to the team, as well as support from themselves.

All incidents involving the use of Restrictive Interventions must be subject to a post incident review facilitated by an appropriately identified clinician. The review must include the views of the service user where possible and all staff involved in the incident.

Where a Patient Safety Incident Investigation (PSII) has taken place the team/s should be supported to collaborate in the development of learning action and a debrief and learning event must be held within the staff team/s to share the findings of the investigation and to enable reflection and learning to be undertaken.

Patient safety incident response planning

Resources and training to support patient safety incident response

A range of resources to support patient safety incident investigations and learning responses are available through the Patient Safety Incident Response Framework and these have been adopted by SHSC. Investigation templates and supportive guidance for learning responses are available at the Learning Hub on Jarvis.

Training for staff to undertake Patient Safety Syllabus, Patient Safety Incident Investigations and Learning Responses is available via SHSC's ESR system. Training to support investigators will be subject to ongoing review and development as SHSC embeds the principles of the PSIRF over the next 18 months.

Our patient safety incident response plan

Our plan sets out how SHSC intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan.

Reviewing our patient safety incident response policy and plan

Our patient safety incident response plan is a 'living document' that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan every 12 to 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months.

Updated plans will be published on our public facing website, replacing the previous version.

A rigorous planning exercise will be undertaken every four years and more frequently if appropriate (as agreed with our integrated care board (ICB)) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

Responding to patient safety incidents

Patient safety incident reporting arrangements

Reporting an Incident

All incidents must be reported via the Ulysses Risk Management System, available via the SHSCApps folder on the desktop of SHSC IT equipment (e.g. PC/laptop). Where SHSC IT equipment is not available, a paper incident reporting form may be completed, or in exceptional circumstances, an incident can be reported via the telephone to the Quality Directorate risk team.

Incidents must be reported as soon as possible following the event and wherever possible, before the end of the working day the incident occurred in. It is expected that all incidents will be reported within 24 hours of them occurring.

When an incident is deemed to have caused significant physical or psychological harm to a patient/s, the following applies:

- **Working hours –** the incident must be recorded on Ulysses as soon as possible. The classification of harm must be accurately selected. The person in charge of the shift/team/service must be informed as soon as possible to assist in the management of the incident, support of all service users and staff involved and preservation of the scene/evidence if this is required.

- **Out of hours (5pm to 9.00am Monday – Thursday and 5.00pm to 9.00am Friday – Monday and Bank Holidays) –** the incident must be logged, managed and reported as above, additionally, the local manager/person in charge must contact the on-call Service Manager, who will then notify the Executive Director on call.

If a ***Never Event*** is deemed to have occurred, the local manager/person in charge must immediately notify the Quality Team (if in working hours) or on-call Service Manager (if outside of working hours), who will notify the Executive Director on call. NHS England » Never events

Initial Response to an Incident

When a significant patient safety incident occurs, staff involved must:

- Secure the area as required by the circumstances of the incident.

- Ensure the safety of all those affected by the patient safety incident and provide emergency/life-saving care if required.

- Ensure the safety of the environment. In the most serious of patient safety incidents this may need to be kept secure to aid with any potential police investigation.

- Notify emergency services as appropriate/required, e.g., Fire and Rescue, Ambulance and/or South Yorkshire Police

- Ensure any equipment involved in the incident is retained in a safe area for further examination/inspection or calibration.

- Offer support where required.
- Notify the service user's next of kin/nominated individual (if/where applicable)
- Escalate to Point of Contact or Senior/on-call Manager/Executive Director as appropriate (described above)
- Report the incident on Ulysses, ensuring this accurately records the facts and any harm caused.
- Write down their recollection of events, as soon after as practically possible, to aide memory capture and information gathering to assist future learning.
- Attend briefings and/or interviews, as required, in conjunction with their team/service manager and the lead investigator, in order to gather information and understand the learning.

Grading the Incident

All reported incidents and near misses are graded initially by the individual reporting the incident according to their **actual impact/effect** using SHSC's approved Risk Grading Matrix attached at Appendix C. This should be part of the initial incident report and be undertaken within 24 hours. It is not necessary for the reporter to be in possession of all the facts at the time of the initial grading of the incident. There is scope for re-grading the incident as relevant facts and issues emerge.

Incident grades will also be reviewed by the nominated reviewers within each service/team the incident is reported in, and an overall rating given. An assessment of the actual impact/effect and likelihood of occurrence of similar incidents in the future will be recorded on Ulysses.

The grading of an incident is one factor that is taken into consideration when determining the level of learning response or investigation required, and the reporting arrangements necessary.

Reviewing an Incident

All incidents reported via the Ulysses system must be reviewed by the nominated reviewers/managers within 5 working days of the incident being reported. For incidents graded moderate or above, an initial review should be undertaken within 24 hours of the incident occurring. This can then be expanded upon within the 5 working day period. The reported incident must be reviewed for accuracy and any corrections made. The Managers Form must be completed to confirm the actions that have been or will be taken to prevent future recurrence.

Identifying Incidents where Learning can be Extracted and Shared

PSIRF supports SHSC to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, SHSC can explore patient safety incidents relevant to our context and the populations we serve rather than only those that meet a certain defined threshold. Every patient safety incident will be considered on an individual basis regardless of the level of harm reported.

All incidents reported in the preceding 24-hour period will be presented and discussed at the Daily Incident Safety Huddle (DISH), chaired by a Quality Team representative. The DISH is made up of representatives across Quality, Health and Safety, Pharmacy, Safeguarding, etc and every incident is considered individually to identify any learning and/or to raise/escalate patient safety concerns, themes and trends.

Where an incident is deemed to require a Patient Safety Incident Investigation (PSII) or a Learning Response, it is escalated to and discussed with the Director of Nursing, Professions and Quality, the heads of Nursing and professional leads, to determine whether a 48-hour report is required to ascertain further information/detail. Where this occurs, the Quality Team will provide the relevant template to the relevant service(s), requesting its completion within a given timescale.

Certain incidents will always require a Patient Safety Incident Investigation (PSII). Incidents of this type have pre-determined notifications built into the Ulysses incident reporting system. These incidents require the completion of a 48-hour report by the service in which the incident occurred and a Flash Report to the Board members by the Quality Team. Notwithstanding the immediate escalation process the incident will still be reviewed in the Daily Incident Safety Huddle (DISH). The local and national incidents that require this response are:

- A homicide or attempted homicide by a service user in receipt of (or has been in receipt of within the previous 6 months) services provided by SHSC.
- An inpatient suicide.
- A Never Event
- Deaths thought more likely than not to have been due to problems in care (ie incidents meeting the learning from deaths criteria)

Any incidents deemed to fall under the Duty of Candour will also be identified through the DISH and contact made with the relevant service to assist in the preparation and deployment of a face-to-face verbal apology and then an approved written apology. Please see the Being Open/Duty of Candour Policy for further details.

Where immediate and urgent learning is identified, or immediate action is required to protect patient safety, a Blue Light Alert will be issued. The Quality team will identify the appropriate person to complete the details of the Blue Light Alert, which will be approved by the Director of Nursing, Professions and Quality prior to circulation. Blue Light Alerts are cascaded through SHSC's email cascade system and are published on Jarvis, the SHSC staff Facebook page and through the Learning Hub, Learning hub | JARVIS (shsc.nhs.uk) They are also included in the quarterly Lessons Learned Reports presented to the Clinical Quality and Safety Group, the Quality Assurance Committee and Board of Directors. All alerts are appended to the initial incident on the Ulysses system. In circumstances where urgent learning needs to be cascaded externally either locally or nationally the Quality Team will ensure this is completed.

Where an incident is identified that is considered to have the potential for learning but does not meet the criteria for a local or national PSII, a learning response process may be initiated that could include the use of one of the national learning tools provided via the Patient Safety Incident Response Framework, NHS England » Patient safety learning response toolkit

Over the ensuing 18 months SHSC will focus on developing the use of the After Action Review, the MDT Review and thematic reviews. As the organisational capacity and expertise in using these tools develops SHSC will expand their use to incorporate all of the learning tools contained within the learning response toolkit. Broadening our organisational capacity and expertise in the use of System Engineering Initiative for Patient Safety (SEIPS) will increase our ability to continually learn and improve. B1465-SEIPS-quick-reference-and-work-system-explorer-v1-FINAL.pdf (england.nhs.uk)

SHSC will also use the Structured Judgement Review (SJR) and the Significant Event Analysis (SEA) tool as a method of reflective learning in order to analyse episodes of care which would benefit from further review and reflection and to inform and develop future practice.

Learning responses will be undertaken with the team/s where the incident/s occurred, the outcomes, including completed SEA's are required to be submitted back to the Quality Team within 20 working days for presentation and approval at the weekly PSII and Learning Oversight Panel. Learning from Structured Judgement Reviews is overseen via the Learning from Deaths and mortality review process, Learning from Deaths Policy (MD 002 V4 March 2022)- extension to review date April 2024 | JARVIS (shsc.nhs.uk)

Once approved, these will be published via the Learning Hub by the Quality Team on Jarvis. The learning will also be highlighted in the Quarterly Lessons Learned Report and the bi-monthly Learning Bulletin.

Patient safety incident response decision-making

The Director of Nursing, Professions and Quality, the heads of Nursing and professional leads will be advised by the Daily Incident Safety Huddle. Subsequent decision making will be based on the findings of the 48-hour report in the weekly PSII and Oversight meeting. The weekly PSII and Oversight meeting is chaired by the Director of Nursing, Professions and Quality or their nominated deputy and is attended by a range of staff including the heads of nursing, clinical leads and members of the Quality Team.

Our Patient Safety Incident Response Plan (PSIRP) supports the proactive allocation of patient safety incident response resources, but there will always need to be a reactive element in responding to incidents. Where a patient safety incident indicates an unexpected level of risk and/or potential for learning and improvement but it falls outside the issues or specific incidents described in our PSIRP, decisions-making will be led by the Director of Nursing, Professions and Quality in consultation with members of the weekly PSII and Oversight meeting members.

Responding to cross-system incidents/issues

Incidents or issues that require a cross-system learning response will be identified by the Daily Incident Safety Huddle (DISH) and escalated to the Director of Nursing, Professions and Quality, the heads of nursing and the clinical leads. SHSC will work collaboratively with all external partners to address cross-system/incidents/issues. How SHSC responds to requests and/or how SHSC makes requests for engagement in cross-system incidents/issues will be determined on a case-by-case basis by the weekly PSII and Oversight meeting members, giving full consideration to the potential for learning and opportunity for organisational quality improvement.

Timeframes for learning responses

SHSC's learning response will start as soon as an incident is identified and will usually be completed within one to three months. The timeframe for completing a Patient Safety Incident Investigation (PSII) will be agreed with those affected by the incident, as part of setting the terms of reference for the PSII, provided they are willing and able to be involved in that decision. PSIIs (and other local responses) will take no longer than six months, but this will not become a new default target. If our local responses are frequently taking more than 6 months, or exceeding timeframes set with those affected, then we will review our processes to understand how timeliness can be improved. In exceptional circumstances (e.g. when a partner organisation requests an investigation is paused), a longer timeframe may be needed to respond to an incident. In this case, any extension to timescales will be agreed with those affected (including the patient, family, carer, and staff).

Where external bodies (or those affected by patient safety incidents) cannot provide information, to enable completion within six months or the agreed timeframe, the local response leads will work with all the information they have to complete the response to the best of their ability; it may be revisited later, should new information indicate the need for further investigative activity.

Safety action development and monitoring improvement

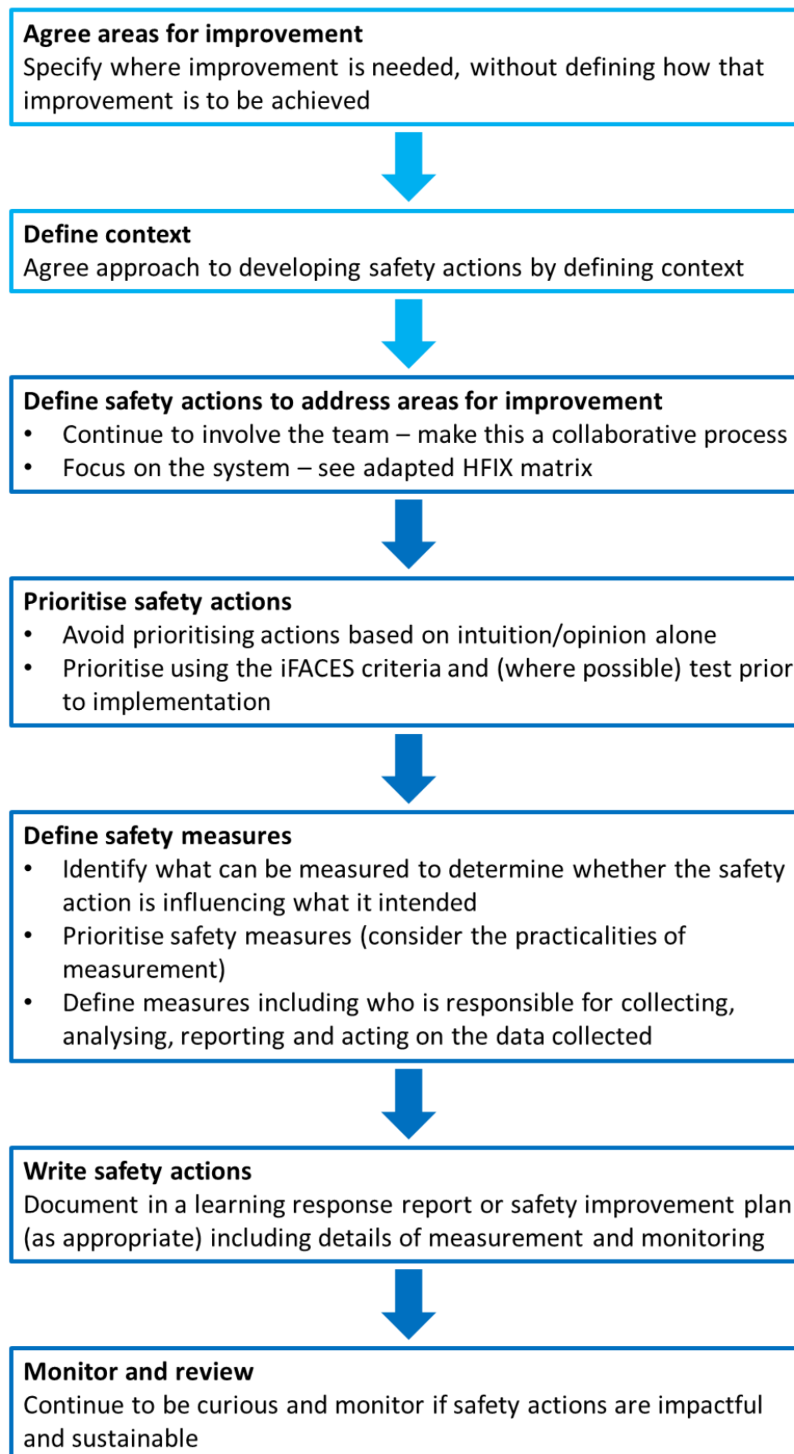
SHSC will follow an integrated process for developing, implementing, and monitoring safety actions. Acting in response to a patient safety incident may take different forms. Sometimes rapid action will be needed to respond to imminent risk e.g. removing broken/faulty equipment or removing identified fixed ligature anchor points. These actions will be completed as soon as practicable and will be captured as part of specific incident response.

Developing safety actions that respond to underlying system issues will start with identifying and understanding aspects of the work system that need to change to reduce risk and potential for harm (i.e. areas for improvement or system issues). Actions to reduce risk (i.e. safety actions) will then be created in relation to each defined area for improvement.

The term 'areas for improvement' will used instead of 'recommendations. This will reduce the likelihood of solution finding at too early a stage of the safety action development process. Understanding contributory factors and work as done should not be confused with developing safety actions. Areas for improvement set out where improvement is needed without defining how that improvement is to be achieved. Safety actions in response to a defined area for improvement depend on factors and constraints outside the scope of a learning response.

The safety action development process, described in Figure 1, will take a collaborative approach throughout, including involvement of those beyond the 'immediate and obvious' professional groups. Involving patients, clients, carers and families, administration, pharmacy, and managers, for example, where appropriate and available, will capture valuable insights that may not otherwise be considered. Imposed solutions will often fail to engage staff and lack sustainability as a result.

Figure 1: Overview of safety action development process



Safety actions will be SMART (specific, measurable, achievable, relevant, time-bound). They will also:

- Be documented in a learning response report or in a safety improvement plan as applicable.
- Start with the owner, eg “Patient Safety Specialist to...”.
- Be directed to the correct level of the system: that is, people who have the levers to activate change (ideally this should include the person closest to the work and who has been empowered to act).
- Be succinct: any preamble about the safety action should be separate.
- Standalone: that is, readers should know exactly what it means without reading the report.
- Make it obvious why it is required (i.e. given evidence in the learning response report or safety improvement plan).

When finalising safety actions, we will continue to work with those to whom they are directed to ensure they are on board and willing to implement change.

Further guidance on developing safety actions will be provided to investigators by the quality team at the commencement of each new Patient Safety Incident Investigation (PSII).

Safety improvement plans

Safety improvement plans will bring together findings from various responses to patient safety incidents and issues. They will take different forms depending on the type of improvement required, for example, SHSC will consider:

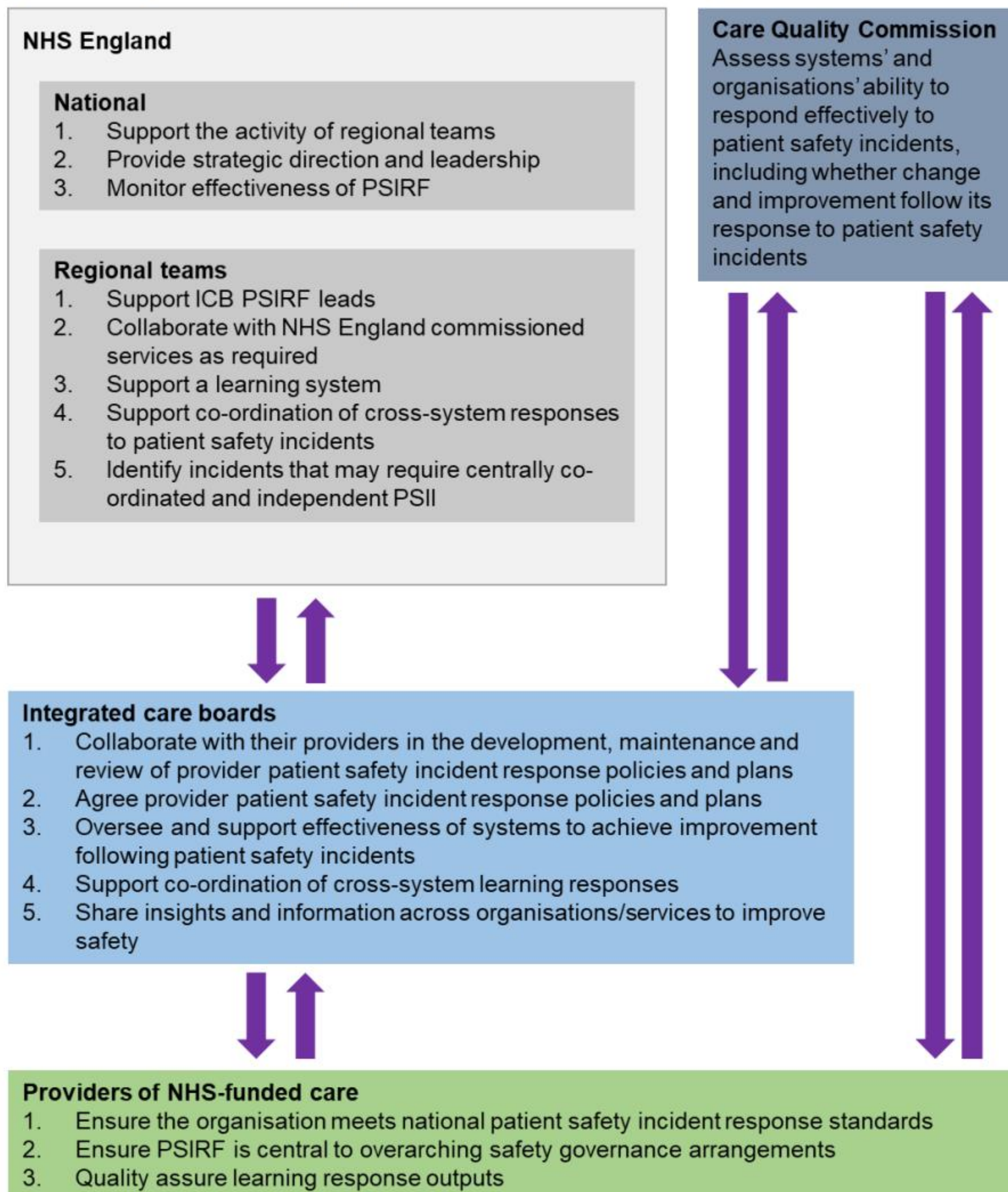
- Creating an organisation-wide safety improvement plan summarising improvement work
- Creating individual safety improvement plans each focusing on a specific service, pathway, or location
- Creating a safety improvement plan to tackle broad areas for improvement (i.e. overarching system issues)

SHSC will consider which approach is best suited to the data we have, and insight gained. The key will be to demonstrate why a specific safety improvement plan approach is the right one based on available data, stakeholder views, improvement priorities, our patient safety incident profile and insight from other related patient safety incident responses. There are no thresholds for when a safety improvement plan should be developed; for example, after completing a certain number of learning responses. The decision to do so will be based on knowledge gained through the learning response process and other relevant data.

Oversight roles and responsibilities

An overview of organisational responsibilities in relation to PSIRF oversight, is shown in Figure 2.

Figure 2: Organisational responsibilities for an effective governance structure



SHSC oversight and Responsibility

The Board

The Board is responsible for:

- Ensuring robust incident reporting, learning and improvement systems are in place and that these are monitored and reviewed and compliant with external regulation.
- Ensuring that patient safety incidents are reviewed, and learning actions and improvement plans are implemented.
- Ensuring that data in relation to patient safety incident reports is analysed to identify themes and trends and appropriate improvements are undertaken.

Director of Nursing, Professions and Quality

The Director of Nursing, Professions and Quality is the accountable officer for Patient Safety, the Patient Safety Incident Response Framework and the accompanying policy and plan.

Quality Assurance Committee

The Quality Assurance Committee is responsible for overseeing that robust incident management processes are in place. The Committee is also responsible for receiving assurance from the Clinical Quality and Safety Group that learning actions and improvement plans following patient safety incidents are effectively monitored and implemented.

Clinical Quality and Safety Group

The Clinical Quality and Safety Group is responsible for ensuring that the Patient Safety Incident Response Policy and Plan is effectively implemented across SHSC; that all directorates have robust governance systems in place to ensure all patient safety incidents are reported and learning occurs at team and directorate/care level and ensure that that the learning actions and improvement plans following learning responses are implemented, monitored and that learning is shared across the organisation.

The Patient Safety Incident Oversight Panel

The Patient Safety Incident Oversight Panel has responsibility for coordinating, overseeing and monitoring learning responses for patient safety incidents.

Mortality Review Group

The Mortality Review Group is responsible for reviewing all deaths reported as incidents and sharing learning from the Structured Judgement Review (SJR) process in line with the Trust's Learning from Deaths Policy.

Director of Human Resources

The Director of Human Resources is responsible for:

- Ensuring that support for staff following incidents is available via the Workplace Wellbeing service;

- Ensuring Occupational Health guidance, advice and service is available for staff following incidents.
- Ensuring that media communications, in relation to incidents, are managed effectively through the Communications Manager.

Heads of Nursing and Clinical Leads

Heads of Nursing and Clinical Leads are responsible for ensuring that their staff comply with the requirements set out in this policy. This will be achieved through:

- Ensuring that all incidents/accidents are reported and managed in accordance with this policy.
- Ensuring that all staff, including temporary staff, are aware of this policy and their duties with regard to incidents/accidents.
- Ensuring all incidents/accident reports and learning actions and improvement plans relating to their directorate are reviewed at the appropriate team or directorate level to support learning, the reduction of risk and the prevention of recurrence.
- Ensuring all risks identified following the investigation of an incident/accident relating to their directorate are recorded on the appropriate electronic risk register and reviewed and updated as required.
- Ensuring that incidents/accidents learning actions and improvement plans relating to other directorate or services in SHSC are communicated effectively within their services, ensuring any identified risks are recorded on the appropriate electronic risk register and reviewed and updated as required.
- Reviewing the data derived from incident reports to identify any themes or trends for their sphere of responsibility, and taking appropriate action as needed.
- Sharing full reports including learning actions and improvement plans through their directorate and team governance framework.
- Ensuring staff, service users and carers or others involved in incidents are kept informed and receive support as appropriate in line with the requirements of the statutory Duty of Candour and this policy.
- Ensuring all staff in their directorate receive training at induction and subsequently as required by this policy.

Accountable Officer for Controlled Drugs

Sharing information within Local Intelligence Networks (LIN) in relation to controlled drug incidents and/or fraudulent behaviour of relevant people: in this context a relevant person is anyone who prescribes, dispenses, administers or transports drugs and information will only be shared about those individuals where there are well founded concerns in relation to patient safety. This is in-line with the Statutory Instrument 3148 of the Health Bill in relation to the Accountable Officers Responsibilities.

Specialist Advisors

Specialist Advisors are staff with particular areas of knowledge and specialist expertise who are available to support staff in implementing this policy. They include the Patient Safety Specialist, Patient Safety Partners, Clinical Risk and Patient Safety Manager, the Health & Safety Risk Advisor, Medicines Safety Officer, Information Governance Officer, the Senior Nurse for Infection Prevention and Control, Local Security Management Service Advisor and Fire Officer and the Safeguarding Adults and Children Lead Nurse (this is not an exhaustive list).

The Clinical Governance (Quality Team) will:

- Act as custodians for Patient Safety Incident Response Policy and Plan and support the monitoring processes in relation to compliance and implementation of learning actions and improvement plans.
- Provide advice and support to all staff and ensure training, resources and information is available to enable the effective reporting, investigation and management of incidents.
- Report externally to the Health & Safety Executive (RIDDOR), Care Quality Commission, Clinical Commissioning Group (CCG), NHS England/NHS Improvement and other agencies as required.
- Maintain the Ulysses database for incidents, learning actions and improvement plans.
- Keep all accident/incident/investigation information in line with SHSC's records retention requirements set out within the Records Management Policy.
- Provide a quality assurance review of all incidents reported.
- Review investigation reports for patient safety incidents against standards set by the Patient Safety Incident Response Plan.
- Prepare overviews of patient safety incident reports for the Quality Assurance Committee and Board.
- Provide a whole range of reports to different levels within the organisation to enable scrutiny of data, identification of risks and the sharing of learning from all incidents.

Investigation and Learning Response Officers

Investigation and Learning Response Officers are responsible for carrying out thorough investigations and learning responses into the incidents they are nominated to oversee, in accordance with the terms of reference set and using approved investigation techniques.

Managers

Under Section 7 of the Health and Safety at Work Act 1974, managers for an area are responsible for ensuring incidents are appropriately managed, investigated, acted upon and lessons are learnt.

Managers are also responsible for supporting staff following a traumatic incident and ensuring that service users and carers or others involved in incidents are kept informed and receive support as appropriate in line with the requirements of the statutory Duty of Candour and this policy.

All Staff

All staff have a duty of care to provide safe services and do no harm, to be responsible for keeping themselves and others safe and are expected to report incidents as part of their general duties under Section 7 of the Health and Safety at Work Act 1974.

All staff members are expected to notice accidents, incidents and near misses and report and manage them in accordance with this Policy.

Complaints and appeals

It is anticipated that by following the processes set out in the Patient Safety Incident Response Framework that patients, family and staff will be appropriately supported to be able to meaningfully input into learning responses and patient safety incident investigations from the outset. However, this does not mean that the right to complain or appeal is removed. It is good practice and an SHSC expectation that those leading learning responses or investigation will provide those involved with contact details for making a complaint or raising a concern.

Patients and their family can raise a complaint via:

By writing to us: Complaints Team, Sheffield Health and Social Care NHS Foundation Trust, Centre Court, Atlas Way, Sheffield, S4 7QQ
By emailing us: complaints@shsc.nhs.uk
By calling us: 0114 2718956

Staff members can raise concerns by contacting:

Freedom to Speak up Guardian, by calling 0114 3050 500 or 07976213844 or by emailing w.fowler1@nhs.net

Appendix A

Equality Impact Assessment Process and Record for Written Policies

Stage 1 – **Relevance** - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? This should be considered as part of the Case of Need for new policies.

NO – No further action is required – please sign and date the following statement. **I confirm that this policy does not impact on staff, patients or the public.**	***I confirm that this policy does not impact on staff, patients or the public.*** Name/Date: Vin Lewin 27/10/2023	**YES,** Go to **Stage 2**

Stage 2 Policy Screening and Drafting Policy - Public authorities are legally required to have 'due regard' to eliminating discrimination, advancing equal opportunity and fostering good relations in relation to people who share certain 'protected characteristics' and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don't know and note reasons). Please see the SHSC Guidance and Flow Chart.

Stage 3 – **Policy Revision** - Make amendments to the policy or identify any remedial action required and record any action planned in the policy implementation plan section

SCREENING RECORD	Does any aspect of this policy or potentially discriminate against this group?	Can equality of opportunity for this group be improved through this policy or changes to this policy?	Can this policy be amended so that it works to enhance relations between people in this group and people not in this group?
Age			
Disability			
Gender Reassignment			
Pregnancy and Maternity			

Race			
Religion or Belief			
Sex			
Sexual Orientation			
Marriage or Civil Partnership			

Please delete as appropriate: - Policy Amended / Action Identified (see Implementation Plan) / no changes made.

Impact Assessment Completed by: Vin Lewin

Name /Date Vin Lewin 27/10/2023

Appendix B

Review/New Policy Checklist

This checklist to be used as part of the development or review of a policy and presented to the Policy Governance Group (PGG) with the revised policy.

		Tick to confirm
	Engagement	
1.	Is the Executive Lead sighted on the development/review of the policy?	√
2.	Is the local Policy Champion member sighted on the development/review of the policy?	√
	Development and Consultation	
3.	If the policy is a new policy, has the development of the policy been approved through the Case for Need approval process?	√
4.	Is there evidence of consultation with all relevant services, partners and other relevant bodies?	√
5.	Has the policy been discussed and agreed by the local governance groups?	√
6.	Have any relevant recommendations from Internal Audit or other relevant bodies been taken into account in preparing the policy?	√
	Template Compliance	
7.	Has the version control/storage section been updated?	√
8.	Is the policy title clear and unambiguous?	√
9.	Is the policy in Arial font 12?	√
10.	Have page numbers been inserted?	√
11.	Has the policy been quality checked for spelling errors, links, accuracy?	√
	Policy Content	
12.	Is the purpose of the policy clear?	√
13.	Does the policy comply with requirements of the CQC or other relevant bodies? (where appropriate)	√
14.	Does the policy reflect changes as a result of lessons identified from incidents, complaints, near misses, etc.?	√
15.	Where appropriate, does the policy contain a list of definitions of terms used?	√

16.	Does the policy include any references to other associated policies and key documents?	√
17.	Has the EIA Form been completed (Appendix 1)?	√
	Dissemination, Implementation, Review and Audit Compliance	
18.	Does the dissemination plan identify how the policy will be implemented?	√
19.	Does the dissemination plan include the necessary training/support to ensure compliance?	√
20.	Is there a plan to i. review ii. audit compliance with the document?	 √ √
21.	Is the review date identified, and is it appropriate and justifiable?	√

Appendix C – Risk Rating Matrices

Choose the most appropriate domain for the identified risk from the left hand side of the table Then work along the columns in same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

Table 1 – Measures of Consequences/Severity

Consequence Score (severity levels) and examples of descriptors

	1	**2**	**3**	**4**	**5**
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
SAFETY Impact on the safety of patients, staff or public (physical/ psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work Incorrect medication dispensed but not taken Incident resulting in a bruise/graze Delay in routine transport for patient Expected death Missing patient (low risk)	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days Wrong drug or dosage administered, with no adverse effects Physical attack, such as pushing, shoving or pinching, causing minor injury	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients Wrong drug or dosage administered with potential adverse effects Physical attack causing moderate injury Self-harm requiring medical attention Grade 2/3 pressure ulcer Healthcare Acquired Infection (HCAI) Incorrect or inadequate information/communication on transfer of care	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects Wrong drug or dosage administered with adverse effects Physical attack resulting in serious injury Grade 4 pressure ulcer Long-term HCAI Slip/fall resulting in injury such as dislocation/fracture/blow w to the head Post-traumatic stress disorder	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients Unexpected death Suicide of a patient known to the service in the past 12 months Homicide (or suspected homicide) committed by a mental health patient Incident leading to paralysis

		Self-harm resulting in minor injuries Grade 1 pressure ulcer Laceration, sprain, anxiety requiring occupational health counselling (no time off work required) Missing patient (medium risk)	Vehicle carrying patient involved in a road traffic accident Slip/fall resulting in injury such as a sprain Missing patient (high risk)		Incident leading to long-term mental health problem Rape/serious sexual assault Loss of a limb
<u>QUALITY</u> Quality/ Complaints/ Audit	Peripheral element of treatment or service sub-optimal Informal complaint/ inquiry	Overall treatment or service sub-optimal Formal complaint Local Resolution Single failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance if unresolved	Treatment or service has significantly reduced effectiveness Serious complaint Repeated failure to meet internal standards Local resolution (with potential to go to independent review) Majority patient safety implications of findings are not acted on	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report Major complaint/ claim	Incident leading to totally unacceptable level of quality of treatment/ service Gross failure of patient safety if findings no acted upon Inquest/ Ombudsman inquiry Gross failure to meet national standards

WORKFORCE Human resources/ organisational development/ staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis
STATUTORY Statutory duty/ inspections	No or minimal impact or breech of guidance/ statutory duty	Breach of statutory legislation Reduced performance rating if unresolved	Single breach in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breeches in statutory duty Improvement notices Low performance rating Critical report	Multiple breeches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report
REPUTATIONAL Adverse publicity/ reputation	Rumours Potential for public concern	Local media coverage – Short-term reduction in public confidence Elements of public expectation not being met	Local media coverage – Long-term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence

BUSINESS Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget Schedule slippage Key objectives not met	Incident leading >25 per cent over project budget Schedule slippage Key objectives not met
FINANCE Finance including claims	Small loss Risk of claim remote	Loss of 0.1-0.25% of budget Claim less than £10,000 Vandalism/ theft <£10k Cosmetic damage to premises	Loss of 0.25-0.5% of budget Claims between £10,000 and £100,000 Vandalism/theft £10-50k	Uncertain delivery of key objective/ loss of 0.5-1.0% of budget Claim between £100,000 and £1 million Purchasers failing to pay on time Vandalism/ theft £50£100k	Non-delivery of key objective of >1% of budget Failure to meet specification/ slippage Loss of contract/ payment by results Claims > £1 million Vandalism/ theft over £100k
ENVIRONMENTAL Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption >8 hours Minor impact on environment Cosmetic damage to premises	Loss/interruption of > 1 day Moderate impact on environment Structural damage to premises	Loss/interruption of > 1 week Major impact on environment Permanent irreparable damages to premises/ damage up to £100k	Permanent loss of service or facility Catastrophic impact on the environment Serious fire Permanent irreparable damage to premises/ damage over £100k

a) Scoring the likelihood

Use *Table 2 – Likelihood,* to score the likelihood of the assessed consequence/s. Use the descriptors as a guide to determine the likelihood score.
I.e. 1 = Rare; 2 = Unlikely; 3 = Possible; 4 = Likely; 5 = Almost Certain.

N.B. Remember you are scoring the likelihood of the consequence/s you have determined being realised.

Table 2 Likelihood

Score/Descriptor	Likelihood	Frequency	Probability
1 Rare	This will probably never happen recur	Not expected to recur for years	<0.1 %
2 Unlikely	Do not expect it to happen recur but it is possible it may do so	Expected to occur at least annually	0.1-1.0 %
3 Possible	Might happen or recur occasionally	Expected to occur at least monthly	1-10 %
4 Likely	Will probably happen/ recur but it is not a persisting issue	Expected to occur at least weekly	10-50 %
5 Almost Certain	Will undoubtedly happen/recur, possibly frequently	Expected to occur at least daily	> 50 %

b) Scoring/Rating the risk

Calculate the risk score by multiplying the consequence score by the likelihood to determine your risk rating score using *Table 3 – Risk Rating.*

It may be appropriate to assess more than one domain of consequence. This may result in generating different scores. Use your judgement to decide on the overall rating/score.

Table 3 – Risk Score

	LIKELIHOOD				
SEVERITY SCORE	**1 Rare**	**2 Unlikely**	**3 Possible**	**4 Likely**	**5 Almost Certain**
1 Negligible	**1**	**2**	**3**	**4**	**5**
2 Minor	**2**	**4**	**6**	**8**	**10**
3 Moderate	**3**	**6**	**9**	**12**	**15**
4 Major	**4**	**8**	**12**	**16**	**20**
5 Catastrophic	**5**	**10**	**15**	**20**	**25**

Table 4 Risk Rating below determines the overall Risk Rating given to the risk based on the scores from *Table 3 Risk Score.*

Table 4 Risk Rating

1-4	**Very Low**	**5-8**	**Low**	**9-12**	**Moderate**	**15-25**	**High**

c) Risk Management Plan (Actions)

Any risk management plan to control the residual risk must be devised and written down in an action plan format with SMART actions (Specific, Measurable, Achievable, Realistic, Timely), a named person and timescales should be allocated for each action.

It is essential that the plan to manage the risk is shared with everyone who needs to know about it, or is affected by it. With clinical risks, this will usually include service users and carers. A plan will not be effective if the people charged with implementing it do not know about it.