Patient Safety Incident Response Policy

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1. INTRODUCTION

The Patient Safety Incident Response Framework (PSIRF) sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety events, for the purpose of learning and improvement.

Patient safety events are unintended or unexpected events (including omissions) in healthcare that could have, or did, harm one or more patients. The PSIRF replaces the Serious Incident Framework (SIF), (2015) and makes no distinction between "patient safety events" and "serious incidents". It removes the "serious incidents" classification and the threshold for it. Instead, the PSIRF promotes a proportionate approach to responding to patient safety events by ensuring resources allocated to learning are balanced with those needed to deliver improvement.

The new framework is not a different way of describing what came before; it fundamentally changes how the NHS responds to patient safety events for learning and improvement.

The PSIRF advocates a co-ordinated and data-driven approach to patient safety responses that prioritises compassionate engagement with those affected, including staff. It embeds a wider system of improvement and prompts significant cultural shift towards patient safety management.

2. PURPOSE

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out how East Coast Community Healthcare (ECCH) will approach the development and maintenance of 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 and which we can also align to ECCH's existing values:

- compassionate engagement and involvement of those affected by patient safety incidents (Accountability, Respect and Support)
- application of a range of system-based approaches to learning from patient safety incidents (Continuous Improvement and Accountability)
- considered and proportionate responses to patient safety incidents and safety issues (Continuous Improvement and Accountability)

- supportive oversight focused on strengthening response system functioning and improvement. (Continuous Improvement, Support, Respect and Enthusiasm)

This policy should read in conjunction with our current patient safety incident response plan, which is a separate document setting out how this policy will be implemented.

3. SCOPE

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

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.

Where other processes exist with a remit of determining liability or to apportion blame, or cause of death, their principal aims differ from a patient safety response. Such processes as those listed below are therefore outside of the scope this policy.

- claims handling,
- human resources investigations into employment concerns,
- professional standards investigations,
- information governance concerns
- estates and facilities concern
- financial investigations and audits
- safeguarding concerns
- coronial inquests and criminal investigations
- complaints (except where a significant patient safety concern is highlighted)

For clarity, ECCH considers these processes as separate from any patient safety investigation. 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.

4. DEFINITIONS

The following definitions are intended to provide a brief explanation of the various terms used within this policy.

Term	Definition

Patient Safety Incident Response Framework (PSIRF)	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 (PSIRP)	Our local plan sets out how we will carry out the PSIRF locally including our list of local priorities. These have been developed through a coproduction approach with the divisions and specialist risk leads supported by analysis of local data.
Patient Safety Partners (PSP)	PSPs can be patients, carers, family members or other lay people (including staff from another organisation) and this offers a great opportunity to share interests, experiences, and skills to help develop the new PSP role and be a part of our team. The Patient Safety Partner (PSP) will offer support alongside staff, patients, families/carers to influence and improve safety across our range of services. The main purpose of the role is to be a voice for the patients and community who utilise our services and ensure that patient safety is at the forefront of all that we do.
Patient Safety Specialist	The Patient Safety Specialist will work to ensure all national patient safety incident response standards are implemented within the organisation and ensure that patient safety is appropriately prioritised and considered across the organisations.
Patient Safety Investigator's (PSII)	Undertake Patient Safety Incident Investigations
Integrated Care Board (ICB))	Integrated Care Boards (or ICBs) are statutory NHS organisations that bring NHS and care organisations together

	locally to improve population health and establish shared strategic priorities within the NHS. They are responsible for developing a plan for meeting the health needs of the population, managing the NHS budget and arranging for the provision of health services in a geographical area. They work alongside integrated care partnerships to form integrated care systems.
Patient Safety Incident Investigation (PSII)	PSIIs are conducted to identify underlying system factors that contributed to an incident. These findings are then used to identify effective, sustainable improvements by combining learning across multiple patient safety incident investigations and other responses into a similar incident type. Recommendations and improvement plans are then designed to address those system factors and help deliver safer care for our patients effectively and sustainably.
Human Factors	Human Factors encompasses all of the factors that can influence the behaviour and performance of human beings in a system. It allows us to understand how people perform under different circumstances and why errors happen.
Systems Approach	A systems approach to investigations considers how a system's structure influences behaviour.
Restorative Just Culture	A restorative just culture is a learning approach to dealing with adverse events that focuses on harm done rather than blame. It aims to repair trust and relationships damaged after an incident. The approach recognises that people make mistakes, while ensuring people are held accountable for their decisions. It allows all parties to discuss how they have been affected, and collaboratively decide what should be done to repair the harm.

5. RESPONSIBILITIES

- **Chief Executive of ECCH** –is overall accountable and responsible to the Board for ensuring that resources, policies, and procedures are in place to ensure the effective reporting, recording, investigation, and treatment of incidents. In practice the Chief Executive will delegate the day-to-day responsibility for this to PSIRF Executive

- **PSIRF Executive** –The PSIRF Executive Lead responsibilities include:
  - Ensuring the organisation meets national patient safety incident response standards.
  - Ensuring PSIRF is central to overarching safety governance arrangements. ○ Quality assures learning response outputs.
  - Provide direct leadership, advice, and support in complex/high profile cases, and liaise with external bodies as required.

- **Patient Safety Specialist** – will work to ensure all national patient safety incident response standards are implemented within the organisation and to ensure that patient safety is appropriately prioritised and considered across the organisation.

- **Patient Safety Partners –** is responsible for offering support alongside staff, patients, families/carers to influence and improve safety across our range of services. Ensuring they are a voice for the patients and community who utilise our services and to ensure that patient safety is at the forefront of all that we do.

- **Patient Safety Investigators** - are responsible for undertaking Patient Safety Incident Investigations in accordance with national guidance and as directed by the Patient Safety Specialist.

- **ECCH Managers** – Are responsible for ensuring that this policy is implemented within all services.

- **ECCH Employees** – Are responsible for the implementation & following of this policy

6. POLICY STATEMENT

ECCH is committed to implementing, monitoring and ensuring compliance with all aspects of the NHS's Patient Safety Incident Response Framework (PSIRF). Ensuring it develops and maintains effective systems and processes for responding to patient safety incidents for the purpose of learning and improving overall patient safety

7. PROCEDURE

7.1 Our patient safety culture

ECCH have worked over a number of years, to move from a retributional approach to types of incidents such as patient safety and workforce, to establishing a restorative just culture within the organisation.

ECCH senior leadership have embraced this work and with support from staff side colleagues and others, have been instrumental in establishing the organisational transition to a restorative just culture.

The main goals of restoration when an incident has happened have been outlined as follows.

- Moral engagement
- Emotional healing
- Reintegration of the practitioner
- Organisational learning
- Prevention

PSIRF will enhance these by creating much stronger links between a patient safety incident and learning and improvement. We aim to work in collaboration with those affected by a patient safety incident – staff, patients, families, and carers to arrive at such learning and improvement within the culture we hope to foster.

This will continue to increase transparency and openness amongst our staff in reporting of incidents and engagement in establishing any learning and improvements that follow. This will include insight from when things have gone well and where things have not gone as planned.

We are clear that patient safety incident responses are conducted for the sole purpose of learning and identifying system improvements to reduce risk. Specifically, they are not to apportion blame, liability or define avoid ability or cause of death.

Our safety culture has also progressed in a positive way with reporting of patient safety incidents improving over time and the introduction of a new incident management system in ‘QUEST’ (**Q**uality/ **U**nderstanding / **E**xcellence / **S**afety and **T**rust) which will simplify internal reporting for staff.

To enhance our safety culture, we encourage safety huddles at all levels of the organisation which consider risks emerging or known and the insight offered from incidents that have occurred and an opportunity to share learning.

We have an established mechanism in place for ‘Freedom to Speak Up’ within the organisation which supports this policy.

We will utilise findings from our staff survey metrics based on specific patient (and staff) safety questions to assess if we are sustaining our ongoing progress in improving our safety culture.

7.2 Patient Safety Partners

The Patient Safety Partner (PSP) is a new and evolving role developed by NHS England / Improvement to help improve patient safety across the NHS in the UK.

At ECCH, we are excited to welcome PSP's who will offer support alongside our staff, patients, families/carers to influence and improve safety across our range of services. PSPs can be patients, carers, family members or other lay people (including staff from another organisation) and this offers a great opportunity to share interests, experiences, and skills to help develop the new PSP role and be a part of our team.

This exciting new role will evolve over time. Within ECCH, the main purpose of the role is to be a voice for the patients and community who utilise our services and ensure that patient safety is at the forefront of all that we do.

PSPs will communicate rational and objective feedback which is focused on ensuring that patient safety is maintained and improved. This may include attendance at governance meetings reviewing patient safety, risk and quality and being involved with contributing to documentation including policies, investigations, and reports. This information may be complex, and the PSPs will provide feedback ensuring that patient safety is our priority. As the role evolves, we may ask PSPs to participate in the investigation of patient safety events, to assist in the implementation of patient safety improvement initiatives and develop patient safety resources, which will be underpinned by training and support specific to this new role in collaboration with the Patient Safety Team, to ensure PSPs have the essential tools and advice they need.

The PSPs will be supported in their role by the Patient Safety Specialist for ECCH who will provide expectations and guidance for the role. PSPs will have regular scheduled reviews and regular one-to-one sessions with our Patient Safety Specialist and training needs will be agreed together based on the experience and knowledge of each PSP.

ECCH's first PSP is in post and the role will be reviewed on an annual basis to ensure the role is kept aligned to the patient safety agenda as this develops.

7.3 Addressing health inequalities.

ECCH 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.

ECCH 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.

Within our patient safety response toolkit, we will directly address if there are any particular features of an incident which indicate where health inequalities may have contributed to harm or demonstrate a risk to a particular population group, including all protected

characteristics. When constructing our safety actions in response to any incident, we will consider inequalities, and this will be inbuilt into our documentation and governance processes. We will also address apparent health inequalities as part of our safety improvement work.

Engagement of patient, families and staff following a patient safety incident is critical to review of patient safety incidents and their response. We will ensure that we use available tools such as easy read, translation and interpretation services and other methods as appropriate, to meet the needs of those concerned and maximise their potential to be involved in our patient safety incident response.

ECCH's commitment to transforming organisational culture to that of restorative justice has already been outlined. Further to this, the organisation has affirmed that it endorses a zero acceptance of racism, discrimination, and unacceptable behaviours from and toward our workforce and our patients/service users, carers, and families. With explicit role modelling led by ECCH's Board, we will use these principles to underpin patient safety training and implement the system-based approach to patient safety responses which is at the heart of PSIRF best practice.

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

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.

ECCH are firmly committed to continuously improving the care and services we provide. We want to learn from any incident, where care does not go as planned or expected by our patients, their families, or carers to prevent recurrence. ECCH recognise and acknowledge the significant impact patient safety incidents can have on patients, their families, and carers.

Getting involvement right with patients and families in how we respond to incidents is crucial, particularly to support improving the services we provide. Part of this involves our key principle of being open and honest whenever there is a concern about care not being as planned or expected or when a mistake has been made.

As well as meeting our regulatory and professional requirements for Duty of Candour, ECCH wants to be open and transparent with our patients, families, and carers because it is the right thing to do. This is regardless of the level of harm caused by an incident. As part of our new policy framework, we will be outlining procedures that support patients, families, and carers – based on our existing Duty of Candour Policy.

In addition, within ECCH, we have a Patient Advice and Liaison Service (PALS). People with a concern, comment, complaint or compliment about care or any aspect of ECCH 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 organisations which can be approached to assist.

We recognise that there might also be other forms of support that can help those affected by a Patient Safety incident and will work with patients, families, and carers to signpost to their preferred source for this.

(Press CTRL + Click to access links below)

National guidance for NHS trusts engaging with bereaved families

- https://www.england.nhs.uk/wp-content/uploads/2018/08/learning-fromdeaths-working-with-families-v2.pdf
- Learning from deaths – Information for families
- https://www.england.nhs.uk/publication/learning-from-deaths-informationfor-families/ explains what happens after a bereavement (including when a death is referred to a coroner) and how families and carers should comment on care received.
- Help is at Hand – for those bereaved by suicide
- https://www.nhs.uk/Livewell/Suicide/Documents/Help%20is%20at%20Hand.pdf specifically for those bereaved by suicide this booklet offers practical support and guidance who have suffered loss in this way.
- Mental Health Homicide support
- https://www.england.nhs.uk/london/our-work/mental-healthsupport/homicide-support/ for staff and families. This information has been developed by the London region independent investigation team in

collaboration with the Metropolitan Police. It is recommended that, following a mental health homicide or attempted homicide, the principles of the duty of candour are extended beyond the family and carers of the person who died, to the family of the perpetrator and others who died, and to other surviving victims and their families.

Child death support

- https://www.childbereavementuk.org/grieving-for-a-child-of-any-age
- https://www.lullabytrust.org.uk/bereavement-support/

Both sites offer support and practical guidance for those who have lost a child in infancy or at any age.

Complaint's advocacy

- https://www.voiceability.org/about-advocacy/types-of-advocacy/nhscomplaints-advocacy The NHS Complaints Advocacy Service can help navigate

the NHS complaints system, attend meetings and review information given during the complaints

Healthwatch

- https://www.healthwatch.co.uk/ Healthwatch are an independent statutory body who can provide information to help make a complaint, including sample letters You can find your local Healthwatch from the listing (arranged by council area) on the Healthwatch site
- https://www.healthwatch.co.uk/your-local-healthwatch/list

Parliamentary and Health Service Ombudsman

- https://www.ombudsman.org.uk/ makes the final decisions on complaints patients, families and carers deem not to have been resolved fairly by the NHS in England, government departments and other public organisations.

Citizens Advice Bureau

- https://www.citizensadvice.org.uk/ provides UK citizens with information about healthcare rights, including how to make a complaint about care received.

7.5 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, 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.

ECCH will take a proportionate approach to its response to patient safety incidents to ensure that the focus is on maximising improvement. To fulfil this, we will undertake planning of our current resource for patient safety response and our existing safety improvement workstreams. We will identify insight from our patient safety and other data sources both qualitative and quantitative to explore what we know about our safety position and culture.

Our patient safety incident response plan will detail how this has been achieved as well as how ECCH will meet both national and local focus for patient safety incident responses.

7.6 Resources and training to support patient safety incident response.

ECCH has committed to ensuring that we fully embed PSIRF and meet its requirements. We have therefore used the NHS England patient safety response standards (2022) to frame the resources and training required to allow for this to happen.

ECCH will have in place, governance arrangements to ensure that learning responses are not led by staff who were involved in the patient safety incident itself or by those who directly manage those staff.

Responsibility for the proposal to designate leadership of any learning response sits within the senior leadership team of the relevant area. A learning response lead will be nominated, and the individual should have an appropriate level of seniority and influence within ECCH – this may depend on the nature and complexity of the incident and response required, but learning responses are led by staff at Band 8a and above.

ECCH will have governance arrangements in place to ensure that learning responses are not undertaken by staff working in isolation. The Quality and Patient Safety Team will support learning responses wherever possible and can provide advice on cross-system working where this is required.

Staff affected by patient safety incidents will be afforded the necessary managerial support and be given time to participate in learning responses. All ECCH managers will work within our just and restorative culture principles and utilise other teams such as Health and Wellbeing to ensure that there is a dedicated staff resource to support such engagement and involvement. There will be processes in place to ensure that managers work within this framework to ensure psychological safety.

ECCH will utilise both internal and, if required, external subject matter experts with relevant knowledge and skills, where necessary, throughout the learning response process to provide expertise (e.g., clinical, or human factors review), advice and proofreading.

7.7 Training

All staff

ECCH will undertake a patient safety training package 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

- Level one

  National – Health Education England patient safety syllabus module (Essentials for patient safety)
  All staff, clinical and non-clinical are expected to undertake these on induction and to repeat each three years.
  These modules are available as eLearning via ESR access.

  National – Health Education England patient safety syllabus module (Essentials of patient safety for boards and senior leadership teams).
  This module can be accessed directly from the Health Education England eLearning for healthcare platform or ESR.

- Level two

  National – Health Education England patient safety syllabus module (Access to Practice) – this is to be undertaken by all clinical staff at AFC Band 7 or above, with potential to support or lead patient safety incident management.
  This module is available as eLearning via ESR access.

Learning response leads training and competencies

- **Training**

  Any ECCH learning response will be led by those who have had a minimum of two days formal training and skills development in learning from patient safety incidents and experience of patient safety response. Records of such training will be maintained as part of their general education governance processes.

  Learning response leads must have completed Level One and Two of the 'National Patient Safety' syllabus.

  Learning response leads will undertake appropriate continuous professional development on incident response skills and knowledge. To maintain expertise ECCH will participate in networking events for all learning response leads.

Learning response leads will need to contribute to a minimum of two learning responses per year. Records for this will be maintained by the Quality Team and the Patient Safety Team will support this.

- **Competencies**

ECCH expects that those staff leading learning responses are able to,

- Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.
- Summarise and present complex information in a clear and logical manner and in report form.
- Manage conflicting information from different internal and external sources.
- Communicate highly complex matters and in difficult situations.

Support for those new to this role will be offered from senior managers, Quality Risk, Governance and Patient Safety staff.

Engagement and involvement training and competencies

- Training

Engagement and involvement with those affected by a patient will be undertaken by those who have undergone a minimum of six hours training.
Those who have previously undertaken training as a 'Family Liaison Officer' will be able to undertake this this role.

Records of such training will be maintained as part of their general education governance processes.

Engagement leads must have complete Level One and Two of the National Patient Safety syllabus.

Engagement leads will undertake appropriate continuous professional development on incident response skills and knowledge.

To maintain expertise, ECCH will participate in relevant networking events minimum yearly.

Engagement leads will need to contribute to a minimum of two learning responses per year. Records for this will be maintained by the Quality and Patient Safety Team.

- Competencies

ECCH expects that those staff who are engagement leads are able to:

a. Communicate and engage with patients, families, staff, and external agencies in a positive and compassionate way.
b. Listen and hear the distress of others in a measured and supportive way.
c. Maintain clear records of information gathered and contact those affected.
d. Identify key risks and issues that may affect the involvement of patients, staff, and families, including any measures needed to reduce inequalities of access to participation.
e. Recognise when those affected by patient safety incidents require onward signposting or referral to support services.

Oversight roles training and competencies

○ Training

All patient safety oversight will be led/conducted by those who have had a minimum of two days formal training and skills development in learning from patient safety incidents and one day training in oversight of learning from patient safety incidents. Records of such training will be maintained as part of their general education governance processes.

Those with an oversight role on our Board and leadership team (i.e., executive leads) must have completed the appropriate modules from the National Patient Safety syllabus - Level One - Essentials of Patient Safety and Essentials of Patient Safety for boards and senior leadership teams.

All those with an oversight role in relation to PSIRF will undertake continuous professional development in incident response skills and knowledge, and network with peers at least annually to build and maintain their expertise.

○ Competency

ECCH expects staff with oversight roles to be able to

a. Be inquisitive with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement).
b. Apply human factors and systems thinking principles.
c. Obtain through conversations and assess both qualitative and quantitative information from a wide variety of sources.
d. Constructively challenge the strength and feasibility of safety actions to improve underlying systems issues.
e. Recognise when safety actions following a patient safety incident response do not take a system-based approach (e.g., inappropriate focus on revising policies without understanding 'work as done' or self-reflection instead of reviewing wider system influences).

f. Summarise and present complex information in a clear and logical manner and in a report format.

7.8 Our patient safety incident response plan

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

A copy of our current plan can be found on ECCHO.

7.9 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 at a minimum every 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 18 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, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

7.10 Responding to Patient Safety Incidents

Safety incident reporting arrangements

All staff are responsible for reporting any potential or actual patient safety incident on ECCH's Quality Assurance System – QUEST and will record the level of harm they know has been experienced by the person affected.

ECCH have daily review mechanisms in place to ensure that patient safety incidents can be responded to proportionately and in a timely fashion. This should include consideration and prompting to service teams where Duty of Candour applies. Most incidents will only require local review within the service, however for some, where it is felt that the opportunity for learning and improvement is significant, these should be escalated (see Patient Safety Incident response decision-making below).

Service Managers will highlight to the Patient Safety Team, any incident which appears to meet the requirement for reporting externally. This will allow ECCH to work in a transparent and collaborative way with our ICB or regional NHS teams if an incident meets the national criteria for PSII or if supportive co-ordination of a cross system learning response is required.

The Patient Safety Team will act as liaison with external bodies and partner providers to ensure effective communication via a single point of contact for ECCH.

Duty of Candor

Duty of Candor is a professional and statutory obligation, for healthcare professionals and organisations, to be open, honest and transparent with patients when something goes wrong. This means informing patients and carers as soon as possible if an error has occurred, explaining what it is that hasn't gone as expected, outlining what has been implemented to mitigate similar errors for occurring and offering an apology.

Duty of Candor is important in building and maintaining trust between patients and healthcare professionals as it ensures that patients are treated with respect and honesty. Duty of Candor can also help support a culture of accountability and learning within the organisation, as it fosters openness, strengthens quality of care and improves patient safety.

Under the statutory Duty of Candor, there is a timeframe of response for 'notifiable incidents', please refer to Duty of Candour and Saying Sorry SOP.

7.11 Patient safety incident response decision-making

ECCH will have arrangements in place to allow it to meet the requirements for review of patient safety incidents under PSIRF. Some incidents will require mandatory PSII, others will require review by, or referral to another body or team depending on the event. These are set out in our PSIRF plan which is accessed on ECCHO.

PSIRF itself sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. ECCH has developed its own response mechanisms to balance the effort between learning through responding to incidents or exploring issues and improvement work. In the work to create our plan, we have considered what our incident insight and engagement with key internal and external stakeholders has shown us about our patient safety profile. We have used this intelligence to build our local priorities for PSII and our toolkit for responding to other patient safety incidents.

Services will have escalation arrangements in place for the monitoring of patient safety incidents which includes daily escalation of incidents that appear to meet the need for further exploration as a rapid review due to possibly meeting the criteria as PSII or PSR or due to the potential for learning and improvement or an unexpected level of risk.

The Quality Team will have delegated responsibility for the consideration of incidents for PSII or PSR and for oversight of the outcomes of such reviews to ensure that recommendations are founded on a systems-based approach and safety actions are valid and contribute to existing safety improvement plans or the establishment of such plans where they are required.

The Quality Committee will have overall oversight of such processes and will challenge the decision making of the Quality Team to ensure that the Board are assured that the true intent of PSIRF is being implemented within our organisation and we are meeting the national patient safety incident response standards.

Local level incidents

Managers of all service areas must have arrangements in place to ensure that incidents can be reported and responded to within their area. Incident responses should include immediate actions taken to ensure safety of patients, public and staff, as well as an indication of any measures needed to mitigate a problem until a further review is possible. This may include for example, withdrawing equipment or monitoring a procedure. Any response to an incident should be fed back to those involved or affected and appropriate support offered. Where Duty of Candour applies, this must be carried out according to ECCH's procedure, led by the Patient Safety Specialist who may commission thematic reviews of such incidents to consider and understand potential emerging risks.

Incidents with positive or unclear potential for PSII

All staff (directly or through their line manager) must ensure notification of incidents that may require a higher level of response as soon as practicable after the event through ECCH escalation processes (including out of hours) Duty of Candour disclosure should take place according to ECCH guidance. Where it is clear that a PSII is required (for example, for a Never Event) Line Managers should notify the Patient Safety Team as soon as practicable so that the incident can be shared to executive level staff.

Other incidents with unclear potential for PSII, must also be reported to the Patient Safety Team for consideration. A rapid review will be undertaken by the team to inform this decision making. Significant incidents which may require consideration for an ad-hoc PSII due to an unexpected level of risk and/or potential for learning should be included in this category.

The Safety and Learning Hub (SaLH) will meet at the earliest opportunity to discuss the nature of any escalated incident, immediate learning (which should be shared via an appropriate platform), any mitigation identified by the rapid review or that is still required to prevent recurrence and whether the Duty of Candour requirement has been met. The panel will define terms of reference for a PSII to be undertaken by an appropriate member of the Patient Safety Team. The panel will also designate subject matter expert input required for any investigation or highlight any cross system working that may be necessary, as well as indicating how immediate learning is to be shared.

Where an incident does not meet the requirement for PSII, the SaLH may request a Patient Safety Review (PSR) or closure of the incident at a local level, with due consideration of any Duty of Candour requirement being met. It will be at the SALH's discretion in such circumstances to specify a particular tool is used to complete a PSR. ECCH's SaLH will also indicate how immediate learning is to be shared.

Incidents requiring possible patient safety review (PSR)

All staff (directly or through their line manager) must ensure notification of incidents that may require a patient safety review response as soon as practicable after the event through ECCH escalation processes (including out of hours). A rapid review will be undertaken by the Quality Team to inform decision making following this.

The SaLH will meet at the earliest opportunity to discuss the nature of the incident the immediate learning (which should be shared via an appropriate platform), any mitigation that is needed to prevent recurrence, and whether the Duty of Candour requirement has been met.

Where it is clear that a PSII is not required, SaLH will consider any incident as having potential for PSR. The tool to be utilised for the review will be specified and a suitable member of the team identified to undertake the review will be allocated. This will not be any staff involved in the incident or by those who directly manage the staff members. The SaLH will also specify any subject matter expert input required. There will be clear records maintained regarding this decision-making process.

SaLH arrangements will include the recording of safety actions arising from any PSR or other learning response and these details will be used to inform potential safety improvement plans.

The Patient Safety Team will have processes in place to communicate and escalate necessary incidents within NHS commissioning and regional organisations and the CQC according to accepted reporting requirements. Whilst this will include some incidents escalated as PSII, the Patient Safety Team will work with services to have effective processes in place to ensure that any incidents meeting external reporting needs are appropriately escalated.

The Quality Committee

The Clinical Quality Group will oversee decision-making of ECCH's Safety and Learning Hub and the incident responses. Assurance from these forums will be provided to the Quality Committee and subsequently the Board. This will support the final sign off process for all PSIIs. Through this mechanism the Board will be assured that it meets expected oversight standards but also understands the ongoing and dynamic patient safety and improvement profile within the organisation. See appendix 1 for ECCH's PSIRF Governance Structure.

7.12 Responding to cross-system incidents/issues

The Quality Patient Safety Team will forward those incidents identified as presenting potential for significant learning and improvement for another provider directly to that organisation's patient safety team or equivalent. Where required, summary reporting can be used to share insight with another provider about their patient safety profile.

ECCH will work with partner providers and the relevant ICB's to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents. 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.

ECCH 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 or where a system patient safety priority is identified. 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.

As part of the Integrated Care System, we commit to contributing to further discussions and agreement of the system pathway priority, in relation to patient flow. Once established we will carry out a focussed review of our organisation's element of the pathway, with particular attention to the transition periods both to and from other organisations. Once a thorough review has been undertaken by each organisation, we commit to contributing to the final write up of the report, identifying and actioning relevant safety recommendations and disseminating learning across the ICS.

7.13 Timeframes for learning responses

Timescales for patient safety PSII

Where a PSII for learning is indicated, the investigation 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 local PSII should take longer than six months.

The time frame for completion of a PSII will be agreed with those affected by the incident as part of the setting of terms of reference, provided they are willing and able to be involved in that decision. A balance must be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant.

In exceptional circumstances (e.g. when a partner organisation requests an investigation is paused, or the processes of an external body delays access to information) ECCH can consider whether to progress the PSII and determine whether new information indicates

the need for further investigative activity once this is received. This would require a decision by the SALH.

In exceptional circumstances, a longer timeframe may be required for completion of the PSII. In this case, any extended timeframe should be agreed between the ECCH and those affected.

Timescales for other forms of learning response

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 the start date.
No learning response should take longer than six months to complete.

7.14 Safety action development and monitoring improvement

ECCH acknowledges that any form of patient safety learning response (PSII or review) will allow the circumstances of an incident or set of incidents to be understood, but that this is only the beginning. To reliably reduce risk, better safety actions are needed.

ECCH will have systems and processes in place to design, implement and monitor safety actions using an integrated approach to reduce risk and limit the potential for future harm. This process follows on from the initial findings of any form of learning response which might result in identification of aspects of ECCH's working systems where change could reduce risk and potential for harm – areas for improvement. ECCH will generate safety actions in relation to each of these defined areas for improvement. Following this, ECCH will have measures to monitor any safety action and set out review steps.

Learning response should not describe recommendations as this can lead to premature attempts to devise a solution - safety actions in response to a defined area for improvement depend on factors and constraints outside of the scope of a learning response. To achieve successful improvement safety action development will be completed in a collaborative way with a flexible approach from Divisions and the support of the Perfect Care team with their improvement expertise.

Safety Action Development

ECCH will use the process for development of safety actions as outlined by NHS England in the Safety Action Development Guide (2022) as follows.

a. Agree areas for improvement – specify where improvement is needed, without defining solutions.
b. Define the context – this will allow agreement on the approach to be taken to safety action development.
c. Define safety actions to address areas of improvement – focussed on the system and in collaboration with teams involved.
d. Prioritise safety actions to decide on testing for implementation.

e. Define safety measures to demonstrate whether the safety action is influencing what is intended as well as setting out responsibility for any resultant metrics.

f. Safety actions will be clearly written and follow SMART principles and have a designated owner.

Safety Action Monitoring

Safety actions must continue to be monitored within the Service's governance arrangements to ensure that any actions put in place remain impactful and sustainable.

Service reporting on the progress with safety actions including the outcomes of any measurements will be made to the SaLH.

For some safety actions with wider significance, this may require oversight by the Quality Committee.

7.15 Safety improvement plans

ECCH's patient safety incident response plan has outlined the local priorities for focus of investigation under PSIRF for the first year. These were developed due to the opportunity they offer for learning and improvement across areas where there is no existing plan or where improvement efforts have not been accompanied by reduction in apparent risk or harm.

ECCH will use the outcomes from existing patient safety incident reviews (SI RCA reports) where present and any relevant learning response conducted under PSIRF to create related safety improvement plans to help to focus our improvement work. The Services will work collaboratively with the Quality Team to ensure there is an aligned approach to development of plans and resultant improvement efforts.

Where overarching systems issues are identified by learning responses outside of our local priorities, a safety improvement plan will be developed. These will be identified through ECCH governance processes and reporting to the Quality Committee who may commission a safety improvement plan. Again, the Services will work collaboratively with the Quality Team to ensure there is an aligned approach to development of the plan and resultant improvement efforts.

Monitoring of progress with regard to safety improvement plans will be overseen by reporting by the designated lead to the Quality Committee on a scheduled basis.

7.16 Oversight roles and responsibilities

Principles of oversight

Working under PSIRF, organisations are advised to design oversight systems to allow an organisation to demonstrate improvement rather than compliance with centrally mandated measures.

ECCH has followed the ‘mindset’ principles to underpin the processes we have put in place to allow us to implement PSIRF as set out in the supporting document (NHS England (2022), p 3).

Responsibilities

Alongside our NHS regional and local ICB structures and our regulator, the Care Quality Commission, we have specific organisational responsibilities with the Framework. In order to meet these responsibilities, ECCH has designated the Executive Director of Quality to support PSIRF as the executive lead.

1. Ensuring that the organisation meets the national patient safety standards, the Executive Director of Quality will oversee the development, review and approval of ECCH’s policy and plan ensuring that they meet the expectations set out in the patient safety incident response standards. The policy and plan will promote the restorative just working culture that ECCH aspires to.

To achieve the development of the plan and policy ECCH will be supported by internal resources within the Quality Team led by the Deputy Director of Quality who reports to the Executive Director of Quality.

To define its patient safety and safety improvement profile, ECCH will undertake a thorough review of available patient safety incident insight and engagement with internal and external stakeholders.

2. Ensuring that PSIRF is central to overarching safety governance arrangements ECCH will receive assurance regarding the implementation of PSIRF and associated standards via existing reporting mechanisms such as the Quality Committee. The Quality Committee bi-monthly safety reporting will comprise oversight question responses to ensure that the ECCH Board has a formative and continuous understanding of organisational safety.

Quality Team, via the Patient Safety Lead will provide assurance to the Quality Committee that PSIRF and related workstreams have been implemented to the highest standards. Services will be expected to report on their patient safety incident learning responses and outcomes. This will include reporting on ongoing monitoring and review of the patient safety incident response plan and delivery of safety actions and improvement.

Services will have arrangements in place to manage the local response to patient safety incidents and ensure that escalation procedures as described in the patient safety incident response section of this policy are effective.

ECCH will source necessary training such as the Health Education England patient safety syllabus and other patient safety training across the organisation 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 3 years to comply with guidance on policy development alongside a review of all safety actions.

3. Quality assuring learning response outputs - ECCH will implement a central Patient Safety Team to ensure that PSIIs are conducted to the highest standards and to support the executive sign off process and ensure that learning is shared, and safety improvement work is adequately directed.

7.17 Complaints and Appeals

ECCH recognises that there will be occasions when patients, service users or carers are dissatisfied with aspects of the care and services provided.

It is important to understand that there is a distinction made between complaints and concerns as the use of the word complaint should not automatically mean that someone expressing a concern enters the complaints process.

The first point of contact with ECCH is the Patient Advice and Liaison Service (PALS) who will support the resolution of any concerns raised. It is important to address any issue raised at the earliest opportunity and may reduce the risk of escalation and increases the possibility of finding a satisfactory resolution to the problem. It may be more appropriate to deal with and resolve in a more immediate and timely manner as long as this is with the agreement of the person raising the concern.

Complaints are defined as expressions of dissatisfaction from a patient, service user, their family or carer, a person acting as their representative, or any person who is affected or likely to be affected by the action, omission, or decision of ECCH and requires a formal review.

ECCH is committed to dealing with any complaints that may arise as quickly and as effectively as possible as set out in the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

Complaints will be handled respectfully ensuring that all parties concerned feel involved in the process and assured that the issues raised have been comprehensively reviewed and the outcomes shared in an open and honest manner. Complaints can be valuable aids in developing and maintaining standards of care and that lessons learnt from complaints can be used positively to improve services.

Outcomes and recommendations from a complaint will be shared with the services to ensure that changes can be considered and implemented where appropriate. If a concern cannot be resolved and the complaints team are undertaking a formal review the complaints team will contact the complainant.

8. MONITORING AND REVIEW

This document will be reviewed by the **Quality Committee annually** or sooner if changes in legislation occur or new best practice evidence becomes available.

9. REFERENCES

NHS England (2021) Core20PLUS5: An Approach to Reducing Health Inequalities
core20plus5-online-engage-survey-supporting-document-v1.pdf (england.nhs.uk)

NHS England (2022) Patient safety incident response standards

B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf (england.nhs.uk)
NHS England (2022) Safety action development guide

https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-actiondevelopment-v1.1.pdf

10. ASSOCIATED POLICIES & PROCEDURES *(To include but not limited to)*

- Patient Safety Incident Response Plan
- Incident Reporting Policy
- Risk Management Policy and Strategy
- Health & Safety Policy
- Safeguarding Adults Policy
- Safeguarding Children
- Medicines Management Policy
- Medical Devices Policy
- Equality Diversity and Human Rights Policy
- Saying Sorry and Duty of Candour SOP
- Information Governance Policy & Framework
- Freedom to Speak Up

11. AUTHOR

Head of Quality & Patient Safety – Sept 2023

12. APPENDIX

Appendix 1 – ECCH's PSIRF Governance Structure


Response
•Patient safety events will be responded to in the immediate, ensuring patient safety established, Duty of Candor is fulfilled, where appropriate and any immediate learning activities take place e.g After Action Review, as deemed useful at the time of the event.
Learning Hub
•All complex or duty of candour incidents will be reported to the weekly Safety and Learning Hub for review. Incidents identified as potentially requiring specific learning response e.g Patient Safety Incident Investigation (PSII) will be discussed and reviewed against the organisations PSIRP. A planned approach for these incidents will be agreed, including cross system/multi agency investigations when appropriate. In addition to this any immediate mitigation or learning will also be identified and disseminated via the appropriate channels.
Group
•All final investigation reports will be submitted and reviewed at the monthly Clinical Quality Group with formal approval and sign-off by the Executive Director of Quality and People. The Clinical Quality Group will also oversee the completion and closure of all actions.
Quality
•The Quality Committee has delegated Board responsibility for effective patient safety incident management across the organisation. The Quality Committee will receive a Chairs Report from the Clinical Quality Group in addition to a Patient Safety Report as a standard agenda item. The Patient Safety Report will include details of patient safety incidents (themes & trends) inclusive of new and ongoing investigations, initial mitigation and learning and details of closed investigations, outcomes and organisational learning.
Board
•The Board has overall responsibility and accountability for effective patient safety incident management in the organisation. The Board will receive a Chairs Assurance Report from the Quality Committee.

13. EQUALITY & DIVERSITY IMPACT ASSESSMENT

In reviewing this policy, the relevant Policy Group considered, as a minimum, the following questions:

- Are the aims of this policy clear?
- Are responsibilities clearly identified?
- Has the policy been reviewed to ascertain any potential discrimination?
- Are there any specific groups impacted upon?
- Is this impact positive or negative?
- Could any impact constitute unlawful discrimination?
- Are communication proposals adequate?
- Does training need to be given? If so is this planned?

Adverse impact has been considered for age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, sexual orientation.

14. DOCUMENT CONTROL SHEET

Name of Document:	Patient Safety Incident Response Policy
Version:	2
File Location / Document Name:	ECCHO
Date Of This Version:	October 2025
Produced By (Designation):	Head of Quality, Patient Safety Specialist
Reviewed By:	Quality Team
Synopsis And Outcomes of Consultation Undertaken:	Addition of commitment to Norfolk and Waveney system Priority as required. Amendment of governance structure and relevant meetings in body of text and Appendix 1
Synopsis And Outcomes of Equality and Diversity Impact Assessment:	No impact
Ratified By (Committee): -	Clinical Quality Group
Date Ratified:	28/10/2025
Distribute To:	ECCHO
Date Due for Review:	September 2028
Enquiries To:	Head of Quality, Patient Safety Specialist
Approved by Appropriate Group/Committee **Approved by Policy Group**	☐ Date: 10 March 2025 ☐ Date: N/A

Version Control

Version Date	Version No.	Author/ Reviewer	Comments
Sept 2023	Draft 1	Head of Quality, Patient Safety Specialist	New policy
Sept 2023	Draft 2	Head of Corporate Governance	Updated to ensure on ECCH policy template added: • Introduction • Definitions • Policy Statement • Responsibilities • Associated Policies and Procedures • Appendices • Monitoring and review Updated content in line with Quality Committee comments: • Quality Committee section updated with responsibilities and Appendix governance structure linked in appendix • Updated any review dates to match the PSIRF plan • Definitions table added and includes Human and System Factors clarification
September 2023	Final 1	Director of Quality and Head of Quality	Updated content in line with ICB and Quality Committee comments: Inclusion of reference to Freedom to Speak Up policy. Addition of Immediate Response Governance Framework
October 2025	V2	Director of Quality and People Head of Quality	Addition of commitment to Norfolk and Waveney system Priority as required. Amendment of governance structure and relevant meetings in body of text and Appendix 1