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Document purpose	Inforn	nation and guida	nce		
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Approving meeting	Quality Committee Meeting date 4 <sup>th</sup> April 2024		24		
Implementation date 4 <sup>th</sup> April 2024		oril 2024	Review date	30 <sup>th</sup> April 20	)27
Trust documents to be read in conjunction with					
4.40 Being C	Open Duty of Candour				
4.26 Listenin	Listening and Responding PALS and Complaints Policy				
Document change history			Version	Date	
What is different? Replacing policies 5.32 Serious incider policy update		t			

Patient Safety Incident Response Framework Policy

What is the impact of change?		
Training		
requirements		
Document consultation		
Directorates		
Corporate services		
External agencies		
Financial resource implications		

Appendices / electronic

forms

Sustainability	<ol> <li>Reduce the environmental impact of health and social care in Staffordshire and Stoke on Trent □</li> <li>Build a network of climate and sustainability champions across Staffordshire and Stoke on Trent □</li> <li>Share learning and best practice □</li> </ol>
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#### External references

- 1. NHS England » Patient Safety Incident Response Framework
- 2. NHS England » Patient Safety Incident Response Framework and supporting guidance
- 3. <a href="https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-1.-PSIRF-v1-FINAL.pdf">https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-1.-PSIRF-v1-FINAL.pdf</a>
- 4. <a href="https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-2.-Engaging-and-involving...-v1-FINAL.pdf">https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-2.-Engaging-and-involving...-v1-FINAL.pdf</a>
- 5. <a href="https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-3.-Guide-to-responding-proportionately-to-patient-safety-incidents-v1.1.pdf">https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-3.-Guide-to-responding-proportionately-to-patient-safety-incidents-v1.1.pdf</a>
- 6. <a href="https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-4.-Oversight-roles-and-responsibilities-specification-v1-FINAL.pdf">https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-4.-Oversight-roles-and-responsibilities-specification-v1-FINAL.pdf</a>
- 7. <a href="https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf">https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf</a>
- 8. <a href="https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-6.-PSIRF-Prep-Guide-v1-FINAL.pdf">https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-6.-PSIRF-Prep-Guide-v1-FINAL.pdf</a>

Monitoring		
compliance	with the	
processes	outlined	
within	this	
document		

Annual review of policy, review via CSIG committee for assurance and compliance

Ec	uality Impact Assessment (EIA) - Initial assessment	Yes/No	Less favourable / More favourable / Mixed impact
	pes this document affect one or more group(s) less or more	e favourably	than another (see
lis	i) (		
_	<b>Age</b> (e.g., consider impact on younger people/ older people)	No	
-	<b>Disability</b> (remember to consider physical, mental and sensory impairments)	No	
-	<b>Sex/Gender</b> (any M/F gender impact; also consider impact on those responsible for childcare)	No	
_	<b>Gender identity and gender reassignment</b> (i.e., impact on people who identify as trans, non-binary or gender fluid)	No	

<ul> <li>Race / ethnicity / ethnic communities / cultural groups (include those with foreign language needs, including European countries, Roma/travelling communities)</li> </ul>					
<ul> <li>Pregnancy and maternity, including adoption (i.e., impact during pregnancy and the 12 months after; including for both heterosexual and same sex couples)</li> </ul>					
<ul> <li>Sexual Orientation (impact on people who identify as lesbian, gay or bi – whether stated as 'out' or not)</li> </ul>	No				
<ul> <li>Marriage and/or Civil Partnership (including heterosexual and same sex marriage)</li> </ul>	No				
<ul> <li>Religion and/or Belief (includes those with religion and /or belief and those with none)</li> </ul>	No				
<ul> <li>Other equality groups? (may include groups like those</li> </ul>					
living in poverty, sex workers, asylum seekers, people					
with substance misuse issues, prison and (ex) offending					
population, Roma/travelling communities, and any other					
groups who may be disadvantaged in some way, who may					
or may not be part of the groups above equality groups)					
If you answered yes to any of the above, please provide details below, including evidence					
supporting differential experience or impact.					
Enter details here if applicable					
If you have identified potential negative impact:					
- Can this impact be avoided?					
- What alternatives are there to achieving the document with	nout the impact?				
Can the impact be reduced by taking different action?  Enter details here if applicable					
Do any differences identified above amount to discrimination					
and the potential for adverse impact in this policy?	No				
If YES, could it still be justifiable e.g., on grounds of promoting equality of opportunity for one group? Or any other reason	Yes / No				
Enter details here if applicable					
Does this document affect one or more group(s) less or more favourably than another (see					
list)?					
Where an adverse, negative or potentially discriminatory impact on one or more equality					
groups has been identified above, a full EIA should be undertaken. Please refer this to the					
Diversity and Inclusion Lead, together with any suggestions as to the action required to avoid					
or reduce this impact.					
For advice in relation to any aspect of completing the EIA assessment, please contact the					
Diversity and Inclusion Lead at Diversity@northstaffs.nhs.uk					
Was a full impact assessment required?	Yes / No				

## Training Needs Analysis for the policy for the development and management of Trust wide procedural / approved documents

Please tick as appropriate

What is the level of impact?

Patient safety incident response framework policy

Low / medium / high

There are no specific training requirements- awareness for relevant staff required,	
disseminated via appropriate channels	
(Do not continue to complete this form-no formal training needs analysis required)	
There <u>are</u> specific training requirements for staff groups	
(Please complete the remainder of the form-formal training needs analysis required-	
link with learning and development department.	

Staff Group	✓ if appropriate	Frequenc y	Suggested Delivery Method (traditional/ face to face / e-learning/handout)	Is this included in Trust wide learning programme for this staff group (✓ if yes)
Career Grade Doctor	✓			
Training Grade Doctor	✓			
Locum medical staff	✓			
Inpatient Registered Nurse	✓			
Inpatient Non- registered Nurse	✓			
Community Registered Nurse	✓			
Community Non-Registered Nurse / Care Assistant	<b>✓</b>			
Psychologist / Pharmacist	✓			
Therapist	<b>✓</b>			
Clinical bank staff regular worker	<b>✓</b>			
Clinical bank staff infrequent worker	✓			
Non-clinical patient contact	✓			_
Non-clinical non patient contact	✓			

Please give any additional information impacting on identified staff group training needs (if applicable)

	ource that has informed the training requir Confidential Inquiry/NICE guidance etc.	ement outline	d within the
Any other additiona	al information		
Completed by	Craig Stone	Date	03/05/2023

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## **Purpose**

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out **North Staffordshire Combined Healthcare 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.

The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

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 each service within the portfolio of services by North Staffordshire Combined Healthcare Trust

Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property 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 are response types that are outside of the PSRIF remit such as complaints, human resources investigations, professional standards investigations, coronial inquests, criminal investigations, claims management, financial investigations and audits, safeguarding concerns, information governance concerns, and estates and facilities issues however these will be managed via other trust processes.

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, 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 should not influence the remit of a patient safety incident response.

## Our patient safety culture

Meaningful learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. PSIRF supports the trusts patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents.

It is important that our approach just culture is being able to explain the approach that will be taken if an incident occurs in a way that support understanding the identification of lessons that are learnt as a result of a patient safety incident occurring and not apportioning blame when an incident does occur, adhering to this policy it will help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Those affected include staff and families in the broadest sense; that is: the person or patient (the individual) to whom the incident occurred, their family and close relations. Family and close relations may include parents, partners, siblings, children, guardians, carers, and others who have a direct and close relationship with the individual to whom the incident occurred. This policy uses the term 'engagement lead' to refer to anyone who leads on engaging with and involving those affected by a patient safety incident. These engagement leads have been identified as Quality Improvement Lead Nurses (QILN) or Service Managers as the role is required to be of a senior staff member (Band 8a or above) in accordance with national guidance.

The key components for fostering the right culture are identified as follows:

**Leadership** – Managers and/or leaders should demonstrate their commitment to compassionate engagement and involvement in their words and actions. Engagement and involvement must be communicated as a genuine priority and not a formality. For example, investment should be made in developing expertise in patient, family and staff support, engagement and involvement (e.g., through providing dedicated time and training for those undertaking and/or developing specific liaison roles across the organisation or system as required).

**Training and competencies** – PSIRF sets specific expectations regarding the training and competencies required for engaging and involving those affected by patient safety incidents. Engagement leads must attend a minimum of six hours of training in 'Involving those affected by patient safety incidents in the learning process

**Support systems** – Families and staff may need to be signposted to support at any point during engagement or involvement in a learning response. We need to assure that there is equity in the support offered to families and staff, and that systems exist for internal and external support so that those affected can access support in the way they prefer wherever

possible. Sources of support for families may include bereavement and mental health services as well as via independent advocacy services.

Support for staff following patient safety incidents also needs to be factored into an overall response and this can include mental health first aid, CISM, staff counselling and well-being.

**Ensuring inclusivity** – Engagement with those affected and their involvement in patient safety reviews must take account of individual needs, the individual affected is the best person to advice on what their needs are, and they should be acted on where appropriate

**Information resources** – Those affected by a patient safety incident must have clear information about the purpose of a learning response, and what to expect from the process. The following will also be made available as to what the expectations are for NSCHT.

- Reviewer guidance: supports patient care reviews to involve patients, families, and staff in learning responses
- Patient and family information booklet informs the patient and their family about how to get involved in learning response.
- Staff information booklet informs staff about how to get involved in learning response.
- Patient safety incident response record supports and prompts investigators to undertake specific involvement activity in individual investigations.

**Processes for seeking and acting on feedback** – As an organisation NSCHT will maintain a curiosity about the effectiveness of how we conduct our business and patient safety is no difference. In addition, the feedback received from patient safety incident responses will be collated with that from other teams for instance Patient Experience Team (PET), to drive further improvement.

Processes for managing dissatisfaction – Where the mutually agreed expectations have not been met in relation to patient safety, families and staff must be given meaningful, open and honest as well as clear explanations into why this was not achieved.

## Patient safety partners (PSPs)

The patient safety partners at North Staffordshire Combined Healthcare Trust are a key component of our patient safety team and are involved in our approach to managing and improving our patient safety outcomes and profile.

Our intention is to use them as subject matter experts as well as that direct link with our patients, service users and families by getting them visible on the inpatients ward areas as well as scoping out the need for this level of intervention in our community services, this will be an ongoing item of work during 2023/24.

With the support of PSP we will start to understand our incident profile from a differing perspective and a different lens this will help us to review the incidents in further detail and offer a differing viewpoint to help challenge the current position as well as support ongoing learning from incidents as well as reporting these back in a manner that is conducive for patients as well as their families.

The profile of PSPs will be one that continues to grow and there will be an increased visibility within our meeting and governance structures, with this growth we will also introduce these PSPs into oversight groups/committees to support feedback to a senior level of the work being completed and/or planned.

## Addressing health inequalities

The Trust recognises that the NHS has 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 Trust as a public authority is committed to delivering on its statutory obligations under the Equality Act (2010) and will use data intelligently to assess for any disproportionate patient safety risk to patients from across the range of protected characteristics.

Health inequalities are evident within society and our challenges at NSCHT, using PSIRF and how we are able to utilise the data we do collect from reported incidents we are able to utilise an inquisitive approach to help review the data to establish and understand the profile of our patient groups and to highlight any evident inequalities that may occur such as health status, access to services, wider determinants of health and their own demographic details/protected characteristics i.e. ethnic background, sex, sexual orientation and disability.

The way these factors combine and interact with each other also influences the health inequalities people experience, by being inquisitive within our patient review forms this allows some of that detail to be reviewed within systems engineering initiative for patient safety (SEIPS) and other human factors and these can be reviewed and added to the overall incident to provide further detailed review of the patients in a holistic way. If there were any lessons learnt from these, they can be detailed in the patient review response and safety actions added and completed.

These outcomes will form the basis of our learning and we will share this information with those that have been involved in the construction of the patient safety review, where there is wider systemic learning then these would be shared via the learning lessons platforms to share these findings across the organisation to help improve any inequalities for others that use our service to improve their own health and well-being.

# 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. It is the role of the patient safety incident investigation (PSII) oversight and learning lead to be the lead point of contact for patients, families and staff.

At the onset of all patient safety reviews, the patients, families and staff will be invited to take part of the process of reviewing the incident. This will be via letter in the first instance offering details of the reviewer and invite to contact them to agree or not to participate within the patient safety review.

Where there is acceptance to this every effort will be made to meet the identified person/s in a manner that is agreeable and safe for them which can be in person, by virtual platforms or via telephone contact.

The contact will be ongoing and completed as agreed at the outset introductory meeting however there is an expectation of frequency during the patient safety review process as directed below.

Patient Safety Incident Response	Contact at which point
Rapid review / Swarm Huddle / MDT review / After action Review (AAR)	Upon initiation of review to offer an understanding of the incident their family member had been involved in

Patient Safety Review (PSR) / Comprehensive Safety Review (CSR) / Falls PSR	When review is commissioned the identified family member will be written to inviting them to be a part of the review process
Patient Safety Incident Investigation (PSII) / Thematic review / Independent review	When review is commissioned the identified family member will be written to inviting them to be a part of the review process

At all points the staff involved will continue to review the incident in relation to the being open policy and where the threshold is met for Duty of Candour (DoC) (moderate level of harm or higher) then the reviewing person / governance group will review the information available with lessons learnt and findings to see if there has been a deficit in care and as a consequence moderate or higher harm was caused either physically or psychologically. If duty of candour applies, then the policy will be followed in relation to how we respond to patients and family members in offering that compassionate and meaningful apology for the deficit received in their care. It is important to recognise that patients, relatives and/or carers can be adversely affected by a serious incident. They may have questions about what has happened and should have access to appropriate support and information, such as discussion/explanation and should be supported by the most appropriate senior person.

It is important that the following policy is reviewed should the duty of candour be identified as applicable, and the policy followed as directed.

#### 4.40-Being-Open-Policy-Inc-Duty-of-Candour.pdf (combined.nhs.uk)

addition. а Patient advice and liaison we have service (PALS) (patientexperienceteam@combined.nhs.uk). People with a concern, comment, complaint or compliment about care or any aspect of the Trust services are encouraged to speak with a member of the care team. Should the care team be unable to resolve the concern then PALS can provide support and advice to patients, families, carers, and friends. PALS is a free and confidential service and the PALS team act independently of clinical teams when managing patient and family concerns. The PALS service will liaise with staff, managers and, where appropriate, with other relevant organisations to negotiate immediate and prompt solutions

PALS can help and support with the following:

Advice and information

- Comments and suggestions
- Compliments and thanks
- Informal complaints
- Advice about how to make a formal complaint

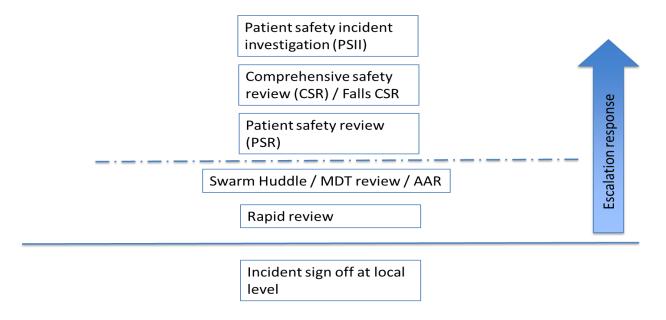
If the PALS team is unable to answer the questions raised, the team will provide advice in terms of how to obtain the response that the person raising the concern/complaint is seeking.

## Patient safety incident response planning

PSIRF supports organisations 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 by NHS England, CQC, Ofsted organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

We will engage with our external auditors / governing bodies to engage them with our approach and to highlight how we review incidents, learn from them as they occur and to provide feedback to all and openly engage with those affected.

At North Staffordshire Combined Healthcare Trust, we have adopted and escalation approach to our proportionate approach to managing patient safety reviews starting from Ulysses incident sign off and escalating as below:



All patient safety reviews commence from the incident form sign off by the designated ward / team management, the sign off will be enhanced to review areas against SEIPS methodology as well as human factors.

If there is an area of concern, then a rapid review would be required to review the incident in more detail to help understand the learning opportunities. Where there has been a death of a patient that falls within our criteria for review then the rapid review

would need to be completed within 72 hours so that we can have an immediate understanding of the incident and establish early learning if identified.

Where there is a parallel report being completed for instance a PSII for in-patient death, domestic homicide review or never event then this will take precedent and an initial review will be completed via rapid review to establish early learning lessons awaiting an outcome of the enhanced review process.

If following the designated proportionate patient review (Rapid review, swarm huddle, MDT review or after-action review) there is any further need to review the incident in more depth to enhance the learning then the next level of review can be commissioned i.e., proportionate review  $\rightarrow$  (next level)  $\rightarrow$  patient safety review  $\rightarrow$  comprehensive safety review  $\rightarrow$  PSII

# Resources and training to support patient safety incident response

#### Our patient safety incident response plan

Our plan sets out how **North Staffordshire Combined Healthcare Trust** intends to respond to patient safety incidents over a period of 12 to 24 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.

We will triangulate all data that we do have available from incidents reports, patient safety reviews, complaints to help understand our presenting profile which in turn will support the understanding of what response is required, this can be with local teams and providers to external partners or stakeholders to provide that support and assurance for that wider collaborative approach. Where there are any gaps or trends that require attention then a consideration is made to involve the use of current/existing quality improvement (QI) methodology to support sustainable and continued change.

With this local data being understood via inquisitive enquiry then this can be measured against regional or national data to see if this is a local issue that requires a bespoke approach or if we are being affected by wider national issues and pressures and need to work in that way to support our local response. The main source of this data will be from learning from patient safety events (LFPSE) as well as the national confidential inquiry into suicide and safety in mental health (NCISH), reports are annually produced for these to allow the profile to be reviewed at board level for oversight, awareness and assurance.

#### **Training**

The Trust has implemented a patient safety training package available on LMS to ensure that all staff are aware of their responsibilities in reporting and responding to patient safety incidents and to comply with the NHS England Health Education England Patient Safety Training Syllabus as follows:

- Essentials to patient safety for all staff
- Essentials of patient safety for boards and senior leadership team

In addition to this there are additional training to enhance further learning:

- Access to practice systems thinking and risk expertise
- Access to practice human factors and safety culture

For those with oversight and learning lead roles will complete the required training elements that are mandated to complete this role.

#### 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 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 months.

Updated plans will be published on our 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 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

The management of incidents forms via the Ulysses incident management system is part of the risk management framework for North Staffordshire Combined Healthcare NHS Trust (hereafter known as the Trust).

The Trust recognises that incident reporting is essential for developing a robust proactive safety culture and aims to maintain an open and fair process. It is committed to ensuring that incident being reporting is encouraged, that incidents are investigated in a consistent way and that lessons learnt are shared within the organisation to reduce the likelihood of similar incidents occurring.

This guidance sets out a framework for identifying and minimising risks, for the protection of patients, staff, visitors, contractors, services and the Trust. This policy provides guidance to all staff in respect of managing incidents and near misses which may occur within the Trust. The Trust acknowledges the vital importance of robust systems and processes for ensuring that the underlying causes of any incident are not simply attributed to the actions of those individuals involved. They must also ensure effective and systematic exploration of all factors which may have potentially contributed to the root causes of the incident, such as the policies, systems, processes and culture that those individuals were working within at the time of the event itself.

To support the staff in the identification, reporting and minimizing of risk the Trust will ensure that there is a programme of education and awareness in relation to risk management and incident reporting.

Where the incident is reported as a patient safety incident (PSI) with the definition of Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare, the Ulysses reporting form will allow exploration of this via additional elements with additional taxonomy to help understand the incident profile based upon national datasets. These will be automatically sent to the learning from patient safety experience platform (LFPSE). Where the incidents do not meet this threshold then they will be kept within Ulysses and not sent out to LFPSE. All data is available for review locally.

The requirement by the ward / team management is that the completed incident forms on Ulysses are reviewed and appropriately signed off within 7 days of submission so that safety concerns can be identified, allows a timely response to reviewing the incident that has occurred, engage with those affected to understand what we can learn. If this deadline is breached then the POST team will be seeking assurance that the breached incidents are updated and reviewed, failure to adhere to the 7-day deadline will result in the directorate senior management team being informed to help resolve any barriers to this. By delaying the learning opportunity review will lead to possible increased risk of reoccurrence and increased harm to patients, family and staff

Where there has been an identified concern raised with system issues then these would be raised with the PSIRF lead for the respective organization for discussion and review. If there is no resolution at this stage, then the local ICB would be contacted to help support and facilitate the discussion required to review the patient safety incident.

#### **IPC**

Where there has been a patient safety incident in relation to an infection and prevention control measure then the review process would be a twofold approach, where there is established reviews such as outbreak meetings then these would be used to monitor and review the situation, however if the incident relates to a matter outside of this regular review process then at least an after action review would be completed to ascertain findings of the incident as the proportionate response to the incident occurrence.

#### Governance

The Clinical Safety Improvement Group has a standing agenda item for open serious incidents and will be updated by the Directorate Service Manager or representative of the Service Manager at each meeting and will reflect actions arising from the meeting via the meeting action monitoring schedule.

Minutes of the Clinical Safety Improvement Group will be available to the Quality Committee and will be submitted in a summary report to the committee. Minutes of the Quality committee meeting will be included in the monthly Trust Board meeting.

Senior managers will receive weekly synopses of all open SI's with progress statement update each week.

Directorate Service Managers will be responsible for tracking progress implementation and impact upon practice of action plans and will provide a monthly update on action plan progress to CSIG as a standing agenda item. Once completed the Service Manager is responsible for forwarding the completed action plan to the Patient and Organisational Safety Team for uploading onto the Trust care review database.

Action plans arising from investigations will be agreed and written by the Directorate Service Manager and the relevant team leader/ward manager and agreed at Directorate level prior to submission with the SI report. Each action plan will have an identified person who is responsible for delivering the action.

The Directorate Service manager will be responsible for updating CSIG on the progress of completed action plans at intervals of 6 months and 12 months. This update will detail changes in practice and provide assurance as to the changes being embedded into practice.

#### Sign off process

The process for appropriate sign off that is agreed within the required timescales (See table Timeframes for learning responses), however the following will be used as the approved standard for approval of patient safety reviews

Approver	Reviews in scope	Remit	Timeframe for completion
QILN	Rapid review / Swarm huddle / MDT review / After action review	Check for factual accuracy, spelling and grammar is correct, all aspects completed as required to support accurate review of patient care	30 days
Clinical Director	PSR / CSR where there has not been a death related to the incident	To review the care offered and provide feedback and seek assurance of care delivery in preparation for chief medical officer review.	60 days
Chief Medical Officer	All sent requiring chief medical officer approval due to proportionate review completed as a result of a death	To review report into incident and seek assurance of learning from incident and to confirm/challenge the details in relation to service delivery and identified treatment offered.	60 days

For all commissioned PSR / CSR there will be a meeting called at the 30-day mark

Patient safety incident response framework policy

to review the report completed so far and will include the following people:

- Care reviewer
- Ward/team manager
- QILN
- Associate director (or authorised deputy)
- Head of patient safety (or authorised deputy)
- Service manager

At this review stage the QILN overseeing the care review will co-ordinate and chair this meeting. The care review will look at all aspects of care and at the end of the meeting an agreement will be made on whether the review is appropriate for next level approval by the associate director. If this is not the case, then at this point an extension would have to be formally requested to allow time for due diligence to occur for remaining review processes. An extension may not always be granted but will be reviewed on a case-by-case basis.

Associate directors will then have up to 15 days to review the report, provide feedback/support/challenge to the review, and obtain feedback from the reviewer. In this also is the need to obtain QILN approval prior to re-submission to the associate director. Once the associate director has approved the review it is then sent on to the chief medical officer for final validation.

At this stage, the chief medical officer has a further 15 days to review the report, provide feedback/support/challenge to the review, and obtain feedback from the directorate. If further responses are required then this must also be completed as above within this period, however at this point the chief medical officer can mandate an extension based upon their findings from the report if this is required to support additional learning. An extension may not always be granted but will be reviewed on a case-by-case basis.

## Patient safety incident response decision-making

The decision-making process for patient safety incidents can be complex but with the guidance from PSIRF it has allowed organisations to become more responsive a respond in a proportionate manner to allow the exploration of learning around the incident rather than focusing on the causation of the incident. With this the below will identify a method of use to follow when we are starting to review our patient safety incidents. In addition, we can focus on using data intelligently to allow the identification of themes and trends and allow us to respond appropriately to manage the presenting risks and reduce the likelihood by sharing lessons learnt from these clustering of incidents.

#### **Emergent themes and trends**

Within the patient and organisational safety team we will utilise the data collection from the incident management system Ulysses to help identify themes and trends of incidents occurring across the trust, with the intelligent ways of monitoring this data it allows us increased visibility of data such as time of occurrence, areas of occurrence, identified patients, incident profile/cause and then associated harm. Not all incidents will require extended inquisitive enquiry and will be managed at local team/ward level by the respective management team, however where there are discernible trends notified during the incident sign off process or by the oversight group being the incident review group then we can request a specific review into patient safety incidents based upon levels of concern with emerging trends, the lowest element of review would be a rapid review into these incidents to understand the profile and learning, this can continue to escalate to other learning responses dependent upon the level of concern raised or found as a result of the rapid review.

#### Appropriate response framework

The below table is constructed to act as a guide to the required level of patient safety proportionate response required, with all frameworks it will act a as a guide to support the appropriate decision making in relation to what response is required for which incidents. The response is not linear and if due to review and further enquiry a further details review is required, or the risk has increased because of the review then the next level of reviews can be completed.

Activity /	Description	Impact score threshold for	<b>Examples</b> However not an exhaustive list, please contact POST /
Learning		activity	PSII oversight lead for support if required
Response		•	
Ulysses incident form	Standard response to all identified patient safety	Identification of patient safety	Any patient safety incident regardless of impact
completion	incidents	incident	
Rapid review	This is completed on incidents where there was a deviation from the perceived normal outcome requiring review into circumstance to identify concern and mitigation for this episode of care.	Patient safety incident that meets threshold of minor impact	Medication errors, self-harm, violence and aggression, post notification of a death to be completed for initial review and findings (within 72 hours)
	This would be completed as a precursor to any death of patient in receipt of service (last 6 months) to determine further patient review response.		
	To be completed if request is received from an external reviewer in relation to a current PSII, if further learning response is required then this can be agreed upon to illicit the correct response.		
MDT review / After	These should be completed where there has been a	Patient safety incident that meets	MDT review / AAR - Falls, medication error leading to harm
Action Review (AAR)	deviation from the perceived normal outcome requiring further review due to the impact of the incident to patient care.	the threshold of minor / moderate impact	caused, self-harm leading to treatment required, patient on patient incidents
	These reviews are to be completed alongside CSIM or formal debriefs if there has been psychological trauma identified from the incident as to not adversely affect staffs wellbeing. If concern please review appropriateness with PSII oversight lead		
Patient Safety Review (PSR)	This is completed on incidents where there has been a deviation from the perceived normal outcome where we need to explore potential implications of care delivery in care that require a detailed review to understand the circumstances that lead to the event	Patient safety incident that meets the threshold of minor / moderate impact and there is a potential deficit in care identified	Falls leading to a fracture of a minor bone, harm caused direct from episode of care, harm caused requiring external acute hospital treatment, breach of mental health act framework
Comprehensive Safety Review (CSR)	This is completed on incidents where there has been a deviation from the perceived normal outcome where we need to explore potential implications of care delivery that require an in depth review to understand the circumstances that lead to the event	Patient safety incident that meets the threshold of moderate / severe / catastrophic impact and there is a potential deficit in care identified	Injury requiring hospitalisation / complex treatment, death, falls leading to a fracture of a major bone, safeguarding concern as a result of care received

Patient Safety Incident	This is completed when an incident or near-miss	Patient safety incident that meets	Deaths related to care delivery received, death of an inpatient
Investigation (PSII	indicates significant patient safety risks and potential for	the threshold of severe /	detained upon the mental health act, never events
	new learning	catastrophic impact and there is an	
		identified deficit in care identified	

**NB** - It is important to distinguish that the approaches taken can be used in an escalating manner to, so incident forms will always be completed however the proportionate response will be directed by local understanding of the incident and the proportionate response can be selected from the menu available. If there is any concern, please refer to the policy for further direction or contact a member of the POST team for additional support / guidance. All examples are not exhaustive and clinical judgement is required in formulating the appropriate proportionate response in managing the identified patient safety incident

# Additional incidents that are recorded but out of scope for PSIRF

#### Children and Vulnerable Adults Safeguarding Incidents

Incident Reporting and Children: All incidents that occur within the Trust's premises which involve children must be entered onto the trust incident reporting system. Consideration must always be given as to if a child protection referral is required, (this must be completed within 24 hrs). If the incident involves a member of staff who has harmed a child or acted in a way which would deem them to be unsuitable to work with children, then this must **ALWAYS** be reported via the safeguarding team in conjunction with internal management procedures.

Incident Reporting and Vulnerable adults: All incidents should be considered in relation to safeguarding, when the incident involves a vulnerable adult then this should be identified by entering onto the trust incident reporting system and ticking the vulnerable adult box on the incident form. If "harm" has been caused to a vulnerable adult, then this will **ALWAYS** require a vulnerable adult referral. If a Vulnerable adult referral is required, then this needs to be identified by ticking the box which states "Interagency policy invoked;" completing this form will produce a vulnerable adult referral form which needs to be forwarded to the relevant local authority

All safeguarding alerts / referrals must be completed immediately and **always within 24 hours**. Relevant policies are detailed on the front page of this policy

#### **Near Miss**

A near miss is an event not causing harm but has the potential to cause injury or ill health. Near misses are as important to record and investigate as those incidents where actual harm was sustained. Near misses can highlight potential problems and allow the organisation to remedy matters before actual harm.

For the purpose of reporting, a near miss must be treated as an actual incident and reported by using the incident reporting form.

### **Dangerous Occurrence**

A dangerous occurrence is one of several reportable adverse incidents as defined in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

## Responding to cross-system incidents/issues

There are occasions where there is a need to work across systems and these are some examples of that are work with coroner's office, medical examiners (at present we do not have these at North Staffordshire Combined Healthcare Trust, however we will have established links with medical examiners locally), incidents of patient safety will be reported by our staff and if there is any external service that may have had a direct impact upon that persons care then the expectation would be that they are invited to the review process to obtain additional support and awareness of service delivery and expected outcomes for that care delivered.

The Patient Safety team will act as the liaison point for such working and will have supportive operating procedures to ensure that this is effectively managed.

If the incident meets the threshold for a PSII then the terms of reference and scope of review would be clearly marked out for specific services involvement and again if there are any barriers to this presented from the service providers, then the local ICB representative would be contacted to help facilitate attendance and support.

Where there is a PSII commissioned where we are not the lead for this learning event, we would complete a rapid review to identify learning that we can use to illicit the next stage approach that we would like to use to enhance the learning outcome form the identified event, as this information would be shared with the lead for the external PSII review upon request.

The Trust will defer to the ICB for co-ordination where a cross-system incident is felt to be too complex to be managed as a single provider. We anticipate that the ICB will give support with identifying a suitable reviewer in such circumstances and will agree how the learning response will be led and managed, how safety actions will be developed, and how the implemented actions will be monitored for sustainable change and improvement.

## Timeframes for learning responses

Activity / Learning	Description	Timescales for completion (*medical director sign off required)							
Response		24 hours	3 days	7 days	14 days	30 days	60 days	90 days	180 days
Ulysses incident form entered	Standard response to all identified patient safety incidents	✓							
Ulysses incident form signed off	Incident form to be signed off by designated manager for ward/team area			✓					
Rapid review	This is completed on incidents where there was a deviation from the perceived normal outcome requiring review into circumstance to identify concern and mitigation for this episode of care		✓ For deaths		~				
MDT review / After Action Review (AAR)	These should be completed where there has been a deviation from the perceived normal outcome requiring further review due to the impact of the incident to patient care					<b>✓</b>			
Patient Safety Review (PSR)	This is completed on incidents where there has been a deviation from the perceived normal outcome where a detailed review to understand the circumstances that lead to the event.					First draft	<b>√</b> *		
Comprehensive Safety Review (CSR)	This is completed on incidents where there has been a deviation from the perceived normal outcome where an in-depth review to understand the circumstances that lead to the event.					First draft	<b>√</b> *		
Thematic review	This is completed on a collection of patient safety reviews where there is a concern raised over a particular element.						First draft	<b>√</b> *	
Patient Safety Incident Investigation (PSII)	This is completed when an incident or near-miss indicates significant patient safety risks and potential for new learning							First draft	<b>√</b> *

The above table looks at the timeframes for completion of the patient learning responses, it covers across all areas and focuses upon sign off timescales however were indicated there is a first draft timescale attached and these are for a comprehensive review at the halfway point to ensure trajectory for completion and to discuss any pertinent areas of lessons learnt and for highlighting.

A learning response must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one to three months of their start date. No learning response should take longer than six months to complete.

Extensions can be considered based upon clinical direction/request and would be agreed upon to maintain the integrity of the review into patients care, however this would need to be done at the earliest opportunity available.

There is an expectation that within the first 72 hours of a patient safety incident occurring requiring further review beyond the Ulysses incident form sign off then a care reviewer will be assigned to complete the review and patient and organisational safety team (POST) team. If there are any concerns with adhering to this timescale, then this should be reported to the POST team and remedial actions put into place.

Once a care reviewer has been identified then a verbal update would be given to the POST team, this will be done via established weekly meetings for this to be completed.

## Safety action development and monitoring improvement

All our patient safety incident reviews include the ability to record learning opportunities and outcomes of the reviews that then directly translate to meaningful actions to enhance the patient safety profile.

While safety action development may be led by one individual (e.g., a learning response lead) or team, a wider team must be engaged during development, including the local team, the quality improvement team and those with broader knowledge of ongoing improvement work related to the defined areas of improvement, or whose work may be informed by the findings from the learning response under consideration.

Quality improvement colleagues are a valuable resource for tools to develop safety actions and associated measures. Where possible, those affected by the patient safety incident should also be involved

Action plans arising from patient care reviews will be agreed and written by the Directorate Service Manager and the relevant team leader/ward manager and agreed at Directorate level prior to submission with the patient care review. Each action plan will have an identified person who is responsible for delivering the action. Directorate Service Manager will be responsible for tracking progress implementation and impact upon practice of action plans and will provide a monthly update on action plan progress to CSIG as a standing agenda item.

Once completed the Service Manager is responsible for forwarding the completed action plan to the Patient and Organisational Safety Team for uploading onto the Trust patient safety incident database.

The Directorate Service manager will be responsible for updating CSIG on the progress of completed action plans at intervals of 6 months and 12 months. This update will detail changes in practice and provide assurance as to the changes being embedded into practice.

The directorate feedback can be done via a delegated/authorised person if this person is not the service manager i.e., quality improvement lead nurse (QILN).

By early review of patient safety incidents, we can start the early understanding of incident profile and make meaningful change to patient care / treatment pathways. By utilising this approach fits alongside the trusts wider vision of utilising quality improvement to help sustain meaningful change that increases the delivery of services, this then can be made available to across the trust via the Life QI platform to allow transference of projects across teams / service lines.

The key points of safety actions are as follows:

- 1. Identify the measures Consider what can be measured to increase confidence that the safety action is influencing what it was intended to
- Prioritise and select safety measures To prioritise your safety measures, consider the practicalities and data available to provide assurance to the action being achieved.
- 3. Define the measure Once a measure has been selected, it must be clearly defined so that it is consistently recorded, reported, and understood across the organisation.





4. Safety actions should be SMART (specific, measurable, achievable, relevant, time bound).

The Clinical Safety Improvement Group (CSIG) will provide oversight of these and contribute to sharing of these learning lessons across all service lines within the trust, any areas of concern would be able to be challenged and assurance requested on reoccurring themes/trends and to understand the barriers/challenges in reducing the likelihood of occurrence.





## Safety improvement plans

The Clinical Safety Improvement Group will review all open patient safety reviews monthly ensuring that any concerns or actions to be taken arising from patient's safety reviews are recorded in the group minutes and an action monitoring schedule maintained for progress and completion of actions.

Safety action plans for each safety review will be reviewed at 6 monthly and 12 monthly intervals to ensure that there is embedded learning, and these will take place during the directorate governance meetings or within service line meetings

Aggregation of numbers, themes, trends and links with complaints, PALS, claims and safeguarding reports will be monitored and analysed via the Trust quarterly Learning from Experience report which will reflect qualitative and quantitative data presented in a standard template.

The report will be facilitated by the Performance Team and be made available to the Quality Committee and Trust Board prior to submission to Commissioners. In addition, the report will be presented at the Directorate Management meetings and cascaded through directorate structures.

The Trust will ensure that there is a system in place to ensure that "lessons learned" from incidents and investigations are shared and disseminate throughout the organisation. The process will support the Trust's efforts to reduce adverse incidents of a similar nature occurring in other areas of the organisation and externally where appropriate.

Learning following patient safety incidents is essential, not only for the ward/team that has been directly affected by the incident, but relevance to other teams and services across the Trust must be considered and shared

The Trust philosophy is to view feedback from patient care reviews and recommend actions arising out of review reports and associated actions as valuable information about the quality of the service we deliver and how we can strive to improve.

Learning from serious incidents to ensure that positive change occurs will be facilitated in the following ways:

- Operational debriefing following a patient safety incident to reflect on the incident will serve as an opportunity to consider the wellbeing of the team affected and provide an opportunity to consider current systems and ensure safe systems are completed to avoid further re-occurrence of an incident. Operational debrief should occur as soon as is practicable following the incident, ideally prior to the end of that shift. The team/service manager will be responsible for ensuring this is completed.
- Care reviewer to offer feedback to the ward/service area team to inform on the findings of the investigation, reflecting on notable practice, lessons learned, identified causative factors and any recommendations following executive director agreement for submission to commissioners.





- Ward/service area will complete an action plan in conjunction with the directorate Service Manager in response to investigation recommendations to ensure initial local ownership and improvement to ensure safe practice.
- Bi-Monthly learning lessons events where an anonymised single case study/investigate or a collection of investigations with common themes are presented to a multidisciplinary audience. This can include GPs, commissioner, UHNM and any other external parties as appropriate.





## Oversight roles and responsibilities

At North Staffordshire Combined Healthcare Trust the role of oversight and learning leads will be the same person but to have these across all directorates to help enhance the clinical awareness of the challenges and successes for those specific directorates and service lines as well as spreading the resource so that there can be resilience put into our oversight structure and allow the potential for challenge cross directorates to help enhance the learning from our incidents.

The identified staff member for this oversight role and learning lead are from the senior staffing group (band 8a and above) and have the ability to have their time protected to complete the required elements of oversight of safety incident reviews as well as completing PSII, the designation or role is not specific across the organisation and the senior leadership in the directorates have nominated the key people within their areas to appropriately support this requirement within our PSIRF plan.

The staff identified will lead on the governance and collation of patient safety response reports and lead on the approval process and escalation to relevant authority for approval, in addition they will lead on trust response PSII reviews when clinically indicated that this is the required proportionate review. They will also ensure that all reviews are completed within the required timeframes and that the learning from these are reported and co-ordinated across the directorate and wider trust. Once this is achieved then the QILN would provide first level approval for the review to be submitted as per governance process.

**The Trust Board** has overall responsibility for governance, including safe clinical and nonclinical practice. The Board will ensure that effective management systems are in place to achieve high standards, the provision of mandatory reports to the Board including minutes of sub-committee meetings.

The Chief Executive Officer (CEO) has overall responsibility for patient safety and risk management within the Trust. The CEO will be responsible for ensuring that the Board, Chairman and Non-Executive Directors are kept informed as appropriate. The CEO will liaise with the Communications Department should media involvement arise following a Serious Incident.

The Chief Medical Officer will be responsible for final approval and ensuring that the report is comprehensive in highlighting the factors for occurrence as well as awareness of safety challenges and subsequent learning opportunities are followed. The viewpoint will be strategic and the review could support wider action across the organisation to support a reduction in likelihood of reoccurrence.

Where there is an external interest then we should actively liaise with these organisations and support them as directed through due process of the PSII process, the PSII process clearly explains to what these are for and who is the lead person for this. Local trust guidance would be to complete a rapid review and decide on next steps in relation to proportionate patient safety review.

When we are reviewing the deaths of our patients we liaise directly with the coroner's office and there is minimal contact with a medical examiner, in addition as any death of our patients under our care would result in a comprehensive safety review (CSR) then we would have minimal involvement with a medical examiner, however if there was a need to liaise with a medical examiner this would be done via the head of patient and organisational safety as well as the





medical lead for mortality to review the concerns and decide the proportionate patient review response.

Where it is required, they will also provide support for other areas if this is required to as a result of leave (planned or unexpected).

The mind-set of the oversight function is to:

- 1. Have improvement as the focus
- 2. Focus on system factors rather than individuals to blame
- 3. Use learning from patient safety incidents as a proactive step towards improvement
- 4. Collaboration with individuals and organisations
- 5. Psychological safety allows learning to occur
- 6. Being professionally curious

The directorate clinical director will be responsible for the second level approval of incidents and they would be checking the clinical impact of the information obtained in the report and to validate and review the evidence provided in the report whilst ensuring that the learning opportunities are highlighted and appropriate recommendations in place to improve safety.

The PSII oversight lead will regularly meet with a member of the POST team to review current progress of all patient reviews, and this will be completed on a weekly basis. Where there are concerns then these will be escalated to the head of patient and organisational safety for further support and resolution. In addition the PSSI oversight lead will report progress and status of action plans at the Clinical Safety Improvement Group ensuring that a programme of audit is implemented to ensure implementation of action plans and record measurable outcomes.

This role will also be the lead named contact who would support with learning responses as well as any ongoing support that may be required above and beyond already offered during this review process.

Furthermore, it will be required that the appointed care reviewer is in receipt of the terms of reference set out for the investigation care review level and the timescales and milestones for completion.

Ensure that the appointed care reviewer is in receipt of all relevant information relating to the incident including completed incident form.

Ensure that each completed care review, (including an action plan, where required) is submitted within the identified timescale. Where reviews are forecast to exceed the agreed timescale; Service Managers will inform the Patient and Organisation Safety Team (POST) at the earliest opportunity, in order that possible extensions to the investigation time scales may be negotiated.

Where there is learning identified that there is a completed action plan to support safety and that the details of these are cascaded for learning purposes, these will be monitored within the patient safety team and added to learning lessons platform and disseminated as required via the learning lessons platform.

The care reviewer will have received the required training to help support the completion of the required patient safety proportionate review, as well as utilising a system learning approach and in accordance with the agreed Terms of Reference, levels and scope of the investigation and within the timescales set out by the Directorate Service Manager. There will be close liaison with POST as well as the PSII oversight and learning lead to ensure that the review is on timescales identified.

The service manager will ensure that any recommendations, learning points and actions are articulated to the teams that they oversee to ensure effective cascade of pertinent information





to the ward/team managers that they oversee, as well as actively collaborating with the completion of these items to ensure learning is completed and evidenced. This is also to be an agenda item to the service line meetings to allow oversight within the governance structure of the directorate.

**The Ward/Team Manager** will ensure that the recommendations, learning points and actions are articulated to their team, as well as actively collaborating with the completion of these items to ensure learning is completed and evidenced. This is also to be an agenda item to the service line meetings to allow oversight within the governance structure of the directorate.

**All staff** have a responsibility for risk management and for reporting incidents. All patient safety incidents must be reported via the electronic Trust incident reporting system Ulysses within 24 hours of the incident occurring or the identification that an incident has occurred and recorded within the electronic patient care record.

The complaints manager will liaise with the Patient and Organisational Safety Team regarding any complaint indicating requirement for a proportionate review in accordance with NPSA guidance and ensure cohesive communication to monitor trends arising from complaints and serious incidents.





## Complaints and appeals

The Trust is committed to providing any service user, families or member of the public with the opportunity to make a compliment, seek advice, raise concerns or make a complaint about any of the services it provides. The Trust views all feedback, as valuable information about how its services and facilities are received and perceived.

The Trust aims to develop a culture that sees feedback and the learning from complaints as opportunities to improve and develop services. In addition, it sees the giving of accurate information about its services and other health- related matters as means of empowering service users and promoting health.

Emphasis is placed on responding to enquiries, feedback and concerns as quickly as possible through an immediate response by front-line members of staff in an open and non-defensive way. However, other processes are also available when desirable or appropriate, through PALS or the Complaints Department.

We are therefore very committed to ensuring that the complaint process is fair to all parties i.e., both complainants and staff. When dealing with complaints we aim to adhere to NHS England's organisation principles and follow the 'Good Practice Standards for NHS Complaints Handling' (Sept 2013)15 outlined by the Patients Association:

- Openness and Transparency well publicised, accessible information and processes, and understood by all those involved in a complaint.
- Evidence based complainant led investigations and responses. This will include providing a consistent approach to the management and investigation of complaints.
- Logical and rational in our approach.
- Sympathetically respond to complaints and concerns in appropriate timeframes.
- Provide opportunities for people to offer feedback on the quality of service provided.
- Provide complainants with support and guidance throughout the complaints process.
- Provide a level of detail appropriate to the seriousness of the complaint. Identify the causes of complaints and to take action to prevent recurrences. •

Effective and implemented learning - use 'lessons learnt' as a driver for change and improvement.

• Ensure that the care of complainants is not adversely affected as a result of making a complaint.

For full details on how to support someone through this process please use the following policy,

4.26-Listening-and-Responding-PALS-and-Complaints-Policy.pdf (combined.nhs.uk)



