Patient safety incident response policy

Effective date: 1 December 2024

Estimated refresh date: 1 December 2028

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Working in partnership
The Royal Wolverhampton NHS Trust
Walsall Healthcare NHS Trust

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Purpose

This policy sets out The Royal Wolverhampton NHS Trust and Walsall Healthcare NHS Trust's ('The Group') commitment, and approach, to deliver the principles and requirements of the new national Patient Safety Incident Response Framework (PSIRF). At its heart, the new national framework drives:

- An effective learning culture that delivers measurable improvements in safety, practice, quality and process
- An approach that actively engages frontline and support staff in a dynamic reflective, analytical and learning system, which inspires confidence and trust in a fair, balanced way
- An approach which invites and enables patients and families affected by unexpected events of harm, and significant near miss events, to work with the care teams involved as partners to evaluate what happened, how and why so that the best lessons can be learnt, and a holistic perspective achieved
- A commitment to proportionality, which allows a range of evaluation, investigation, and learning responses to be employed so that the application of limited NHS resources can be best utilised to answer patient, family and staff questions. Further, that these resources are effectively used to identify areas for improvement without the burden created by an automatic requirement for formal investigations as with the Serious Incident Framework for England.
- A more robust method of oversight which provides assurance of these drivers via evidence, and not reassurance via platitudes.

This policy sets out how The Group will deliver on the above principles.

This policy is to be read together with the current patient safety incident response plan, which sets out how this policy will be implemented, in conjunction with Royal Wolverhampton's Incident Reporting and Monitoring Procedure 1 (OP10), and Walsall Healthcare's Incident Reporting, Learning and Management Policy (OP917), which set out how incidents outside of this policy are managed, and their respective Duty of Candour Policies (OP60 and OP929) which set out the requirements where harm has been caused as a result of a patient safety incident. Definitions and a glossary of terms related to this policy are outlined in Appendix 1.

Scope

This policy applies to patient safety events and unexpected events of harm, which have impacted on patients in the care of The Group. It also applies to the assessment of events where the start of an event of harm occurred in a local care provider (NHS or local authority, or private care home) within the health system serving the population of Wolverhampton and Walsall.

There are two primary avenues for the assessment and learning review process:

- The patient safety review (PSR)
- The patient safety incident investigation (PSII)

All events resulting in moderate or greater harm (including psychological harm), and events where there is evidence indicating a significant concern, will be screened (assessed) to determine which avenue it will be reviewed under, and also to determine the depth and breadth of assessment and analysis required.

Where the nature of the event matches either a national priority for the PSII process, or one of the Group's local priorities (outlined in the Patient Safety Incident Response Plan), one of the following will apply:

- The 'subject' will already be under evaluation via a planned systems-based evaluation, whose purpose is to identify where the system is well designed and mostly working well, and where it is not. In this circumstance, the evaluation and assessment of this new event of harm will form part of this wider systems-based piece of work to identify the most important areas for improvement. The approach will enable The Group to meet the reasonable need of the patient and family and answer their questions directly, without having to wait for the conclusion of the wider systems-based work.
- The 'subject' is not already being systemically evaluated. In this situation, the event, its immediate impact and longer-term implications for the patient will be considered, alongside knowledge of other similar type events over the preceding 6, 12, and 18 months. This information will support The Group in deciding whether a system-wide assessment is necessary, or whether this event can be examined using a focused (narrowed) systems-based approach[1].

[1] The systems-based approach means that investigations and reviews for learning are not based on a 'who done it' principle. Rather, the approach looks at a holistic range of systemic elements (training, workplace design, tools and technology, the design/content of standard operating policy, procedures and guidelines, staffing, skill mix, leadership, *alongside* the actions and non-actions of staff involved). This gives a better insight as to what contributed to a harm and what we can do to modify that risk in the future.

What is outside of the scope of a systems-based approach to learning and improving, is a person focused or scapegoating approach, which unreasonably holds one or more individuals accountable where wider systemic weaknesses contributed.

On the rare occasion where a system is found to be well designed, well understood and mostly adhered to and working as intended, and the harm has been caused or contributed to by the significant underperformance of one or more individuals, there are different systems and processes for addressing this. Where a systems-based review identifies such concerns, in the first instance:

- NHS England's Just Culture Guide will be applied to the presenting scenario(s)[2]
- Advice will be sought from the relevant Human Resources departments regarding next steps
- Any further evaluation of individual performance will be conducted by independently appointed professionals[3] support by human resources, and the staffs own professional representatives
- The findings of the systems-based assessment/evaluation will be considered alongside the individual performance review before any individually focused remedial action or sanction is determined

It is only by applying these strict principles that Trust staff can have confidence in the Executive level assertion that fairness, and equity, are at the heart of our learning approach.

Issues of liability and causation are outside the scope of this policy and systems-based approach to learning. Where a patient, or their family raises such issues, they will be directed to Action against Medical Accidents (AvMA)[4] who are best place to provide independent and well-informed advice to the patient/family. The decision of a patient/family to explore medico-legal options open to them will not interfere with The Group's commitment to concluding its internal learning review process.

Other event types[5] which are not covered by the scope of this policy are:

- Claims handling.
- Human resources investigations into employment concerns.
- Professional standards investigations.
- Information governance concerns.

[2] NHS A Just Culture Guide
[3] Such an evaluation will not be conducted by the team undertaking the wider systems analysis
[4] https://www.avma.org.uk/
[5] Refer to the Trust intranet for the relevant Trust policy

- Health and Safety incidents (that do not highlight a significant patient safety concern)
- Digital and IT concerns
- Financial investigations and audits
- Estates and facilities concerns
- Safeguarding concerns
- Coronial inquests and criminal investigations; and,
- Complaints (that do not highlight a significant patient safety concern)

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

A focus on our patient safety culture

The Group commits to delivering a just, fair and equitable approach (in line with the NHS England's Just Culture Guide) as part of its approach to learning from patient safety incidents.

The Group has a range of approaches to promote and enable the reporting of patient safety concerns and occurrence of harm, and near miss events. Included are:

- Incident reporting systems
- Freedom to speak up via Freedom to Speak Up Guardians
- Patient Advice and Liaison Service (PALs)
- Formalised complaint route (predominantly for patients and families)

To foster trust and confidence in staff to highlight safety concerns, and to report near miss events, alongside incidents resulting in no harm through to non-recoverable harm (i.e. death), the Executive Teams and Boards of both NHS Trusts commit to the following:

- There will be no individual sanctions against employees who formally report a patient safety issue and/or near miss or harm event even where there have been deviations from documented Trust policies, procedures, and guidelines. The limitation of this commitment is as follows:
    - Where information comes to light that reveals a standard of practice that is considered by a body of peers to constitute reckless endangerment (the substitution and validation test is used to discern this)
    - Where information comes light that shows a malicious (purposeful) intent to cause harm
    - Where the staff involved have been involved in previous harm events, and demonstrate no willingness, or commitment to learning or improving

In the interests of credibility, which also goes to the heart of staff trusting and having faith in The Group's commitment to a fair, just, open learning culture, the term 'blame free' and 'no blame' have no place in a system that is committed to a just and fair approach.

Justifiable accountability is an integral part of being professional. It is right and proper that our qualified professionals, who are registered with a professional body embrace all facets of what it means to 'be a professional'. However, The Group commits to not holding individual members of staff, or teams, accountable for malfunctions within a system, nor the consequences of this or an inadequately designed, incomplete and inadequately tested system.

For more information on how incidents are reported and managed in an open and transparent manner to focus on learning without blame please refer to The Royal Wolverhampton's Incident Reporting and Monitoring Procedure 1 (OP10), and Walsall Healthcare's Incident Reporting, Learning and Management Policy (OP917),

As part of The Group's commitment to a Just and Fair culture, all related policies and procedures are being reviewed to ensure consistent messaging throughout.

Oversight – Just Culture

To measure our progress against statement commitments and our group wide aspirational goals both Trust Boards will receive information based on:

- Exit questionnaires completed by staff involved in patient safety reviews, Patient Safety Incident Investigations, and systems-wide evaluation projects
- Assessment of all cases referred for individual performance review and evaluation because of a reported patient safety event to ensure that in 100% of cases the principles of NHS England's Just Culture Tool and the commitments made in this policy have been adhered to
- The national staff survey includes questions about the culture of work, and the outputs of these surveys will be used as indicators of progress towards an embedded safety and learning culture for both organisations.

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

Inextricably linked to The Group's commitment to achieving a fair, open and just learning and safety culture are the mechanisms by which employed staff, our patients and families can become actively involved in the learning review process. Historically this involvement has been passive, and it does not lead to the dynamic culture we wish to achieve. Pivotal to achieving meaningful engagement and involvement is our commitment to:

- Equity
- Compassion
- Respect
- Empathy
- Communication
- Invitation

Involving our patients and families

In the aftermath of a patient safety incident, patients and families will experience a range of emotions and feelings, particularly where it has resulted in harm. They will include, outrage, anger, disappointment, feeling letdown. Our patients and their families will have questions about what happened, how it happened and why it happened. They will also have needs, including:

- Emotional support,
- To be heard,
- To have the opportunity to share their experience, and
- To ask the questions they have with confidence.

Patients and families need to have confidence that they will receive well informed, straight forward honest answers, as well as honesty about why not, if we cannot answer all questions.

Every patient and family are different. How we engage with and work with affected patients and families must be guided by their needs, and wants, albeit within a structured framework that enables The Group to be fair and equitable across diverse communities.

The minimum standards for The Group in striving to a more meaningful and engaging approach with families are as follows:

- 100% of patients who experience a harm impact (moderate or greater) will, as soon as it is clinically practically possible, have the situation explained to them by their lead clinician, and/or a supporting senior nurse at matron or senior matron grade

- 100% of such patients will be asked what questions they have for the team who cared for them. If, in the immediate aftermath of the harm event they, or their family, are unable to think of any questions, they will be provided with the contact details of the 'named contact' for any questions they have later.
- 100% of patients/families who experienced moderate or greater harm, are proactively offered a meeting with the leaders of their care team within 4-6 weeks of the harm event so they can hear firsthand the teams understanding of what happened, and how. If further evaluation of the sequence of events is necessary, including finding answers to unanswered questions, the patient/family are advised of who will be leading this further work and how the lead individual will contact them and in what timeframe.
- For cases that can be concluded via face-to-face communications between the care team and the patient/family a follow up letter is sent to the patient/family. This will set down the key areas discussed, reiterating answers to questions asked, and setting down any improvements agreed on, and how they are to be progressed. This letter will also provide a direct point of contact should the patient/family wish to make future contact.
- **Where further evaluation of the event is necessary:** The lead facilitator for the learning review, or lead investigator if required, makes written contact in the first instance offering a date and time to speak on the phone, or via a video calling platform accessible to both the Trust and patient, – whichever is preferred by the patient/family. Direct contact details are provided for the lead facilitator/investigator.
- **Then:** A personalised approach and plan are agreed between the patient/family and the lead facilitator/investigator. This may or may not result in the patient/family being appointed a support person who is independent of the lead facilitator/reviewer. Where all the needs of the patient/family cannot be met by the Group, then they are signposted to an individual or group that might be able to assist
- **During the evaluation period:** Update communications occur in line with the personalised plan, and the patient/family are involved in the learning review/investigation process in line with their personalised plan.
- **Once the interim report has been assessed for factual accuracy**: The patient/family are asked to read the report and to provide their own comments and considerations about it. These comments and considerations will be read and considered by the learning review/investigation team. A reason will be provided back

to the family for observations/comments not acted on or accepted. The patient/family will also be provided with a copy of the report sent to the Learning Response Panel.

Oversight – Engagement with patients and families after harm

In line with The Group's commitment to a Just Culture, patients and their families will be offered:

- An exit interview and/or questionnaire where they can tell us how they found the review process. Specifically, whether they were able to be involved in line with their wishes, felt respected and heard, and considered the findings of the event evaluation to be credible and trustworthy
- The process of the learning review/investigation will also be benchmarked against the involvement and engagement standards committed to by the Group.

Involving staff, colleagues, and partners

Learning and change arises from active engagement not passive involvement. The Group is therefore committed to a learning review and investigation process that give involved staff a voice and promise to uphold the same standards for them as it affords its patients and families. Notably:

- Respect
- Compassion
- Empathy
- To be heard, and
- To be a partner in the process of learning

The achievement of these basic principles requires a significant shift in the way the Groups approach learning reviews and investigations. Central to this shift is hearing from staff rather than asking them to write statements. Another activity will be to spend time watching their day-to-day work environments so learning reviews are grounded and have a keen appreciation of the challenges facing staff on a day-to-day basis. Involved teams must also be engaged in the initial assessment of:

- What went to plan
- What did not go to plan and why not
- What are the next sensible assessment and evaluative steps in the learning review process

To facilitate all the above, The Group commits to establishing a choice-based approach for the early assessment of, and onward consideration of patient safety incidents and events of unexpected harm. The structure for this will be embedded in each directorate/care group and division, supported with advice from the Assurance team. The process to be employed is depicted in Appendix 2.

Oversight– Engagement and Involvement of Staff

In line with The Group's commitment to a Just Culture, staff involved will be offered:

- An exit interview and/or questionnaire where staff can tell us how they found the review process. Specifically, whether they were able to be involved, felt respected and heard, and considered the findings of the event evaluation to be credible and trustworthy
- The process of the learning review/investigation will also be benchmarked against the involvement and engagement standards committed to by The Group.

Patient safety partners

The Patient Safety Partner (PSP) is an evolving role developed by NHS England and Improvement to help improve patient safety across the NHS in the UK and is involved in the designing of safer healthcare at all levels in the organisation. At this current time neither Trust have appointed Patient Safety Partners; however, aspects of the role are included in the existing Patient Involvement Partner Programme, led by the Patient Experience Team. The Trusts are exploring how this role can work in the diverse communities The Group serves, and how equity can be achieved.

PSPs are intended to support the Trusts in their commitment to value, listen and provide meaningful involvement opportunities for patients, their carers and families and staff in the ongoing patient safety work of the organisation. Principally their role is to support a culture that is 'patient centred'. Most PSPs should not have worked for either Trust or the NHS so they can bring an independent, neutral perspective. Scope for involvement for PSPs is via wide range of activities including, but not limited to:

- Acting as a patient/family advocate at learning review meetings
- Supporting the proof reading of learning review reports from the lens of family/lay person
- Participating in task and finish groups
- Supporting the exit evaluation by patient/families and staff of their involvement experiences
- Participating as a member of an observation group during the conduct of a systems wide assessment

All PSPs should have a lived experience as a patient, carer, family member or as a member of the local community.

PSPs will be supported in their role by the Group Patient Safety Specialist and the Patient Experience Team for the Trusts who provide expectations and guidance for the role, along with any support requirements they may need to maximise their opportunities for involvement and ensure they are fully supported and enabled. PSPs will have regular scheduled reviews and one-to-one sessions with the Patient Experience Team and/or Group Patient Safety Specialist. PSPs are volunteers not employees of either Trust.

Addressing health inequalities

Health Inequalities, and inequality in the way staff, patients and their families are involved and engaged in learning reviews after unexpected and unintended harm are real issues. The Group is already committed to delivering on the statutory obligations under the Equality Act (2010). This includes a zero tolerance of racism in all of its forms, discrimination in all of its forms, and unacceptable behaviours[6] arising from and/or toward our workforce; and also arising from and/or towards our patients/service users, carers and families. The Group recognises there is a core role to play in reducing inequalities in health by improving access to services and tailoring those services around the needs of the local population in an inclusive way.

The commitment of The Group to the core principles of the national framework means that in this specific aspect of our work we must be alert to indictors of health inequality in our care provision, and inequality, and inequity in how we approach, and engage with our staff, patients and their families in the after-harm learning review and investigative processes.

A key question for our clinical assessment staff to ask and answer, after harm will be the presence or absence of health inequality in terms of access to the necessary care pathway, and in the design of and delivery of that pathway, including communication routes with our patient(s), relevant health professionals, and relevant other health and social care partners.

A key question of our patients, their families, who have been involved in the after-harm learning processes, will be related to the extent to which they considered the care pathway to be universally accessible to them regardless of their background, colour, orientation or social standing, or disability (physical, cognitive, mental health and neurodivergent).

For our staff similarly, their experience of being engaged in the learning review process, information will be gathered about cultural heritage, colour, orientation, etc, and this information will be used to determine whether non-white and/or non-British born, or non-heterosexual members of staff report differing experiences relating to the engagement and involvement agendas. Also, the number of referrals for professional performance review. All information gathered will need to be balanced against the cultural mix of all professionally employed, and support staff employed so the data analysis is not skewed.

[6] Examples of unacceptable behaviours include but are not limited to being unkind, unprofessional, excluding others or not listening

Oversight:
Discerning whether inequality and inequity is a feature that contributed to a harm event or poses a day-to-day threat to both Trusts commitment to delivering its statutory obligations as set down in the Equality Act (2010) is challenging. Meaningful and credible consideration of this is achieved as a component of The Group's approach to the planned in-depth assessments from its local priorities.

Consideration of equity and inequality will also be included for the narrower focus of an individual event review through. Templates such as structured assessment method and the approach chosen for contributory factors analysis following significant care misses. How information is captured over time will require careful scrutiny to enable meaningful conclusions to be reached after individual event reviews, as well as aggregated thematic analysis.

Examples of the considerations for contributory/systems-based analysis will be questions such as:

- Availability of easy read treatment information leaflets
- Accessibility and timeliness of interpreters
- Appropriate use of appropriate artificial intelligence (AI) translation tools
- Accommodating neurodiversity needs
- Reasonable adjustments being made in systems and processes for physical and mental health disability

Where the evidence is presented that inequality and/or inequity negatively impacted on care and service delivery, and the system design has inbuilt error producing opportunities in this respect, recommendations for improvement will be made. These will then be considered in line with the Group's approach to the accepting, or not of recommendations using good risk management principles, alongside the principle of As Low As Reasonably Practicable (ALARP).

Patient safety incident response planning

The two primary routes for reviewing and learning from unexpected and unintended patient safety events are:

- The patient safety review (PSR)
- The patient safety incident investigation (PSII) of which two mechanisms are employed (a) Patient Safety Individual Event Review (PSIER) or (b) PSII (Improvement Project)

This section of the policy sets down the agreed approach to the local priorities chosen for the Group.

The flowchart included in Appendix 2, depicts what is to happen to all events that result in a moderate or greater impact for the patient (as well as events where there is evidence indicating a significant concern), regardless of whether the event meets the Groups' or the national threshold for a Patient Safety Incident Investigation. Appendix 3 shows the process steps for a local area. We have determined that a sensible assessment of the event is required first to support the objective of proportionality. This includes selecting the most appropriate review and investigatory approach and having a clear rationale for decisions made regarding the depth and breadth of review/investigation conducted.

It is expected that the dominant patient safety review (PSR) approaches to sense check and screen events of harm or significant concern will be:

- Rapid review
- A Corporate SWARM
- Structured Audit/gap analysis/change analysis
- Structured Assessment

These approaches are deliverable and sustainable within our limited resources and practical for clinical areas that are increasingly under pressure.

The After-Action Review (ARR) and Learn Together Event (LTE) are approaches that frontline senior leaders have stated their support for in principle. The most significant obstacle is the time to arrange them and taking clinical and support staff off the frontline to participate. Therefore, it will be determined at Directorate/Care Group leadership level where and when these approaches can be achieved. Appendix 4 highlights the process for Directorates/Care Groups

The individual event review is reserved for events where significant/serious concerns are raised via audit, structured assessment, or rapid review, about the care and management of the patient. In this circumstance, a robust approach is required that facilitates an appropriate depth of assessment and analysis. It is anticipated that the number of such events will be low, but when they do occur the standard of learning

review, and principles employed will mirror the PSII requirement for systems thinking, and the application of systems assessment tools on a proportionate basis. Undoubtedly degrees of systems analysis/contributory factors analysis will be required.

Note: Despite the similarity to a PSII, individual event reviews are not to be confused with the PSII process, which should deliver a more substantial systems assessment and analysis approach. Appendix 5 provides a visual display of the filtering process from event through to consideration for PSII local priority.

The process The Group has agreed to for its PSII local priorities is as follows:

- Each local priority will have defined boundaries targeting a specific aspect of the area of interest (refer to Patient Safety Incident Response Plan). For each local priority theme, and its agreed area of focus a Systems Analysis Project Group will be formed. This will comprise of:
    - A patient safety leader,
    - An individual skilled and experienced in Quality Improvement methodology,
    - Research & Development (R&D) guidance and expertise.
    - A representative group of staff who work in the system under analysis,
    - A governance/safety facilitator,
    - Administration support.
    - Advice and support from Health Innovation West Midlands and its Human Factors Community of Practice.

- The purpose of each project group will be to:
    - Map the pre-existing systems and processes in place, which are intended to minimise the risk of the patient safety issue under analysis
    - To employ a range of tools and techniques designed to assist the mapping and assessment of the system in place
    - Conduct a failure modes and effects analysis on these systems to clarify known weak points, and discernible weak points, and their likely impact on the system under assessment
    - Seek information from a credible sample of staff working in the system about what they understand about the system in terms of, what they know to work well, and know to underperform
    - To take a sample of cases where the issues under review have been identified and to determine whether there are common elements leading to the problem

- To determine whether the current system design, and operation delivers a situation in the day to day where risk exposure is already at its lowest level possible, and thus the Group can demonstrate reasonable best, and 'safe enough' in line with the Health & Safety Executive (HSE) principle of As Low As Reasonably Practicable (ALARP)
- Where 'safe enough' cannot be demonstrated, or where ALARP is met, but risk exposure remains intolerable, a safety action recommendation will be presented to the Risk Management Executive Group or Quality and Safety Group. The presentation of the safety actions will reflect good practice standards in recommendation formulation, and subsequent implementation plans will meet the Health Foundation good practice standards (2013).

- Where individual events (harming or near miss) occur that match the subject and specific area under assessment (i.e. PSII project aims), a pre-agreed screening tool will be applied so that information relating to it, and the system, can be taken into the overarching systems analysis work. This screening tool will also enable a proportionate approach to be taken to the ongoing evaluation and/or investigation of the individual event.
  - **Note 1:** Where a harm has occurred that meets the threshold for the statutory Duty of Candour, the relevant Trust will collaborate with the patient/patient's family, in line with the Duty of Candour Policy, to enable the Group to meet its legal obligations. This enables the Group to 'do the right thing' and to deliver its ethical and moral obligations, without the risk of becoming entangled with the wider systems analysis work.
  - **Note 2:** Where it is determined that an individual in-depth investigation (PSII) is necessary because of unique features of the event or the magnitude of impact, dedicated key lines of enquiry will be formulated in partnership with the patient/family and the service(s) involved. The individual in-depth investigation PSII will be linked to the systems analysis project (PSII Improvement Project), and overseen by the project lead, who will be Band 8A equivalent or more senior. The timescales and project plan for delivery will be agreed between the project lead, the appointed investigation team, and the patient/family. In most instances this will not exceed six months.

National Priorities:

Where The Group is aware that several 'national priority' events have occurred in the preceding 12-24 months prior to the implementation of PSIRF, these subjects will be treated like the identified local priorities. This means a proactive systems analysis

project team will be convened, and the treatment of individual events that occur over the life of the project, and this policy document, will be a component of the wider systemic evaluation. This enables the Group to optimise its scarce resource, and to perform meaningful systemic analysis and identify meaningful safety improvement opportunity alongside the ability to demonstrate where the system is well designed and working as intended.

Where the Group has no history of experiencing a particular national priority event, should the situation arise, a contained, structured, systems analysis approach will be taken in line with PSIRF policy expectations.

At the end of the Patient Safety Incident Systems Analysis Project

Each project team will formulate a technical report setting down:

- A clear picture of the system at the start of the project, where it is well designed and working, and elements that require redesign, or other types of improvement
- The report will be systems orientated and will not comment specifically on individual events, or the staff involved in them. Where individual events are referenced, they will only be notated by their Datix reference number. This protects the anonymity of the patient and the staff,
- Where a single event has occurred that required an individual in-depth investigation or a Patient Safety Individual Event Review (PSIER) using systems thinking (a systems-based contributory factors analysis approach), the findings will be written up in a dedicated report template that will mostly mirror the new national PSII report template[7]. Further, where such a review/investigation was necessary the Group will deliver all its engagement and involvement commitments as set down in this policy in the consideration of the interim report through to its conclusion and final acceptance.

[7] The Group may adapt this template, so it meets the needs of its intended audience, i.e. the patient and his/her family. However, the primary headings in the national template will remain.

Responding to patient safety incidents

Day to day arrangements for reporting and responding to patient safety events

The approach in both Trusts remain the same. PSIRF does not change any of the established reporting, and local action arrangements in the immediate aftermath of a near miss or harm event. Specified incidents continue to require external reporting to national bodies. The Assurance Team will liaise with relevant Trust departments to ensure this happens. For full details and guidance see the Trust's Incident Reporting and Monitoring Procedure 1 (OP10) for Royal Wolverhampton and Trust's Incident Reporting, Learning and Management Policy (OP917) for Walsall Healthcare.

Local autonomy, responsibility, and accountability

A feature of the Serious Incident (SI) Framework for England 2013 and 2015 was a loss of local autonomy, responsibility and accountability for how patient safety events were responded to. PSIRF provides a good opportunity to restore this situation.

Now each local leadership team responsible for the area in which an event happened will have clear responsibilities to support staff, the patient and their family, to preserve good quality information and memory of situational context, alongside an initial rapid review of all moderate and greater harm events.

Each Directorate/Care Group leadership team will meet on a weekly basis to learn about the initial rapid review. This should provide credible insights to aspects of care that met Trust standards, and areas where this was not achieved.

It will be for the Directorate/Care Group leadership team in partnership with local team leaders to determine credible and defendable next steps (see flow diagram Appendix 1 and 4). Consideration of professional and/or statutory Duty of Candour obligations are considered and planned for here (see OP60 – Royal Wolverhampton and OP929 – Walsall Healthcare). Timescales are also agreed at this meeting.

Bi-Monthly Divisional Review

To prevent a backlog of work each Divisional leadership team, along with the relevant Directorate/Care Group leaders, will be presented the output (findings and conclusions) of the completed reviews. Ideally the individuals tasked with leading this work and their subject advisors, will present. Following this process, which will deliver opportunity for supportive check and challenge, the learning reviewer/team will write up their interim

report for sharing with the staff involved, the patient and his/her family. This process will be in line with the Trusts' engagement and involvement commitments.

Oversight of how incidents are chosen and ensuring none are overlooked:

- Monitoring of patient safety incidents locally, through the Directorate/Care Group's governance meetings will remain the same, supported by their respective Assurance team members.
- A 20% sample of events that are closed following the rapid review, and/or structured assessment and/or audit methods are assessed by an independent group of professionals in the directorate/care group or division with Assurance Team involvement. The purpose to determine the rate of agreement regarding learning review outcome. A confidence rate of 95% is sought.
- A 20% sample of events reviewed via After-Action Review or a Learning Together Event is undertaken to determine whether or not it was reasonable not to progress to a more in-depth individual event review/PSII investigation
- A 10% sample of individual event reviews and individual PSII will be undertaken to determine whether the approach was proportionate and a fair and reasonable use of scarce NHS resource.

Oversight of the outputs of Patient Safety Reviews:

Once presented as complete, each findings report, or detailed letter of findings proposed to send to a patient/family will be assessed by:

- A relevant technical advisor(s)
- A lay person/patient safety partner
- A member of the Divisional/Care Group leadership team
- Someone identified as a competent proofreader and editor

An assessment tool will be used for uniformity and consistency which will address:

- Technical accuracy
- Readability and understandability
- Robustness of evidence base where criticisms are made about a patient's care and management
- Tone (compassionate, empathetic, objective and balanced)
- Key lines of enquiry clearly set down and responded to
- Grammar, syntax, and spelling
- Systems focused safety, practice, and quality recommendations

A focus on safety action development and monitoring improvement

PSIRF promotes the term ‘areas for improvement’ (Figure 1) instead of ‘recommendations’. The rationale for this is to limit the practice of taking a recommendation and translating that into an action plan without embracing any of the good practice features of effective action planning. This has been referred to as ‘solutionising’.

Alongside the practical and auditable approach to effective action planning identified via the Health Foundation’s Safer Clinical Systems Project (2008 – 2013) the Group will draw on the process for developing safety actions outlined by NHS England in the Safety Action Development Guide (2022):

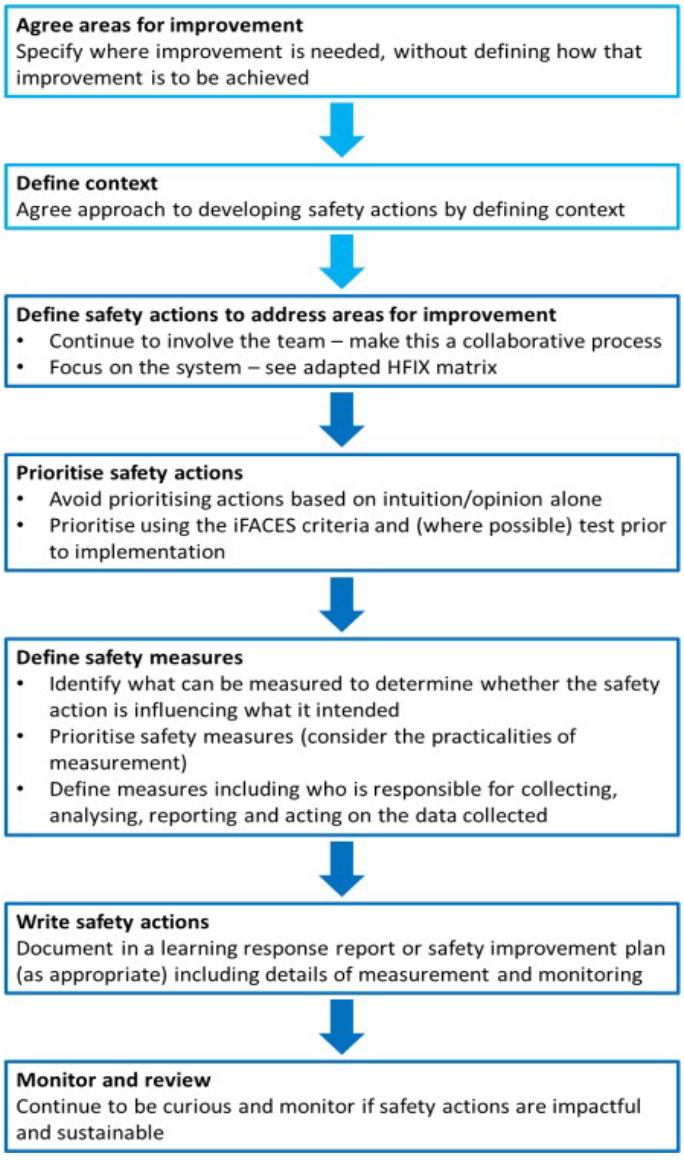


Figure 1: Safety Action Development Process

Oversight of recommendations agreed for implementation:

The corporate, and/or the divisional safety and governance groups will:

- Audit the robustness of action implementation plans to ensure they meet the Health Foundation Standards as set down in its safer clinical system project findings (2013)
- Assess whether the right people were appointed to the action planning / task and finish group
- Seek information about the impact of actions implemented and the sustainability of improvements achieved
- Where impact cannot be determined, the corporate / divisional safety and governance committee will commission further work to address this, and the above cycle repeated

In addition to the above, the existing Corporate, Divisional and Directorate/Care Group safety and governance related group and committees will instruct quarterly thematic analysis of agreed safety improvement actions to ensure that there is no duplication of work.

Optimising safety improvement success

The Quality Improvement (QI) Teams across the Trusts will be integral members of the Divisional and Corporate Safety and Governance Committees so that their expertise is always present where safety improvement plans are being considered for support and implementation. Further, QI representation will be a core member of each systems analysis project team, so that tried and tested QI tools and techniques can be efficiently and expertly utilised across the Trusts for the service of these projects.

The active presence of QI professionals and team members will also ensure that each project team is fully informed about related projects already being undertaken and/or completed within a contemporary time frame. This will avoid unnecessary duplication of work and will help ensure the scarce time and energy resource of all involved, particularly staff engaged in care delivery is used wisely.

Oversight roles and responsibilities – general principles

Responsibility for effective patient safety event management sits with the Trust Boards. This includes supporting and participating in cross system/multi-agency responses and/or independent patient safety incident investigations (PSIIs) where required. The Executive Lead is the Group Chief Assurance Officer who holds responsibility for effective monitoring and oversight of PSIRF.

The Trust, through the Executive lead, has a responsibility to:

1. Ensure the Trust meets the national patient safety response standards
2. Ensure PSIRF is central to overarching safety governance arrangements
3. Quality assure learning response outputs

The approach to oversight set down in this policy documents supports an active approach where improvement and delivery of commitments can be demonstrated. The Trusts are not passive in their approach and believe they have struck the right balance between corporate and group oversight, alongside individual divisional accountability and responsibility. Figure X outlines the oversight and assurance structure.

For clarity the Trust acknowledges the 'oversight mindset' principles that will underpin the processes put in place to allow PSIRF to be implemented in line with the oversight roles and responsibilities specification supporting document[8] (NHS England 2022, p 3).

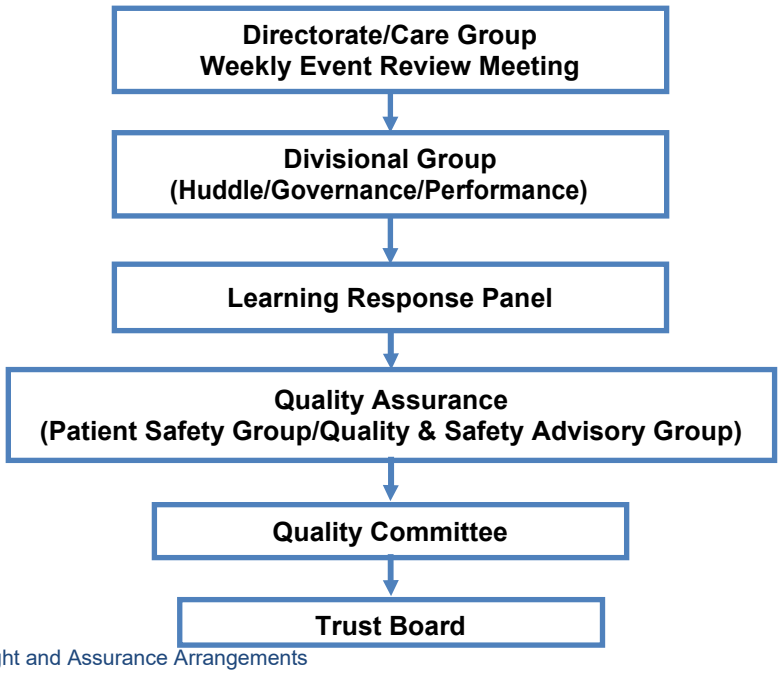


Figure 2: Oversight and Assurance Arrangements

[8] Oversight roles and responsibilities specification

The Trust is firmly committed to partnership working, with the local ICB and other national commissioning bodies as required. Oversight and assurance arrangements will be developed through joint planning.

The Trust will source necessary training such as the NHS Health Education England patient safety syllabus and other patient safety training available as appropriate to the roles and responsibilities of its staff in supporting an effective organisational response to incidents.

Updates will be made to this policy and associated plan as part of regular oversight. A review of this policy and associated plan should be undertaken at least every four years alongside a review of all safety actions.

Complaints and appeals

Any complaints relating to this guidance, or its implementation can be raised informally with the Group Patient Safety Specialist, initially, who will aim to resolve any concerns as appropriate.

Formal complaints from patients or families can be lodged through the Trusts' complaints procedures here for Royal Wolverhampton and here for Walsall Healthcare.

Part A - Document Control

Policy number and Policy version: GOP02 V1	**Policy Title:** Patient Safety Incident Response Policy/Plan	**Status:** Final		**Author:** Dee Johnson, Group Patient Safety Specialist **Chief Officer Sponsor:** Kevin Bostock, Group Director of Assurance
Version / Amendment History	Version	Date	Author	Reason
	1.0	September 2024	Group Patient Safety Specialist	Implementation of Group policy
Intended Recipients: All Staff				
Consultation Group / Role Titles and Date: **Divisional Management Teams** **Quality Nursing Leads** **Sponsor of Policy and Chair of Trust Policy Group**				
Name and date of Trust level group where reviewed	Trust Policy Groups: WHT PMCG – 9.12.24 RWT TPG – **Date TBA**			
Name and date of final approval committee	Trust Management Committees: WHT TMC – 30.1.25 RWT TMC – **Date TBA**			
Date of Policy issue				
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)				
Training and Dissemination: This policy will be communicated to all staff via the Trusts' weekly communications and made available to all staff via the Trust intranet. All primary recipients will be informed of the policy to ensure they can effectively carry out their functions.				
To be read in conjunction with: OP10 Risk Management and Patient Safety Reporting Policy - RWT OP917 Incident Reporting, Learning and Management Policy - WHT OP60 Being Open (Duty of Candour) - RWT OP929 Duty of Candour Policy - WHT				
Initial Equality Impact Assessment (all policies): A national EIA has been completed and therefore an internal assessment is not required**.**				
Monitoring arrangements and Committee				
Document summary/key issues covered: This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out The Royal Wolverhampton NHS Trust and Walsall Healthcare NHS Trusts' approach to developing and				

maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.	
Key words for intranet searching purposes	OP10, Safety, Patient, Incident, Response, PSIRF, Reporting, Patient Safety, Incident Response, Safety Incidents, Patient Safety Incident Response, Incident Response Plan

Appendix 1: Definitions/Glossary of Terms

Term	Definition/Description
As low as reasonably practicable (ALARP)	'As low as reasonably practicable' is the level to which we expect to see workplace risks controlled by weighing a risk against the trouble, time and money needed to control it.
After Action Review (AAR)	AAR is a structured facilitated discussion used by teams when outcomes of an activity or event, have been particularly successful or unsuccessful. It provides individuals involved with the ability to reflect on and contribute to the understanding about why the outcome differed from what was expected. The aim is to capture learning from these to identify opportunities to avoid failure and promote success for the future. It is based around four questions: • What was the expected outcome/expected to happen? • What was the actual outcome/what actually happened? • What was the difference between the expected outcome and the event? • What is the learning?
Change Analysis	A tool to examine a process where tasks are carried out in a prescribed format, in order to determine if any alteration in the way it was carried out had an impact on the incident that occurred. The differences are analysed to understand why the change occurred.
Compassionate engagement	An approach that prioritises and respects the needs of people who have been affected by a patient safety incident.
Contributory factors	Factors that were influential to an event or outcomes. They may be separated in space and time from the actual event itself, and even from outside the organisation.
Deaths thought more likely than not due to problems in care	Incidents that meet the 'Learning from Deaths' (LfD) criteria. Deaths clinically assessed as more likely than not due to problems in care - using a recognised method of case note review, conducted by a clinical specialist not involved in the patient's care, and conducted either as part of a local LfD plan or following reported concerns about care or service delivery.
Duty of Candour	Care Quality Commission Regulation 20 on Duty of Candour describes how providers should be open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things don't go to plan with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things don't go to plan.
Engagement	Everything an organisation does to communicate with and involve people affected by a patient safety incident in a learning response. This may include the Duty of Candour notification or discussion, and actively engaging patients, families, and healthcare staff to seek their input to the response and develop a shared understanding of what happened.

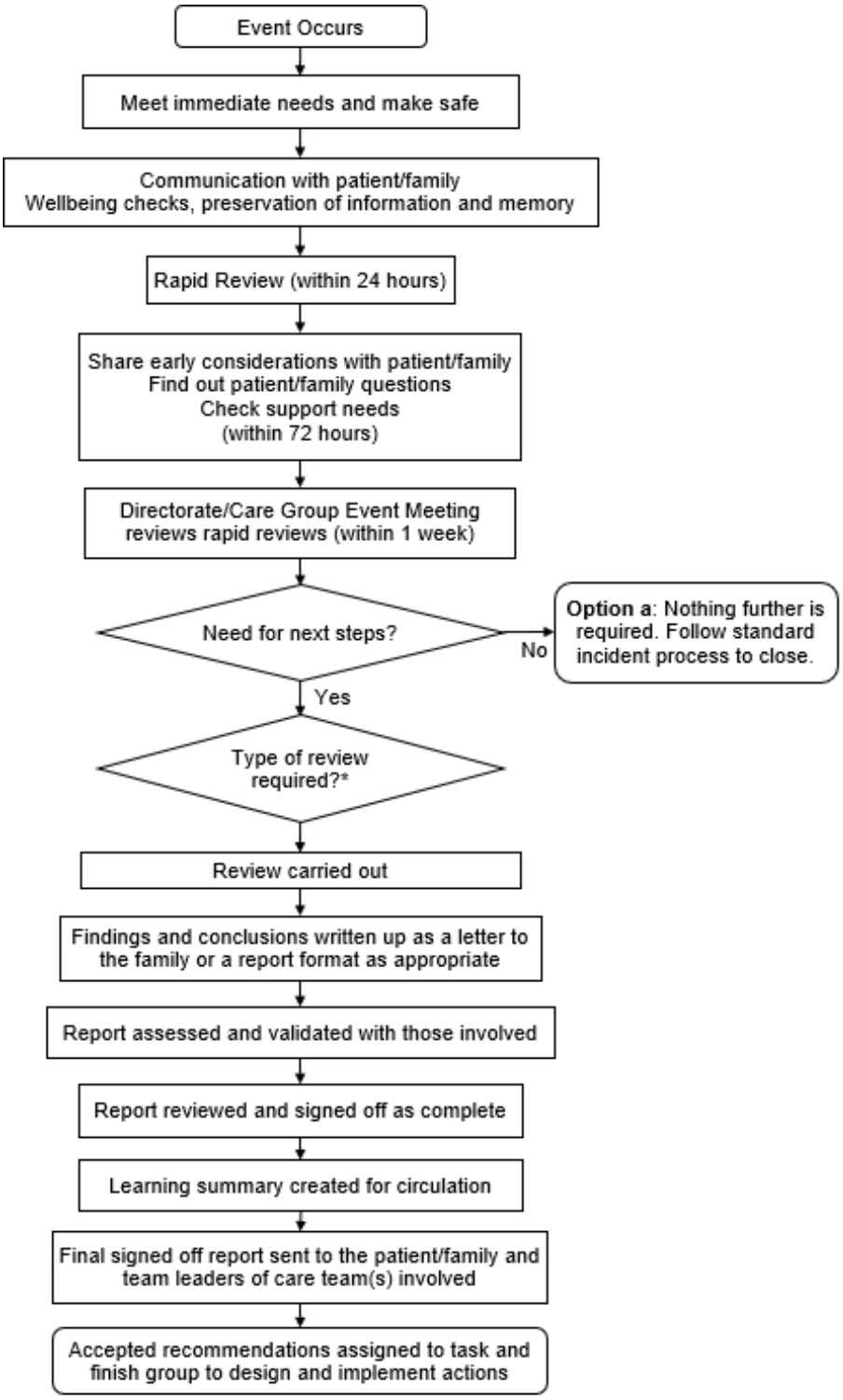
Term	Definition/Description
Engagement Lead	Anyone who leads on engaging with and involving those affected by a patient safety incident. This may be a person leading a learning response or a different dedicated liaison.
Freedom to Speak Up Guardian	Freedom to Speak Up Guardians support workers to speak up when they feel that they are unable to do so by other routes. They ensure that people who speak up are thanked, that the issues they raise are responded to, and make sure that the person speaking up receives feedback on the actions taken.
Gap analysis	The steps taken to support the development of knowledge and understanding of an area of enquiry by identifying evidential gaps to be addressed, to ensure a comprehensive set of evidence informs the analysis and conclusions made within an investigation.
HSIB	Healthcare Safety Investigation Branch (now superseded by HSSIB and MNSI)
HSSIB	The Health Services Safety Investigations Body (HSSIB) is an independent body that conducts major safety investigations into the most serious risks to NHS patients in England.
Involvement	The process that enables patients, families, and healthcare staff to contribute to a learning response.
Just Culture	Just Culture is about creating a culture of fairness, openness and learning in the NHS. This is to make colleagues feel confident to speak up when things go wrong, rather than fearing inappropriately placed blame.
Learn Together Event	A Learn Together Event supports teams to learn from patient safety events: • that occurred in the significant past and/or • where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. • to explore a safety theme, pathway, or a process. The aim is, through open discussion (and other approaches such as observations and walkthroughs undertaken in advance of the review meeting(s)), to understand how care is delivered in the real world i.e., work as done, using experts of that lived experience (it can be structured around a system model such as SEIPS), and to agree key contributory factors and system gaps that impact on safe patient care.
Learning Disability Mortality Review	The Learning Disability Mortality Review (LeDeR) programme was commissioned to improve the standard and quality of care for people with a learning disability
Learning Response	Any response to a patient safety incident that incorporates a systems-based approach to capturing learning to inform safety actions for improvement.
Learning Response Lead	This is someone that has experience and training in conducting patient safety incident responses
LeDeR	Learning Disability Mortality Review

Term	Definition/Description
Maternity and Newborn Safety Investigations (MNSI)	A special health authority, The Maternity and Newborn Safety Investigations (MNSI) programme was formed from 1 October 2023, to undertake investigations into brain injuries in babies and maternal and neonatal deaths and stillbirths.
Never Event	Patient safety incidents that are considered to be wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.
NHS	National Health Service
PALS	Patient Advice and Liaison Service
Patient Safety Incident (PSI)	Any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS funded healthcare.
Patient Safety Incident Investigation (PSII)	An in-depth investigation aimed to identify underlying system factors surrounding an incident or event. It typically includes four phases: planning, information gathering, synthesis & interpreting, and improving. The findings are then used alongside other learning to identify effective, sustainable improvements for a similar incident type. Recommendations and improvement plans are then designed to effectively and sustainably address those system factors and help deliver safer care for patients.
Patient Safety Incident Response Framework (PSIRF)	This is a national framework applicable to all NHS commissioned outside of primary care. Building on evidence gathered and wider industry best-practice, the PSIRF is designed to enable a risk-based approach to responding to patient safety incidents, prioritising support for those affected, effectively analysing incidents, and sustainably reducing future risk.
Patient Safety Incident Response Plan	A Patient Safety Incident Response Plan sets out how an organisation providing NHS care will carry out the PSIRF, including a list of local priorities and how it intends to respond to them.
Patient Safety Partners (PSPs)	PSPs are 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 an NHS organisation.
Patient Safety Review	Patient Safety Review is the approach used to sense check and review events of harm or significant concern. These include Rapid Review, Structured Audit, Gap/Change Analysis, Structured Assessment, After Action Review, Learn Together Event and Individual Event Review.
Rapid Review	Although not a learning response, the rapid review acts as a first stage case note review for an incident to help understand the care given and if there were any problems. The review enables managers to make a safety statement about the care provided and identify if care was reasonable under the circumstances or if further exploration is needed.

Term	Definition/Description
Recommendation	A statement to indicate the system improvement required (also called Areas for Improvement). Recommendations from an investigation will result from analysis of themes identified in an investigation.
Safety Culture	The combination of values, perceptions, beliefs, and leadership styles which define the landscape of an environment or organisation. They are not easily visible without 'diving' below the surface.
SEIPS	See System Engineering Initiative for Patient Safety
Serious Incident Framework	Previous framework to manage reporting and investigating of serious incidents. Replaced by PSIRF.
Structured Assessment	A structured assessment is based on the standard format of a structured judgement review. Reviewers make safety and quality judgements (based against the Trust standards or expectations) on a particular area of care or sequence of events. The assessment considers whether the information that has been captured demonstrates adherence to the documented standards and policies as well as professional expectations, or identifies gaps or adaptations in practice/service/care provided or process. The aim is to be clear on where care and management: • met or exceeded expectations • could have been improved or delivered differently • fell significantly below the requirement and/or was unsafe.
System Engineering Initiative for Patient Safety (SEIPS)	SEIPS is a framework that can be used in understanding the inter-relationships across structures, processes and outcomes in healthcare. It describes how a work system (socio-technical) can influence processes (work done), which in turn shape outcomes. The work systems consist of six elements: external environment; internal environment; tools and technology; tasks; and people. The model proposes people cannot be separated from their work system; therefore, patient safety incidents result from multiple interactions between work factors. When a learning response thoroughly examines the different work system components and their interactions, safety actions can focus on wider systems issues, not individuals.
Systems Based Approach	A systems-based approach recognises that patient safety arises from interactions and not from a single component, such as actions of people. A system-based approach therefore recognises that it is insufficient to look only at one component, such as only the people involved.
Systems thinking	A mindset of ensuring that an investigation explores the multiple interacting contributory factors across the care. The mindset seeks to understand the differing entities and activities that may (over time) contribute to an outcome or an incident.

Term	Definition/Description
Task and Finish Group	A task and finish group is convened to facilitate a collaborative discussion on potential actions to address recommendations/areas of improvement. Its purpose is to ensure safety actions have a defined context, involves the right stakeholders in design and development, and applies a process of scrutiny that ensures actions will be impactful and sustainable.
Team Leader	For the purposes of reviewing patient safety events, a team leader is anyone who acts in the capacity where they are in charge of a department, clinical service or working shift at/or above a Band 6 or equivalent.

Appendix 2: Patient Safety Event Response Process



*Next Steps/Review Options: Option a: Nothing further. Option b: Structured audit or gap/change analysis
Option c: Structured Assessment. Option d: After Action Review
Option e: Learn Together Event. Option f: Individual event review with KLOE

Patient Safety Event Response Process Detail

1. Event Occurs

i. Staff on the ground attend to the immediate needs of the patient and make safe
ii. The senior staff on duty, including the lead doctor/ clinician for the patient communicate with the patient, the patient's family and the staff involved. The purpose of this is wellbeing, and preservation of information and memory
iii. Within 24 hours of moderate and greater harm events occurring the designated Band 7 (or equivalent) +/- the Matron, and the consultant in charge of the patient's care undertake a rapid review
iv. Within 72 hours one of the reviewers speaks with the patient and/or the patient's family to share early considerations, and to find out what questions the patient/family has, and what we (the Trust) can do to provide support at this time
v. Within 1 working week, the information emerging from the rapid review is considered by the Directorate/Care Group Event Review Meeting and next steps are determined

2. Next step options are

a) Nothing further is required
b) Structured audit/gap/change analysis against documented Trust standards
c) Structured Assessment with two seasoned and credible peer professionals
d) After Action Review – individual team event
e) Learning Together Event – more than one team and service
f) Individual event review with agreed key lines of enquiry and most likely a contributory factors/systems analysis component

Timescales for all the above to be agreed on a case-by-case basis. It is expected that options b) – d) are completed within 4-6 weeks. Option e and f are likely to require 10 – 20 weeks depending on complexity.

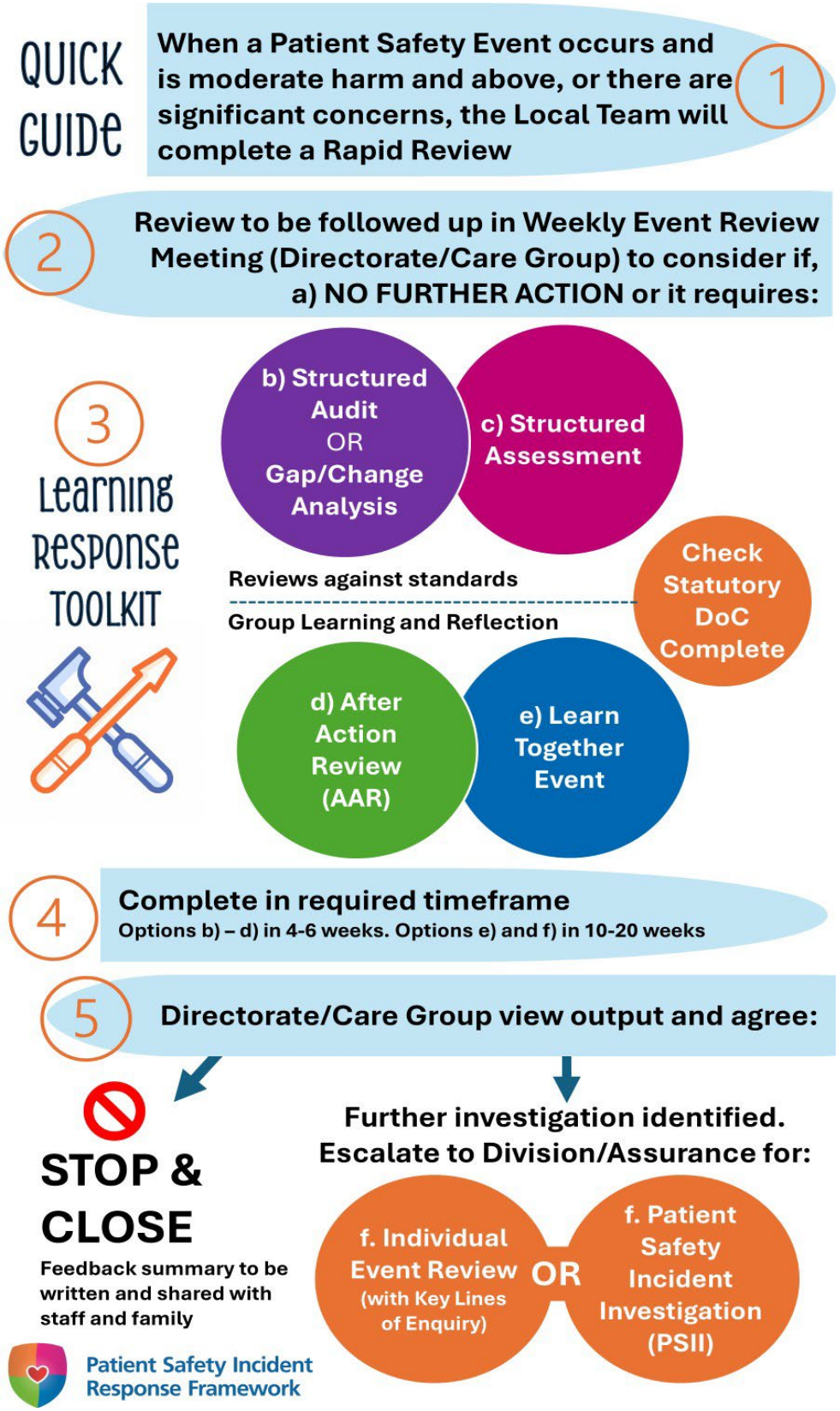
3. Review and Sign Off

i. The findings and conclusions are proportionately written up either as a letter to the family, or in a structured but flexible report format.
ii. The report, following assessment and validation by the involved staff, technical advisers, the patient/family, and senior members of the speciality/ directorate/care group leadership team, is considered by the leaders of the division, and signed off as complete as appropriate.
iii. A learning summary document is created for wide circulation across the division/Trust

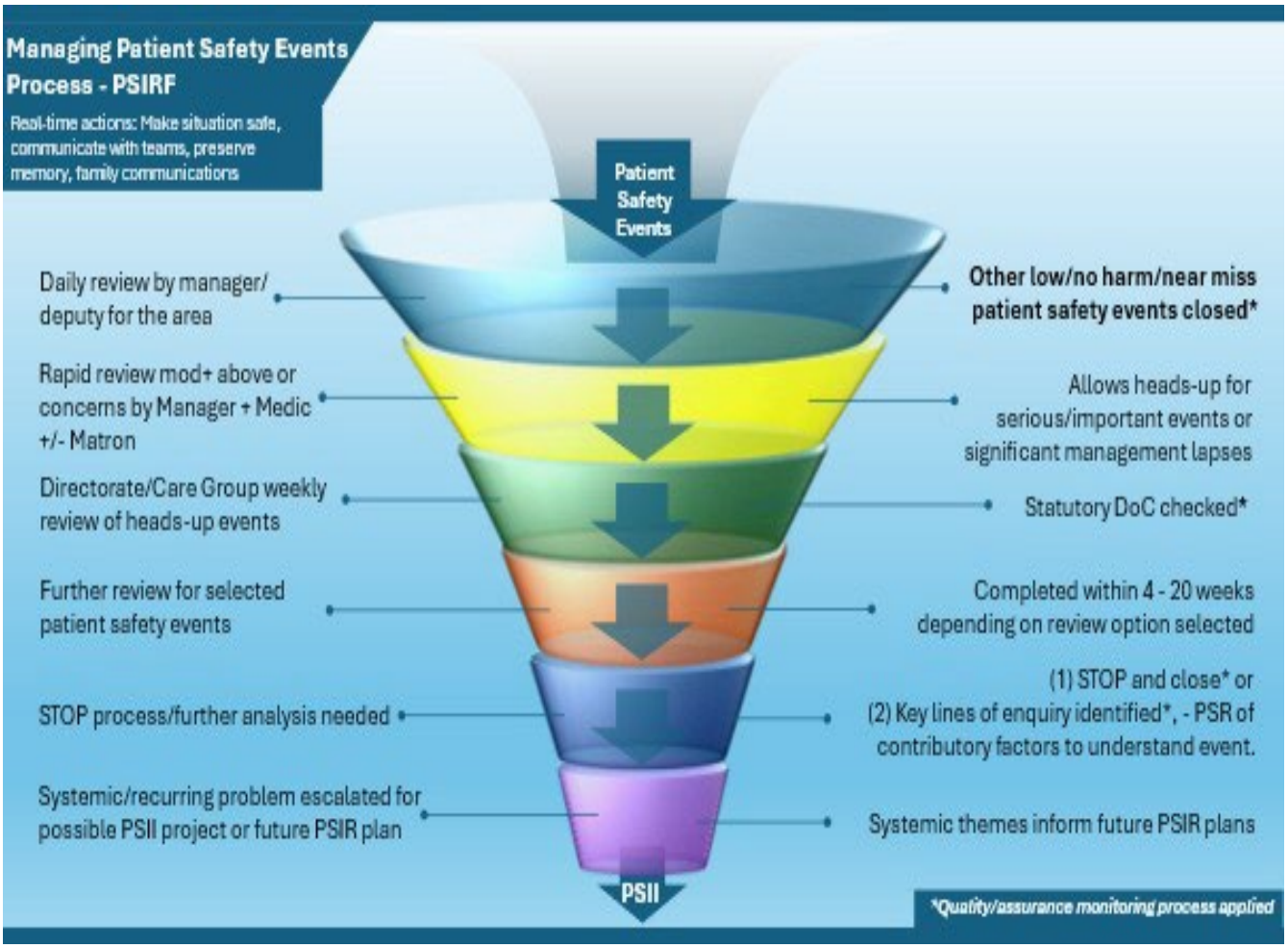
iv. A copy of the final signed off report is sent to the patient/family, and the team leaders of the care team(s) involved.
v. Accepted recommendations are assigned to a task and finish group so that worthwhile action plans can be designed and implemented.

Appendix 3: Patient Safety Event Response – Local Area

Appendix 4: Patient Safety Event Response - Directorate/ Care Group



Appendix 5: Patient Safety Events Process Funnel



Appendix 6

Patient Safety Incident Response Plan

Contents

Introduction

This patient safety incident response plan sets out how The Royal Wolverhampton NHS Trust and Walsall Healthcare NHS Trust intends to respond to patient safety incidents over a period of 12 to 24 months. The plan is not a permanent rule that cannot be changed. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected

Our Services Overview

The Royal Wolverhampton NHS Trust and Walsall Healthcare NHS Trust are registered with the Care Quality Commission to provide services in the following locations:

- New Cross Hospital
- Manor Hospital
- Cannock Chase Hospital
- West Park Rehabilitation Hospital
- Homer Building
- Holly Bank House
- Goscote Hospice
- Community sites
- GP practices

An overview of services provided are:

- Emergency and Urgent Care
- Cardiac and Lung treatment as a regional referral unit
- Surgery
- Maternity
- Diagnostic services
- End of Life care
- Services for children and young people
- Medical care including older people's care
- Critical Care
- Outpatients
- Community Services
- Day case services
- Therapy services
- Rehabilitation services
- GP services
- Pharmacy services

Further information can be found about services offered by each Trust via their websites:

https://www.royalwolverhampton.nhs.uk/

https://www.walsallhealthcare.nhs.uk

Both Trusts provide services to a wide and diverse community embracing many cultures and religions. This has specific relevance to the Trust's PSIRF plan in respect of engagement, inclusivity, and equity.

Defining our patient safety incident profile

In addition to the national priorities set for all Trusts, this document sets out the local priorities for the Wolverhampton – Walsall Group of Trusts and how we intend to address these over the next 12 – 24 months. Our approach will include reference to those national priorities we have experienced previously, and those rare events of harm that indicate that the individual event requires an expansive assessment of the system in which it occurred is required, to discern what happened, how it happened and why it happened through a wide systemic lens.

To discern the local priorities across the group an analysis of information gathered between 2021 and 2024 has been conducted. This has provided an insight into the patient safety incident themes, patterns of recurrence and trends. In conducting the analysis of electronically held qualitative and quantitative information, both Trusts engaged with key stakeholders to sense check what the electronic information said, against their day-to-day experiences of work.

Where a safety issue or incident type was well understood (e.g. previous events have been thoroughly investigated, including the context and underlying system factors, where national or local improvement plans targeted at contributory factors are being implemented and monitored for effectiveness), it was established that resources would be better directed at improvement rather than repeat investigation.

Based on this assessment, local priorities have been chosen that the Group believes represent the best opportunities for systemic evaluation using the principles of the Safety Engineering Initiative for Patient Safety to delivery improved safety, quality and practice.

The stakeholder work combined with the information analysis resulted in the creation of five clinically focused related themes and five other issues that emerged from the information, but which were too broad a subject matter to make a dedicated local priority (Appendix 1 sets down the information sources utilised).

The five patient care themes:

Theme	Sub-themes	Sources of information used to determine this
Responding to patient condition	• *Delays in recognising* • *Delays in escalating* • *Barriers to escalation* • *Sepsis management* • *Deterioration vs. dying patient*	Claims data Mortality data Risk registers Incidents Serious incident data
Delay in treatment and Delay in follow up	• *Lost to follow up* • *Referral management*	Incidents Complaints

	• *MDT processes* • Safeguarding Risk registers	
Admission, Transfer of care and Discharge of patients	• *Handover of outstanding investigations or tasks for patient care* • *Inappropriate transfer* • *Unsafe discharge* • *Unexpected readmission* • *Post-discharge arrangements*	Incidents Quality Surveillance Complaints Safeguarding Risk registers
Diagnostics	• *Urgent/non-urgent pathways for diagnostic requests* • *Incorrect diagnosis* • *Delays in acknowledging significant diagnostic test results*	Claims Serious incident data Risk registers
Medication errors – administrative, dispensing and prescribing	• *Time critical medications* • *Administration delays or non-administration due to prescribing errors or issues* • *Discharge medications*	Incidents Complaints Safeguarding Risk registers

The five other issues emerging were:

- Staff behaviours
- Inequality of care
- Staffing levels
- Lack of involvement of patients in their care planning and decision making
- Communication - of all types, verbal, written and electronic

All five issues are important and are recognised as contributory factors in enabling error producing conditions to flourish. However, as 'priorities' they are challenging to quantify therefore, these subjects will form a component of each of the systems evaluation projects the Group will commission.

The enduring nature of the priorities selected

The five patient care themes identified above are therefore the Group's local priorities chosen for the first 12 – 24 months of the Trusts implementation of PSIRF. It is recognised that over such a period different priorities and issues may emerge that must take precedence. Such decisions will be made by the Learning Response Panel as and when such occasions arise.

Further, should a single event happen, that causes such a degree of harm, and/or poses such a high risk to future patients, and the issues giving rise to it are not easily evaluated or understood, then the Learning Response Panel will commission an appropriate depth and breadth of systemic evaluation and investigation using an approach such as SEIPS (Safety Engineering Initiative for Patient Safety) as it considers necessary and in the best interests of safe patient care delivery. The occasions where such a depth and breadth of investigation is necessary because of a single event is expected to be rare.

Our patient safety incident response plan: national requirements

The list of national priorities requiring a systems-based learning approach when such events happen is extensive. The entire list is set down in Appendix 2. The issues listed below, are those national priorities that the Trusts have previously experienced or consider it a realistic probability that they may experience them over the next 12 – 24 months.

Patient safety incident type	Required response	Anticipated improvement route
Incidents meeting the Never Events 2018 criteria	A proportionate systems-based investigation using the principles of Systems Engineering Initiative for Patient Safety (SEIPS) or other known systems evaluation approach. The approach for the categories of event will be pre-determined to optimise systems-based learning, and the duty of each Trust to meet the needs of the affected patient, their family and staff.	Until the systemic evaluation and investigation is complete it is not possible to pre-determine the learning route or improvement route. However, all safety improvement suggestions and actions where identified, will be considered at divisional and corporate safety and quality groups to discern which will deliver the most improvement impact and sustainability. It is in these groups that the approach to the improvement plan design, implementation and measurement for success will be agreed.
Deaths thought more likely than not due to problems in care (meeting the learning from deaths criteria)		
Maternity incidents meeting Maternity and Newborn Safety Investigations (MNSI) criteria	Refer to MNSI for independent patient safety incident investigation	Consider recommendations made by MNSI , using auditable considerations and Health & safety Executive (HSE)'s principle of As Low As Reasonably Practicable (ALARP).
Child deaths	Referred for Child Death Overview Panel Also conduct proportionate internal learning review or investigation as the initial case screening indicates is necessary.	Consider any improvement recommendations in line with recognised risk management principles, and the HSE principle of ALARP.
Safeguarding incidents in which: • babies, children, or young people are on a child protection plan; looked after	Referred to Trust Safeguarding Lead	Respond to recommendations from referred agency/ organisation as required The Trust Safeguarding Groups will take the lead in this.

Patient safety incident type	Required response	Anticipated improvement route
plan or a victim of wilful neglect or domestic abuse/violence • adults (over 18 years old) are in receipt of care and support needs from their local authority • the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence		

Our patient safety incident response plan: local focus

For the five local priorities previously listed (page 5), the Trusts have agreed the following approach:

For each priority more discrete focal points will be agreed, alongside the departments and services most affected. For example, the subject of 'delay'. A more discrete area may be focus on urgent cardiac assessment referrals. The national standard is two weeks from referral to assessment. A focal point for the Trust may be an examination of the systems and processes enabling or preventing this so opportunity for system improvement is identified and acted on where possible.

1. Once the discrete areas for close examination have been agreed on, for each area/subject the Trusts will design a hub and spoke approach. The hub will represent the detailed in-depth systemic assessment and evaluation work to be undertaken, and the spokes will represent the core activities to be undertaken for each individual event that happens, and which meets the inclusion criteria agreed. This approach enables an evaluation of the system and how it operates on a day to day to basis, alongside any differences that emerge when an untoward event has happened. It is the evaluation of the day to day, and the retrospective post event assessment that will enable the Trust to make informed and sound decisions about how it will use its limited resources to achieve the best safety and performance improvements where the information shows this is necessary.

2. To deliver the hub and spoke approach, a Systems Analysis Project Group will be convened consisting of the following types of staff:
    - The leaders of those services experiencing the highest volumes of the topic (e.g. delay in follow up after urgent referral, or medicines administration errors (oral, IM and IV as subcategories))
    - Frontline practitioners and support staff who do the work
    - Quality Improvement and Research and Development professionals who have a good understanding of information gathering tools and techniques alongside expertise in information analysis
    - At least one systems safety advisor who is expected to have a good appreciation of SEIPS, other systems base approaches, and safety science
    - Administrative and project management support

***Note 1*:** The Hub for each discrete area will include: An evaluation of work as prescribed, work as understood, and work as done. It presents a significant undertaking and will more likely than not, require the investigative tools and techniques of:

- Task Analysis
- Swim Lane Analysis
- Failure Modes and Effects Analysis
- Serial episodes of observation practice in multiple locations and at varying times of the day
- Focus groups
- Interviews
- Semi-structured surveys
- Case Notes Analysis and audit using pre-designed tools
- Contributory factors analysis

The use of these tools/techniques will be determined as part of the project planning process and facilitated with guidance as required. The timescales for the meaningful assessment and evaluation of the relevant system of work is expected to take at least 6 months, possibly longer.

***Note 2*:** The treatment of the individual event as it happens
Each event will be screening against pre-existing standards (where these exist) to discern the degree of adherence and non-adherence to expectations. The outputs of this initial assessment, plus questions contributed by the family/affected patient, will determine the scope of the individual event review.

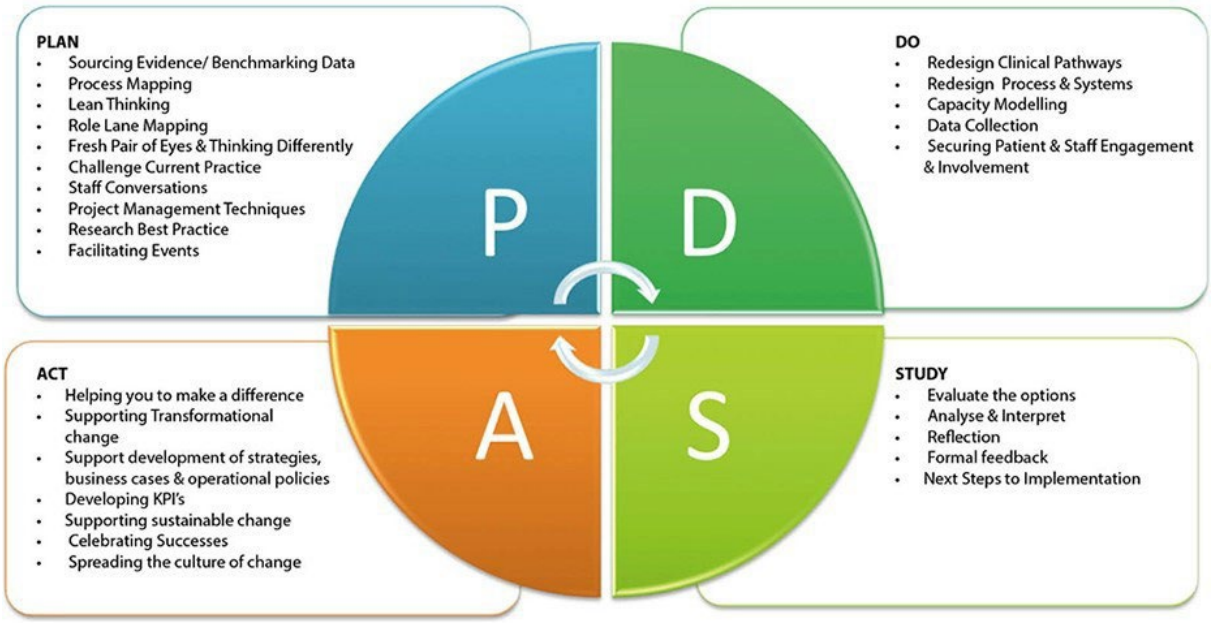
The principles of systems analysis will be applied, and a contributory factors analysis conducted for any significant deviation from expected standards and/or adaptation of care process.

It is expected and anticipated that information gathering tools will be agreed, that allow for individual responses to be made to patients, their family, and affected staff. This will be alongside gathering this information so that thematic analysis can occur efficiently over the period agreed for the entire project, and beyond.

This will prevent the risk of improperly blending or thwarting the intent of the national PSII commitment to systems-based learning. Both Trusts consider the approach agreed will optimise the ability to deliver the intent of PSIRF.

Defining our patient safety improvement profile

Both Trusts have a comprehensive quality improvement programme in place, using the Quality Service Improvement and Redesign (QSIR) methodology. The Plan, Do, Study, Act process forms the basis for our improvement work:



The quality improvement programme has patient safety as a theme of its work. The aim of this theme is that the use of QI methodology will help staff on the front line identify methods to deliver a safer service. The principles underlying this are to:

- Learn from accurate data from mortality, governance, benchmarking, complaints etc.
- Reduce unwarranted variability
- Develop safe reliable systems that support and empower staff to do the right thing, first time and record it correctly

Our improvement priorities are directly informed by our quality and patient safety priorities, identified from patient safety investigations and identification of themes, as well as by key operational and pathway improvement priorities from across the organisation. Future quality improvement priorities will be directly informed by implementation of the PSIRF, providing an opportunity to streamline and prioritise future improvement activity.

Our improvement priorities are supported by a specialist team of improvement practitioners, our Quality Improvement Team who provide support, facilitation and coaching for improvement activity across the Trust as well as providing a range of training/development opportunities to build capacity and capability at all levels of the Trust.

Appendix 6.1: Information Sources

- Incident data 2020-21 to 2022-23
- Key themes from complaints, PALs, claims and inquests
- Key themes from specialist safety and quality groups (e.g., falls, pressure ulcers, Learning from Experience Group)
- Themes from learning from deaths reviews
- Trust and divisional risk registers
- Key themes from FTSU, safeguarding and staff survey
- Key themes from GIRFT
- Key themes from mortality reports
- ICS Quality surveillance reports
- Clinical audit data

Appendix 6.2 National event response requirements[1]

Event	Action required	Lead body for the response
Deaths thought more likely than not due to problems in care (incidents meeting the learning from deaths criteria for PSII)	Locally-led PSII	The organisation in which the event occurred
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	Locally-led PSII	The organisation in which the event occurred
Incidents meeting the Never Events criteria 2018, or its replacement.	Locally-led PSII	The organisation in which the event occurred
Mental health-related homicides	Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII Locally-led PSII may be required	As decided by the RIIT
Maternity and neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to HSIB or SpHA for independent PSII	HSIB (or SpHA)
Child deaths	Refer for Child Death Overview Panel review Locally-led PSII (or other response) may be required alongside the panel review – organisations should liaise with the panel	Child Death Overview Panel
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) Locally-led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this	LeDeR programme

[1] Guide to responding to proportionately to patient safety incidents p20

Event	Action required	Lead body for the response
Safeguarding incidents in which: • babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence • adults (over 18 years old) are in receipt of care and support needs from their local authority • the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence	Refer to local authority safeguarding lead Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards	Refer to the local designated professionals for child and adult safeguarding
Incidents in NHS screening programmes	Refer to local screening quality assurance service for consideration of locally-led learning response See: Guidance for managing incidents in NHS screening programmes	The organisation in which the event occurred
Deaths in custody (e.g. police custody, in prison, etc) where health provision is delivered by the NHS	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations Healthcare organisations must fully support these investigations where required to do so	PPO or IOPC
Domestic homicide	A domestic homicide is identified by the police usually in partnership with the community safety partnership (CSP) with whom the overall responsibility lies for establishing a review of the case Where the CSP considers that the criteria for a domestic homicide review (DHR) are met, it uses local contacts and requests the establishment of a DHR panel The Domestic Violence, Crime and Victims Act 2004 sets out the statutory obligations and requirements of organisations and commissioners of health services in relation to DHRs	CSP