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PATIENT SAFETY INCIDENT RESPONSE FRAMEWORK (PSIRF) POLICY

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1. INTRODUCTION

The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds a patient safety incident response within a wider system of improvement and underlines the importance of learning and improvement.

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF which we can also align to our existing InHealth values:

- Compassionate engagement and involvement of those affected by patient safety incidents (Trust, Care and Passion)
- Application of a range of system-based approaches to learning from patient safety incidents (Care and Fresh Thinking)
- Considered and proportionate responses to patient safety incidents and safety issues (Trust, Care and Fresh Thinking)
- Supportive oversight focused on strengthening response system functioning and improvement. (Trust, Passion, Care and Fresh Thinking)

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

2. PURPOSE

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out how InHealth will approach the development and maintenance of effective systems and processes for responding to patient safety incidents.

3. SCOPE

This policy is specific to patient safety incident responses and their role in developing learning and improvement across the InHealth group.

Responses under this policy follow a systems-based approach to learning. It is the new approach by the NHS to developing and maintaining effective systems and processes, when incidents occur in a health care setting. This approach recognises that patient 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 and are therefore outside the scope of 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
- Coroners' inquests and criminal investigations
- Complaints (except where a significant patient safety concern is highlighted)

For clarity, InHealth 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.

This policy applies to all InHealth staff, practitioners with practising privileges, agency workers and contractors working for or on behalf of InHealth.

'InHealth' or the 'Company' refers to all Companies in the InHealth Group of Companies including holding, subsidiary and associated companies within the meaning of the Companies Act 2006 Section 1159.

4. DEFINITIONS

Patient safety event	(PSE) Umbrella term used to describe an incident, patient safety incident or near miss event.
Patient safety incident	(PSI) Any unintended or unexpected incident which could have or did lead to harm, loss or damage to any individual for one or more people receiving care or treatment within the organisation.
After Action Review	(AAR) A discussion of an event that enables the individual involved to learn for themselves what happened, what went well, what needs improvement and the lessons learnt.
Patient Safety Incident Response Plan (PSIRP)	A concise systems-based investigation coordinated by the Clinical Quality Team.
Patient Safety Incident Investigation (PSII)	Led by patient safety incident investigators who are skilled in systems-based investigations
Patient Safety Audit	(PSA) A process to assess and evaluate care in a systematic way, useful for low harm, high volume incidents
SQAS	Screening Quality Assurance Service
Swarm	Multi stakeholder discussion to understand context of situation and implication for systems
Near miss event	An event or circumstance that did not lead to unintended or unexpected harm, loss or damage to any individual, the environment or the organisation but had the potential to do so. This includes events which did not

Notifiable safety incident

happen because of a fortunate break in the chain of events including staff intervention.

Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional:

(a) appears to have resulted in:

(i.) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition,

(ii.) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,

(iii.) changes to the structure of the service user’s body,

(iv.) the service user experiencing prolonged pain or prolonged psychological harm, or

(v.) the shortening of the life expectancy of the service user; or

(b) requires treatment by a health care professional to prevent—

(i.) the death of the service user, or

(ii.) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).

Level of Harm

Levels of harm were previously set out in the National Reporting and Learning Service guidance on reporting patient safety incidents.

In summary harm is defined as follows:

No harm

This has two sub-categories:

No harm (Impact prevented)

Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be locally termed a ‘near miss’.

No harm (impact not prevented)	Any patient safety incident that ran to completion, but no harm occurred to people receiving NHS funded care.
Low harm	Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.
Moderate harm	Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
Severe harm	An event or condition that reaches the individual, resulting in life-threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring or a surgery, invasive procedure, or treatment to resolve the condition.
Death	Any unexpected or unintended incident that directly resulted in the death of one or more persons
Apology	An expression of sorrow or regret that PSE has occurred. For clarity an apology in this context is not an admission of liability for any harm or injury caused.
Working days	Monday to Friday (Corporate and support functions)
CLIC	Complaints, litigation, incidents and compliments weekly review.
Learning organisation	In literature this is also referred to as ‘an organisation with a memory’.
Just culture	An atmosphere of trust in which people are encouraged to or even rewarded for providing essential safety-related information and which looks at wider system issues where

things go wrong, but which also holds people accountable where there is evidence of gross negligence or deliberate acts. also

Never event	<p>Serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. An updated list of 'never events' is published annually by the department of health and is available at:</p> <p>https://www.gov.uk/government/organisations/department-of-health</p>
LFPSE	<p>Learn from Patient Safety Events service is a new national NHS service for the recording and analysis of patient safety events that occur in health care. It replaces the Strategic Executive Information System (STEIS) – NHS England's web-based serious incident management system.</p>
Regulated Activity	<p>Activities as described within schedule 1 of the health and Social Care act 2008 (regulated activities) regulation 2014 which must be registered with the Care Quality Commission.</p>
CQC	<p>Care Quality Commission.</p>
NICE	<p>National Institute for Clinical Excellence.</p>
Screening Safety Incident	<p>Any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme.</p> <p>Harm or a risk of harm because one or more persons eligible for screening are not offered screening.</p>
Duty of Candour	<p>The statutory responsibility placed on providers of health and social services to be open and transparent in the event of a notifiable safety event occurring.</p>

5. REGULATORY AND ACCREDITATION FRAMEWORK

Regulatory or accreditation Body	Relevant Regulatory or accreditation Standard or requirement	How is compliance with this standard demonstrated or supported within this policy?
Care Quality Commission (CQC) and NHS England (NHSE)	Regulation 12: Safe care and treatment Regulation 16: Receiving and acting on complaints Regulation 17: Good governance Regulation 20: Duty of Candour	Aligns with new CQC Single Assessment Framework and its association with best practice standards and guidance for the Learning Culture Quality Standard
NHS England	https://www.england.nhs.uk/publication/patient-safety-incident-response-framework-and-supporting-guidance	

6. ROLES & RESPONSIBILITIES

6.1. Chief Executive Officer

Overall responsibility for the safety and quality of services provided within the organisation.

6.2. Chief Medical Officer (CMO)

To provide Executive lead and oversight for the implementation of PSIRF.

6.3. Director of Clinical Quality and Chief Nursing Officer (DoCQ/CNO)

To ensure that InHealth meets the national Patient Safety Incident Response standards (PSIRS).

To ensure that PSIRF is central to InHealth's overarching clinical governance arrangements to allow recognition, reporting, investigation and remedial action in response to patient safety events.

To provide quality assurance and oversight of learning response outputs.

To ensure compliance with the national PSIRF training requirements.

6.4. Digital Clinical Safety Officer (CSO)

To ensure that incidents related to digital clinical safety and the use of healthcare IT systems are reported and managed effectively.

6.5. Senior Operational Leaders

To ensure that this policy is fully implemented and applied within their specific areas of responsibility.

6.6. Senior Clinical Governance and Risk Business Partners (SCGR BPs)

Providing support to operational leaders and managers in the implementation and use of this policy.

Ensuring that the contents of this policy reflect relevant national and industry guidance and regulations.

To ensure that this policy is reviewed following publication of new or to provide revision of existing guidelines or regulations.

To support patient and organisational safety as the named patient safety specialist.

To provide guidance and support as a patient safety expert in relation to Learning from Patient Safety Events (LFPSE).

6.7. Sustainability Steering Group

To Provide subject matter expertise in relation to the management of Environmental events.

6.8. Clinical Quality Team

To dedicate time to conduct learning responses.

To be compliant with the relevant national PSIRF training requirements.

To contribute to a minimum of two learning responses per year.

To engage with the patient/family/other relevant stakeholder as appropriate in relation to their involvement in the learning response.

To support the delivery of appropriate training to Investigation Officers.

6.9. CQC Registered Managers and Service Managers (or their nominated deputy)

To ensure that this policy is implemented and adhered to within their area or responsibility.

To ensure that staff are appropriately trained and supported in the implementation of this policy.

To ensure robust investigation and implementation of remedial action following the occurrence of patient safety event.

6.10. All Staff

To comply with the requirements of this policy in relation to patient safety event reporting and management.

7. OUR PATIENT SAFETY CULTURE

InHealth has worked over several years to move from a retribution approach to the investigation of patient safety events, to establishing a restorative just culture within the organisation.

The senior leadership team have strongly embraced this work and with support from staff/ colleagues 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

Our safety culture has progressed in a positive way with reporting of patient safety incidents improving over time and the introduction of a new incident management system InPhase which is compliant with LFPSE reporting. Our safety culture is enhanced with weekly governance huddles (CLIC meetings) which include all modalities of the organisation. These meetings consider risks emerging or known and the insight offered from incidents that have occurred. In addition, other quarterly meetings such as the Clinical Quality Sub Committee, Medicines Management Group, Radiation Protection Group, MR Safety and Quality Group, Risk and Governance Committee that form part of our governance framework also provide opportunities to share learning and discuss actions taken to prevent/mitigate incidents and risks.

PSIRF will enhance our current process by creating much stronger links between a patient safety incident and learning and improvement by working in collaboration with those affected by a patient safety incident – staff, patients, families, and carers to increase transparency and openness amongst our staff in reporting of incidents and engagement in establishing learning and improvements that follow. This will include insight into things that have gone well, as well as where they have not gone as planned.

We will also 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.

8. 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 healthcare organisations in the UK.

At InHealth, we are looking into how we can welcome PSPs, who we envisage 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 NHS staff from another organisation). 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 across all healthcare organisations will evolve over time and within InHealth 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 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 to ensure that patient safety is our priority. As the role evolves, we may ask PSPs to participate in the investigation of patient safety events, 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 honorary role by the SCGR BPs for the organisation who will provide expectations and guidance for the role.

PSPs will have regular scheduled reviews and regular one-to-one sessions with our SCGR BPs and training needs will be agreed together based on the experience and knowledge of each PSP.

The PSP placements are on an honorary basis and will be reviewed after one year to ensure we keep the role aligned to the patient safety agenda as this develops.

9. ADDRESSING HEALTH INEQUALITIES

The organisation recognises that all healthcare services have 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.

InHealth 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. The introduction of a new incident management system will allow for the details of patients to be directly drawn from the healthcare record and incidents can then be analysed by protected characteristics to give insight into any apparent inequalities.

Within our patient safety response toolkit, we will directly address if there are any features of an incident which indicate that health inequalities may have contributed to harm or demonstrate a risk to a 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 LFPSE documentation and governance processes.

We will also address apparent health inequalities as part of our safety improvement work. In establishing our plan and policy we will work to identify variations that signify potential inequalities by using our population data and our patient safety data to ensure that this is considered as part of the development process for future iterations of our patient safety incident response plan and this policy. We consider this as an integral part of the future development process.

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.

InHealth's commitment to transforming organisational culture to that of restorative justice has already been outlined. Further to this, InHealth 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. As part of this, discrimination of any kind including racism will be dealt with appropriately. We will use PSIRF 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.

10. 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.

We 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.

We 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, both for the patients and 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, we want to be open and transparent with our patients, families, and carers because it is the right thing to do 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. This will be underpinned by our Service Leads who are able to guide patients, families and carers through any investigation or learning review. Please see the Patient Safety Investigation Report in Appendix 5

In addition, at InHealth we have a feedback service (your.experience@inhealthgroup.com). People with a concern, comment, complaint or compliment about care or any aspect of the organisation's services are encouraged to speak with a member of the Clinical Quality Team, who will forward the concern to the appropriate manager. Should the manager be unable to resolve the concern the Clinical Quality Team can provide support and advice to patients, families, carers, and

friends. The Clinical Quality Team will liaise with staff, managers and, where appropriate, with other relevant organisations to negotiate immediate and prompt solutions.

The Clinical Quality Team can help and support with the following:

- Comments and suggestions
- Compliments and thanks
- Concerns
- Advice about how to make a formal complaint.

To leave feedback about your experience the team can be contacted at the email address above.

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.

National guidance for NHS trusts engaging with bereaved families.

<https://www.england.nhs.uk/wp-content/uploads/2018/08/learning-from-deaths-working-with-families-v2.pdf>

Learning from deaths – Information for families

<https://www.england.nhs.uk/publication/learning-from-deaths-information-for-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-health-support/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.

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.

11. 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.

InHealth 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 as per the PSIRF plan. 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 the InHealth will meet both national and local focus for patient safety incident responses.

11.1. Resources and Training to support Patient Safety Incident Response

InHealth 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.

Responsibility for the proposal to designate leadership of any learning response sits within the Clinical Quality Team. A learning response lead (investigation lead) will be nominated by the Clinical Quality team in partnership with a senior manager/clinician from the modality in which the incident occurred. The individual should have an appropriate level of seniority. The Clinical Quality Team will ensure the rigour of the approach to the review and will maintain records to ensure an equitable allocation of PSII's is maintained in the Clinical Quality dashboard. The Clinical Quality Team will support learning responses wherever possible and can provide advice on cross-system and cross-divisional working where this is required.

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

InHealth 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.

Training

InHealth has implemented 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 - Essentials for patient safety (Part 1).

All staff, clinical and non-clinical are expected to undertake these on induction and to repeat every three years. These modules are available as eLearning via InHealth's Inspire portal.

- Level One - Essentials for patient safety (Part 2).

Executives and Senior Leadership are expected to undertake this module on induction and to repeat every three years. These modules are available as eLearning via InHealth's Inspire portal. These should be undertaken at induction and should be repeated every three years.

- Level Two- Access to practice (Part 1 and Part 2)

This is to be undertaken by all clinical staff and management staff, who are or have the potential to support or lead patient safety incident management investigations.

This module is available as eLearning via InHealth's Inspire portal.

Learning response leads training and competencies.

- Training

InHealth's learning responses will be led by those who have had a minimum of two days formal training. Med Led is a company we currently use to deliver PSIRF training. Topics covered include: Understanding systems and the purposes of PSII, Cultures in Practice, Patient, Family and Staff Involvement in PSII and Practical Application's.

- Staff from different modalities should attend this training. Records of such training will be maintained by the Learning and Development team as part of their general education governance processes.
- Learning response leads will undertake appropriate continuous professional development on incident response skills and knowledge.
- Competencies

As an organisation we expect that those staff leading learning responses are able to:

- a. Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.

- b. Summarise and present complex information in a clear and logical manner and in report form.
- c. Manage conflicting information from different internal and external sources.
- d. Communicate highly complex matters and in difficult situations.

Support for those new to this role will be offered from Director of Operations, Operational Leads and the Clinical Quality Team.

Engagement and involvement training and competencies

Engagement and involvement with those affected by a patient safety incident will be undertaken those who have undergone appropriate training (such as the Duty of Candour training provided via Health Education England, Patient Safety Syllabus).

Records of such training will be maintained by the Learning and Development team as part of their general education governance processes.

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

- Competencies

As an organisation we expect that those staff who are engagement leads to be 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.

All those with an oversight role in relation to PSIRF will undertake continuous review of our Patient Safety Incident Response Plan.

Our plan sets out how InHealth intends to respond to patient safety incidents over a period of 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.

A copy of our current plan can be found at (Insert link to PSIRF plan once plan has been finalised)

11.2. 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 24 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 24 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.

12. RESPONDING TO PATIENT SAFETY INCIDENTS

12.1. Safety Incident Reporting Arrangements

All staff are responsible for reporting any potential or actual patient safety incidents on the InHealth incident reporting system called InPhase which will record the level of harm they know has been experienced by the person affected.

The Clinical Quality Team will have daily alerts from InPhase to ensure that patient safety incidents can be responded to proportionately and in a timely fashion, in collaboration with the specific modality. Most incidents will only require a local review within the modality, however for some, where it is felt that the opportunity for learning and improvement is significant, these will be escalated to the Clinical Quality Team by the modality (see Appendix 2 on patient safety incident response decision-making template and further information below).

Modality leads will highlight to the Clinical Quality Team any incident which appears to meet the requirement for reporting externally. This may either be to allow InHealth to work in a transparent and collaborative way with the relevant ICB or regulatory body if an incident meets the national criteria for PSII set out in the PSIRF plan.

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

12.2. Management of screening safety incidents within InHealth NHS Screening programmes

Safety concerns and incidents in screening services need special attention because of the characteristics of screening.

Screening is the process of identifying healthy people who may be at increased risk of disease or condition. Local screening services offer information, further tests and treatment. This is to reduce the risks or complications of the disease or condition.

Screening is a pathway not a test. Local screening services may span several clinical departments, organisations and geographical boundaries.

Screening rarely benefits all sections of the population and needs to be targeted. As some false positives and false negatives are unavoidable there is potential harm for an individual. There is an ethical responsibility to do as little harm as possible.

This means that:

- apparently minor local incidents can have a major service impact due to the large number of people screened
- if the problem is widespread in other local screening services there can be an impact on the population and screening can do more harm than good
- incidents often affect the whole screening service not just the local department or provider organisation in which the problem occurs
- incidents may involve several organisations across geographical boundaries
- local incidents can affect public confidence in screening services in other areas

As part of NHSE, the Screening Quality Assurance Service (SQAS) screening gives advice on screening incidents and takes action to help prevent incidents elsewhere, including sharing lessons identified from incidents, developing new guidance and training.

Guidance on reporting and managing screening incidents is found in the flow chart at Appendix 10 and here [Managing safety incidents in NHS screening programmes - GOV.UK](#)

12.3. Patient Safety Incident Response Decision-making

InHealth have arrangements in place to allow us to meet the requirements for review of patient safety incidents under PSIRF. Some incidents will require mandatory PSIRP, others will require review by, or referral to another body or team depending on the event. These are set out in our PSIRF plan

PSIRF itself sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. InHealth has developed its own response mechanisms to balance the requirement for 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.

We have established a process for our response to incidents which allows for a clear 'Floor to Board' set of mechanisms allowing for oversight of incident management and our PSIRF response. This is achieved via a monthly Grad Report. This report aims to provide assurance to the InHealth Executive Team of the quality and safety of services delivered as well as highlighting areas for improvement and quality improvement initiatives being undertaken within practice for the benefit of patient and organisational safety.

This report is aligned with the Care Quality Commission's 'Key Lines of Enquiry' and aims to demonstrate compliance with the regulations as specified within the Health and Social Care Act 2008 Regulated Activity Regulations 2014.

The report aims to identify and alert the executive team to areas where improvements or developments may be required and as such utilises 'RAG' rating where possible to highlight performance against accepted standards or targets.

Modalities will have escalation arrangements in place for the monitoring of patient safety incidents and this includes daily escalation of incidents which 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. Modalities will consider any such incidents for further escalation to the Clinical Quality Team.

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

Any incident highlighted will follow the process outlined below which can be seen in diagram form in Appendix 1.

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 indication of any measures needed to mitigate a problem until 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 InHealth guidance (see Duty of Candour Procedure).

The Clinical Quality Team may commission thematic reviews (see appendix 6) 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 the appropriate escalation processes (including out of hours) and this must include the Clinical Quality Team. Duty of Candour disclosure should take place according to InHealth guidance. Where a PSII is required (for example, for a Never Event) the Modality should notify the Clinical Quality Team as soon as practicable so that the incident can be shared to executive level staff. The incident will be escalated to the Chief Medical Officer. An SI decision making panel will be undertaken by the modality lead in conjunction with the

Clinical Quality Team to ascertain the events that led to the patient safety event and inform onward escalation following this.

Other incidents with unclear potential for PSII, must also be reported to the Clinical Quality Team. A Patient Safety Review Panel will be undertaken by the modality lead in conjunction with the Clinical Quality Team to ascertain the events that led to the patient safety event and inform onward escalation following this. Significant incidents which may require consideration for ad-hoc PSII due to an unexpected level of risk and/or potential for learning should be included in this category.

The Patient Safety Review Panel will be held 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 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 within the modality. If necessary, the panel will also designate subject matter expert input for any investigation or highlight any cross system working, as well as indicating how immediate learning is to be shared.

Where an incident does not meet the requirement for PSII the Clinical Quality Team may request a patient safety incident review (PSIR see appendix 5) 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 Clinical Quality Team's discretion in such circumstances to specify if a tool is used to complete a PSIR. The Clinical Quality Team will also indicate how immediate learning is to be shared.

Incidents requiring possible patient safety incident investigations – all staff (directly or through their line manager) must ensure notification of incidents that may require a patient safety incident review response as soon as practicable after the event through appropriate escalation processes and this must include the Clinical Quality Team. A Swarm huddle (see appendix 3) must then be undertaken by the Modality with appropriate members represented.

SWARM HUDDLE

A swarm is designed to start as soon as possible after a patient safety incident occurs to identify learning from patient safety incidents. Immediately after an incident, staff 'swarm' to the site to quickly analyse what happened and how it happened and decide what needs to be done to reduce risk. They can prevent:

- those affected forgetting key information because there is a time delay before their perspective on what happened is sought
- fear, gossip and blame; by providing an opportunity to remind those involved that the aim following an incident is learning and improvement.
- information about what happened and 'work as done' being lost because those affected leave the organisation where the incident occurred.

During the meeting there will be a discussion regarding the nature of the incident, immediate learning (which should be shared via an appropriate platform), any mitigation that is needed to prevent recurrence and whether the Duty of Candour is needed.

Where a PSIRP is not required, the Clinical Quality Team will consider any incident as having potential for an After Action Review (AAR, see appendix 4) or a Thematic Review (see appendix 6). The tool to be utilised for the review will be specified during the PSIR meeting and a suitable member of the modality will be agreed to undertake the AAR or Thematic Review. The AAR or Thematic Review will not be conducted by any staff involved in the incident. The Modality should also specify if any subject matter expert input is required. There will be clear records maintained regarding this decision-making process.

Lead investigators will record on InPhase any safety actions arising from any PSIR, Swarm huddle or other learning response and these details will be used to inform potential safety improvement plans.

The Clinical Quality Team will have processes in place to communicate and escalate necessary incidents to the appropriate commissioners, regional organisations, CQC, MHRA etc. according to accepted reporting requirements. Whilst this will include some incidents escalated as PSII, the Clinical Quality Team will work with the Modalities to have effective processes in place to ensure that any incidents meeting external reporting needs are appropriately escalated.

12.4. Responding to Cross-System Incidents/Issues

The Modality Lead in collaboration with the Clinical Quality 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.

InHealth will work with Trusts/ Partner providers and the relevant ICBs to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents. The Clinical Quality team will act as the liaison point for such working and will have supportive operating procedures to ensure that this is effectively managed.

InHealth will defer to the appropriate 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.

12.5. 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.

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) InHealth 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 Clinical Quality Team.

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

12.6. Safety Action Development and Monitoring improvement

InHealth 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.

InHealth 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. InHealth will have measures to monitor any safety action and set out review steps.

Safety Action development

InHealth 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 – focused 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 Modality's governance arrangements to ensure that any actions put in place remain impactful and sustainable.

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

12.7. Quality Improvement Plans

Quality improvement plans bring together findings from various responses to patient safety incidents and issues.

InHealth's patient safety incident response plan has outlined the local priorities for focus of investigation under PSIRF. 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.

InHealth 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 Modality Leads will work collaboratively with the Clinical 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 the InHealth local priorities, a safety improvement plan will be developed. These will be identified through Modality governance processes and reporting to the Clinical Quality Team who may commission a safety improvement plan. Again, the Modalities will work collaboratively with the Clinical Quality Team and others to ensure there is an aligned approach to development of the plan and resultant improvement efforts.

Monitoring of progress regarding safety improvement plans will be overseen by the Clinical Quality Team.

13. 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.

InHealth 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 (Mindset Principles, NHS England (2022), P3).

Responsibilities

Alongside our NHS regional and local ICB structures and our regulator, the Care Quality Commission, we have specific organisational responsibilities with the Framework.

To meet these responsibilities, InHealth has designated the Chief Medical Officer to support PSIRF as the executive lead.

1. Ensuring that the organisation meets the national patient safety standards

The Chief Medical Officer will oversee the development, review and approval of the InHealth'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 InHealth is committed to.

To define its patient safety and safety improvement profile, InHealth 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

The Executive Board will receive assurance regarding the implementation of PSIRF and associated standards via existing reporting mechanisms such as the Risk and Governance Committee and People Business Review to ensure that the Executive Board has a formative and continuous understanding of organisational safety.

The Clinical Quality Team will provide assurance to the Risk and Governance Committee that PSIRF and related workstreams have been implemented to the highest standards. Modalities 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.

Modalities 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.

InHealth will source necessary training such as the Health Education England superseded by NHSE 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 InHealth guidance on policy development, alongside a review of all safety actions.

3. Quality assuring learning response outputs

InHealth has a robust system in place to ensure that PSIRFs are conducted to the highest standards and to support the sign off process and ensure that learning is shared, and safety improvement work is adequately directed.

14. COMPLAINTS AND APPEALS

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

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.

There are several ways in which a patient can raise a concern or complaint. This can be done via email your.experience@inhealthgroup.com or this sometimes done by emailing PRC prc.complaints@inhealthgroup.com. It is important to address any issue raised at the earliest opportunity as this may reduce the risk of escalation and increase the possibility of finding a satisfactory early resolution to the problem.

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 InHealth and requires a formal review.

InHealth 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 2022.

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.

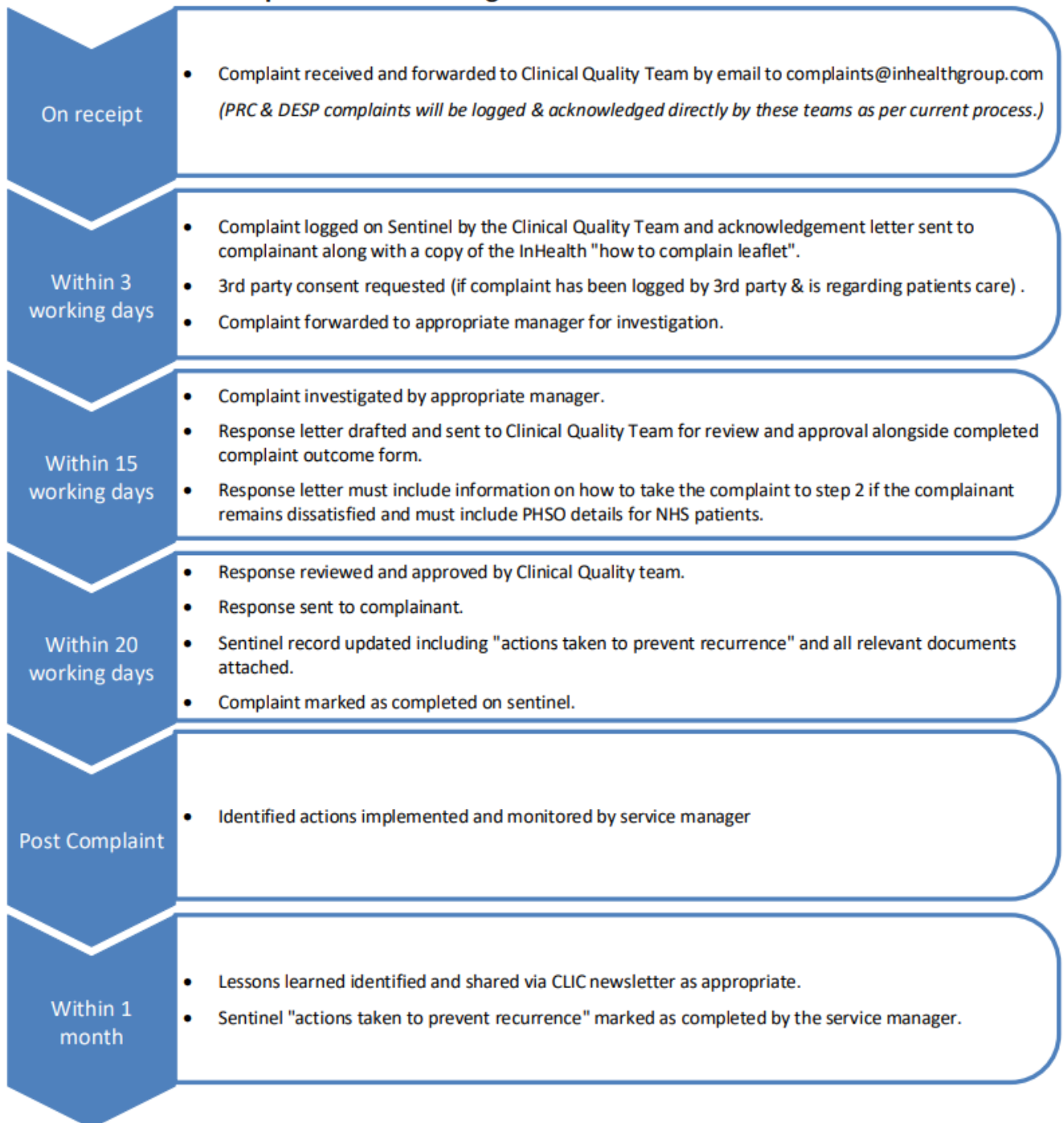
Complaints can be valuable aids in developing and maintaining standards of care and that lessons learnt from complaints can be used positively to improve services.

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 and can be contacted directly on your.experience@inhealthgroup.com.

The flow charts below outline the process for the management of a complaint.

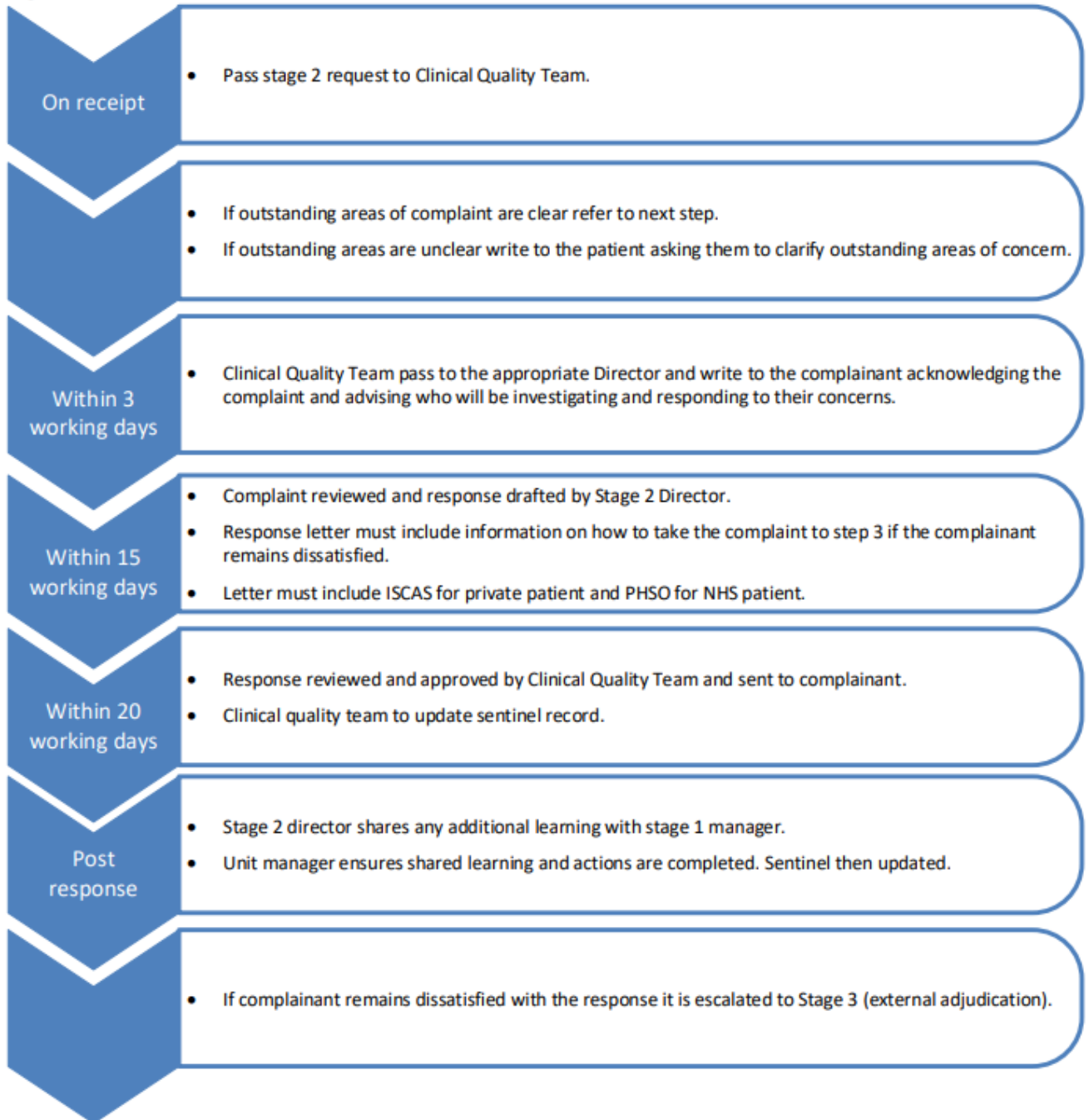
Complaints Process- Stage 1: Local Resolution



Complaints Process- Stage 2: Director review

If complainant is not satisfied with the response and further issues have been raised: original responding manager should address the further issues. (Complaint remains at stage 1)

If complainant is dissatisfied with response and no new issues raised complaint should be escalated to stage 2:



15. MONITORING & COMPLIANCE

Compliance with this policy will be monitored by the Clinical Quality team and reported to the executive team via monthly quality reporting systems.

A quarterly report in relation to patient safety event reporting and lessons learned will be reviewed by the Clinical Quality Sub Committee.

Monitoring requirement to be monitored	Process for monitoring e.g. audit	Responsible individual/committee	Frequency of monitoring	Responsible individual/Committee for review of results	Responsible individual/committee for development of action plan and implementation
PSII are completed within 60 days	<p>Monthly dashboard reporting to InHealth Executive team.</p> <p>Dashboard reporting to Commissioners as required.</p> <p>Quarterly reporting to clinical quality sub committee</p>	Clinical Quality Team	Monthly	<p>Director of Clinical Quality and Chief Nursing Officer</p> <p>SCGR BPs</p>	Clinical Quality Team
PSIRP is reviewed and approved in line with this policy	<p>Monthly dashboard reporting to InHealth Executive team.</p> <p>Dashboard reporting to Commissioners as required.</p> <p>Quarterly reporting to clinical quality sub committee</p>	Clinical Quality Team	12-18 months	<p>Director of Clinical Quality and Chief Nursing Officer</p> <p>SCGR BPs</p>	Clinical Quality Team
A comprehensive review of the PSIRP is undertaken in line with this policy	<p>Monthly dashboard reporting to InHealth Executive team.</p> <p>Dashboard reporting to Commissioners as required.</p> <p>Quarterly reporting to</p>	SCGR BP	4 yearly	<p>Director of Clinical Quality and Chief Nursing Officer</p> <p>SCGR BPs</p>	Clinical Governance

	clinical quality sub committee				
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16. ASSOCIATED DOCUMENTS

Management of Safety Alerts Policy

Duty of Candour – Procedure for the disclosure of a notifiable safety incident

Risk Management Policy

Safeguarding Vulnerable Adults Policy

Safeguarding Children Policy

Freedom to Speak Up (Whistleblowing) Policy

Health and Safety Policy

Infection Prevention and Control Policy

Environmental and Energy Management Policy

17. REFERENCES

NHS England (2022) Patient safety incident response standards

NHS England (2022) Swarm Huddle [B1465-Swarm-huddle-v1-FINAL.pdf](#)
([england.nhs.uk](#))

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-action-development-v1.1.pdf>

NHS Improvement Just Culture Guide:

https://improvement.nhs.uk/documents/2490/NHS_0932_JC_Poster_A3.pdf
(Accessed 28/10/2020)

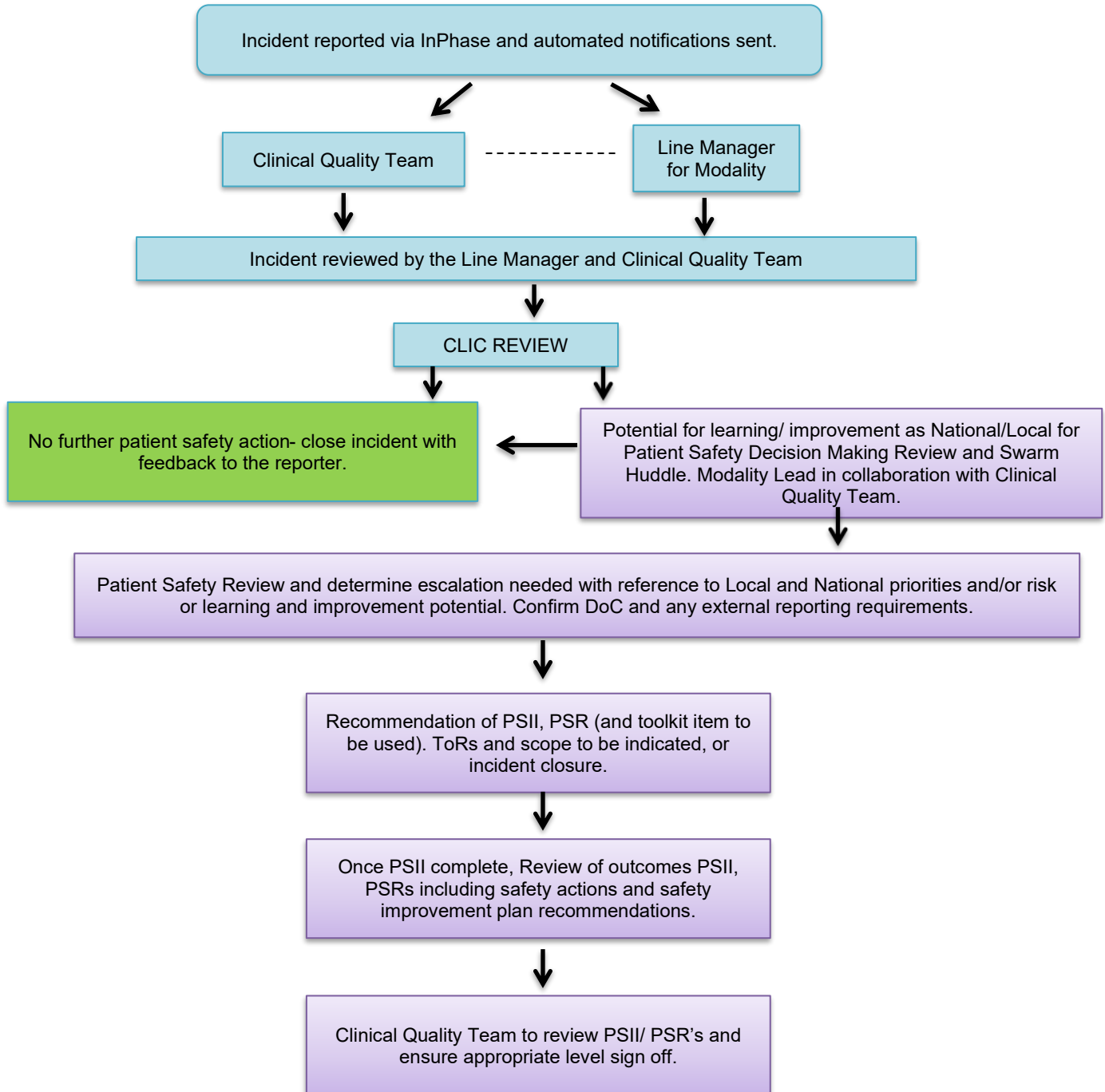
18. EQUALITY, DIVERSITY AND INCLUSION IMPACT ASSESSMENT

		Yes/No N/A	Comments or actions to mitigate
1	Does the policy/guidance affect one group less or more favourably than another based on:		
	• Age	No	
	• Disability, including learning disabilities and learning difficulties	No	
	• Gender reassignment	No	
	• Marriage and civil partnership	No	
	• Pregnancy and maternity	No	
	• Race and ethnicity	No	
	• Religion and belief	No	
	• Sex	No	
	• Sexual orientation	No	
2	Is there any evidence that some groups are affected differently by this policy?	No	
3	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4	Is the impact of the policy/guidance likely to be negative?	No	
5	If so can the impact be avoided?	N/a	
6	What alternatives are there to achieving the policy/guidance without the impact?	N/a	
7	Can we reduce the impact by taking different action?	N/a	
8	Has this policy been reviewed for appropriate use of language that ensures inclusivity in how we refer to groups of people? Please refer to this best practice guidance for support: - Writing about ethnicity - Writing about disability - Inclusive language	Yes	

19. APPENDICES

Appendix 1	Patient Safety Incident Response Decision Making Flow Chart
Appendix 2	Patient Safety Incident Review Template
Appendix 3	Swarm Huddle
Appendix 4	After Action Review Template
Appendix 5	Patient Safety Incident Investigation Report
Appendix 6	Thematic Review Template
Appendix 7	Action Plan
Appendix 8	Externally reportable events roles and responsibilities
Appendix 9	NPSA contributory factors classification framework
Appendix 10	Reporting and Managing screening incidents
Appendix 11	A just culture guide (NHS Improvement 2018)

APPENDIX 1: PATIENT SAFETY INCIDENT RESPONSE DECISION MAKING FLOW CHART



APPENDIX 2 PATIENT SAFETY INCIDENT REVIEW BRIEF AND DECISION-MAKING RECORD

This document is designed to be used as a working template; Blue text throughout the document aims to provide guidance and assistance to the author and must be deleted prior to final approval.

InPhase Reference	
Date and Time of Incident	
Location of Incident	
Modality/ Business Area:	
Responsible Manager	

Section 1: Incident Details	
Incident description Include a brief factual description of what is known about the incident so far:	
Incident Identification Include a brief overview of how the incident was identified	
Risk Grading From InPhase	
Impact on affected Person/ business area/ organisation Please provide information known regarding the impact	
Immediate remedial action taken Describe remedial action taken following the incident	

Section 2 – Post Incident review and decision-making meeting	
Date and Time of meeting	
Attendees	Name all attendees. Please record name of chair and notetaker.
Meeting Comments	Summary of discussion
Is further remedial action required?	Yes/No* If yes state action required and responsible person
Patient Safety Incident Response Criteria met?	Yes/No* State reason for decision
Is the incident reportable to an external body?	Yes/No* If yes state body and arrangements for reporting
Is patient disclosure required?	Yes/No* State reason for decision and arrangements for disclosure
Arrangements for further investigation	Level of Investigation: Lead Investigation: Target completion date: Scope: Terms of Reference:

APPENDIX 3: SWARM HUDDLE

An effective swarm involves six steps:

1. Introduce all participants so everyone knows who each other's name and their role in the swarm.
2. Create a safe and 'brave' space by reassuring participants that the purpose of the swarm is to identify what happened and why by exploring the systems and contexts in which patient care was being delivered (i.e. work as done).
3. Replay the events that led to the swarm.
4. Explore what happened and why, through the lens
5. Identify where else in the organisation the learning from the swarm may be relevant.
6. Identify safety actions, and where feasible, assign specific deliverables and completion dates to leads.

Swarm Huddle Template

Swarm Title:	Modality:
Incident No:	Swarm Date:
Name	Job Title

Reason for calling the swarm	
1. Who called this Swarm? What has led to this Swarm being called?	
2. What is the problem that we are here to solve?	
3. Who is here? Have we got the right people to solve this challenge?	
4. Who is the best person to chair and facilitate this Swarm?	
Current situation and causes	
1. What happens currently?	
2. Who does this affect?	
3. Where does it happen and have an impact?	
4. When does it occur	
5. Why is it a problem for us?	
Goal	
1. What are we trying to achieve? In an ideal world, what would this look like?	
2. What can we do about this?	

3. Which of these options are we going to take forward?	
Agreed actions, who will be responsible and timelines	
1. What actions are we taking forward?	
2. What do we expect to happen if we do this?	

Action Log			
Action	Name of individual	Completion target date	Status

Please note: All actions should be logged and monitored on InPhase

APPENDIX 4 AFTER ACTION REVIEW TEMPLATE

After Action Review

Incident number:	
Location:	
Date of incident:	
Completed by (name):	
Job title:	
Date of review:	
Staff involved:	
After Action Review Approved by:	
Job title:	
Date:	
Date attached to InPhase:	

What was supposed to happen?	What did happen?
Why was there a difference?	What can we learn from this?

APPENDIX 5 PATIENT SAFETY INCIDENT INVESTIGATION REPORT

Patient Safety Incident Investigation Report

Private & Confidential

This document is designed to be used as a working template; BLUE text throughout the document aims to provide guidance and assistance to the author and must be deleted prior to final approval.

Patient Safety Incident Investigation description	Brief incident description e.g. Radiation Incident –Name of Unit	
Service/ Modality		
Date of Incident	Enter the incident date if known or the date of discovery if not known	
InPhase number		Date:
LFPSE number or StEIS number		Date:
Lead investigator	Name and Job Title	
Executive Lead		

Final Approval of PSII

Approval of PSII and Action Plan			
	Signature (Electronic accepted)	Date	Name and Designation
PSII Lead Author:			
PSII sign off Executive lead.			
Governance Group Monitoring Action Plan			

Once the final signature approval of the document is confirmed this then can be shared with the family, legal services and/ or relevant parties. This final signature confirms that all action plans have been dated and agreed and that all quality checks have been completed.

(Delete all blue guidance text and, if relevant, replace with text in black).

This report may be shared with the patient, family, HM Coroner and may find its way into the public domain and should be written, as far as is possible, with these audiences in mind. It must be an objective, open and honest account of the investigation findings. If you commission an independent expert/opinion as part of your investigation, please attach their report as an appendix.

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2: Investigation overview – including: <ul style="list-style-type: none"> • Identification of the reference event (incident); • Investigation process and methodology; • Decision to investigate and terms of reference • The clinical area where the incident occurred 	
3: Background – including: <ul style="list-style-type: none"> • Context about the incident • The reference event (Incident) 	
4: Involvement <ul style="list-style-type: none"> • Patient and family involvement • Staff involvement 	
5: Analysis <ul style="list-style-type: none"> • Identification of issues/ problems • Understanding why these occurred • Highlighting potential barriers to prevent recurrence 	
6: Summary of Findings, Observations, Recommendations and Actions <ul style="list-style-type: none"> • Findings • Observations • Recommendations • Actions 	
Appendix 1 Duty of candour	
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About InHealth

As the UK's largest specialist provider of diagnostic and healthcare solutions, we make healthcare better by working with hospitals and commissioners across the NHS and independent sector. With more than 30 years' experience, this approach is helping to meet some of health's most pressing challenges – reducing waiting times, speeding up diagnoses, saving money and improving the overall patient experience.

We work collaboratively with NHS and private sector referrers to improve access, affordability and timely diagnosis and treatment for patients, providing tests, scans and examinations for more than 4 million patients a year, across the UK.

Across a range of different services, we work in community diagnostic and treatment centres, community-based medical centres, hospitals, GP surgeries and health clinics.

InHealth is registered with the Care Quality Commission to provide services in multiple locations under the following legal entities:

- Diagnostic World Ltd
- InHealth Endoscopy Limited
- InHealth Intelligence Limited
- InHealth Limited
- InHealth Pathology Limited
- InHealth Reporting Limited
- InHealth Echotech Limited
- Preventicum UK Limited
- Prime Endoscopy (Bristol) Limited
- United Open MRI Limited
- Vista Diagnostics Limited

InHealth services are delivered under the following CQC regulated activities [Scope of registration: Regulated activities - Care Quality Commission \(cqc.org.uk\)](#)

- Diagnostic and screening procedures (DSP)
- Treatment of disease, disorder and injury (TDDI)
- Surgical procedures (SP)

All our services are registered to deliver the DSP regulated activity, a small number additionally deliver care that falls under the TDDI regulated activity. The SP activities are only delivered in our cardiac catheter laboratories.

InHealth aims to improve patient safety through effective impartial investigations that do not apportion blame or liability. This is delivered through

- **Learning for improvement** – by using findings to deliver practical solutions, address causes and contributory factors and provide safety observations, safety recommendations and actions.

- **Sharing learning** – through effective communication and engagement with the InHealth Group and where applicable the wider health community.

Acknowledgements

InHealth is grateful for the ongoing support and involvement of the [xxx](#), the patient or [family of xxx](#), whose experience is central to this report. [XXX's](#) name is used throughout this report at [the xxx/family's](#) request and their clinical details have been shared, with their consent.

Our investigation process and approach

Patient safety Incident investigations (PSIIs) are conducted for systems learning and safety improvement. This is achieved by identifying the circumstances surrounding incidents and the systems-focused, interconnected causal factors that may appear to be precursors to patient safety incidents. These factors must then be targeted using strong (effective) system improvements to prevent or continuously and measurably reduce repeat patient safety risks and incidents.

PSII's are initiated following a report by staff of an incident of concern, a complaint raised by patients or families or through an enquiry raised from the wider health community. An open incident reporting culture that does not apportion blame and seeks to investigate and address learning is fundamental to ensuring a patient focussed safety culture exists within InHealth.

The initial facts of an incident are presented to either the Chief Medical Director, Director of Clinical Quality and Chief Nursing Officer or a SCGR BP (or a designated representative) at an incident review meeting. It is their decision as to what type of further investigation is undertaken and to define the specific terms of reference for that investigation (TOR) (See: Patient Safety Incident Investigation Policy).

The decision to undertake a Patient Safety Incident investigation (PSII) is based upon:

- a. actual and potential impact of the incident's outcome (harm to people, service quality, public confidence, products, funds, etc.)
- b. likelihood of recurrence (including scale, scope and spread)
- c. potential for new learning in terms of:
 - enhanced knowledge and understanding of the underlying factors
 - improved efficiency and effectiveness (control potential) opportunity to influence wider system improvement.

Terms of Reference

To investigate the known facts relating to this care episode

To ensure concerns raised are addressed and a factual response is provided

For an accurate chronological timeline of events to be obtained from the healthcare records and staff directly involved in the care of the patient

To explore the wider management of the episode of care against local and national clinical guidelines and protocol.

Sharing Report Findings

InHealth works closely with patients and families, healthcare staff and where relevant other organisations during an investigation. Our reports are provided directly to the families involved and shared with our commissioners.

The investigation will identify safety actions and make safety recommendations and safety observations to influence and support change.

Safety Recommendations are directed to clinical teams and services within InHealth for action. The recommendation(s) are based on information from the investigation and/or other eligible sources. Recommendations are made with the intention of preventing similar events.

Safety Observations These are incidental learning that do not directly impact or contribute to the casual findings of the event that is being investigated are directed to clinical teams and services for action.

Safety Actions are actions taken to address immediate identified safety concerns found during the investigations or are further actions linked to the report's recommendations.

1. Executive Summary

The summary should be short and succinct. It should provide an introduction, a short description of the reference event (incident), the findings, the safety recommendations and safety observations. This could all be done as a list of bullet points.

The Reference Event (Incident):

- Bullet points

The Purpose of the Investigation (TOR):

- 1.
- 2.

Investigation Findings, Causality and Lessons Learnt:

Bullet points on all aspects not just problems.

The investigations made the following Safety Recommendations:

1. Safety Recommendation
2. Safety Recommendation
3. etc

The Investigation Team made the following Safety Observations:

1. Safety Observations
2. Etc.

1: Investigation overview

1.1 Identification of the reference event (incident)

The incident was reported to InHealth's incident management system (InPhase) on **XXX**.

This report reviews the care episode from **XXX** until **XXX**.

1.2 Investigation process and methodology

A variety of methodologies were used in this investigation. This included review of patient healthcare records, hospital policies, procedures and practice. Furthermore, interviews and insights from staff involved took place including communication with relevant subject matter experts, both clinical and non-clinical.

The objective of this report is to review the care episode using a systems-based approach, without attributing blame or liability to individuals. It is to understand the events and identify opportunities to learn and to improve patient safety across the system. InHealth fully supports a "just culture" approach and encourages those involved to contribute openly to the review process.

1.3 Decision to Investigate and Terms of Reference (Use Decision making Brief template)

1.3.1 Decision to investigate

Describe the process by which this incident was recognised and the decision-making meeting that was undertaken to make the decision to investigate.

1.3.2 Terms of Reference

This is where you will explain the rationale under the three headings mentioned earlier -:

- Outcome of the incident – what was or is the impact of the safety issue on people and services.
- Systematic risk and learning potential – how widespread and common a safety issue is this
- Learning Potential – what potential is there for the investigation to lead to positive changes and improvements to patient safety

Plus add in any additional terms of reference from the executive review/rapid incident review.

1.4 The clinical area where the incident occurred

Add in a brief description of the area and any additional information about the working context at the time of the event.

2. Background

2.1 Context about the incident

In this section you need to set out in detail the background against which the incident will be measured using national and local policy/best practice. This includes photos and graphics to help the reader's understanding. By having the background earlier in the report will enable the reader to have a clearer understanding of the incident and the findings.

This may include:

- Researched information on the actual condition/procedure involved in the incident. Need to reference local /national policy standards.
- Risk assessments
- Previous relevant investigations and action plans

2.2 The Reference Event (Incident)

In this section of the report you will need to include the impact on the patient and the clinical outcomes for the organisation at this stage in the report.

- This is basically the incident description/chronology in one.
- Pre-incident if relevant
- Day of the Incident
- Post incident
- Impact on the patient/ families

2.3: Chronology of events. See Appendix 2.0

The chronology should focus upon the key events and relevant factors of the incident for this investigation only.

3. Involvement

3.1 Patient and Family Involvement

In this section include conversations with patient/family and any questions they have plus their involvement in the investigation process/reviewing the report, etc. Support provided to patient and/or families. Please ensure that all contributors can see the final version before divisional sign off.

3.2 Staff involvement

3.2.1. Contributors to the Investigation

In this section please include details of the contributors to the investigation outlined in this report who were directly involved in the incident and/ or have been requested to provide an expert opinion or narrative that contributes to the investigation's recommendations.

3.2.2 Supporting Staff (Please see Appendix 4)

4.0 Analysis

In this section you need to identify any issues/problems in the patients care and the reasons why these occurred.

State how the analysis undertaken e.g. clinical record review, mortality and morbidity meeting, interview of staff?

4.1 Identification of issues/ problems

- What were the identified issues/problems that led to the incident occurring
- Refer to the specific events detailed in section 2.2 and compare these with the information presented in section 2.1 regarding policies procedures and identify any variances changes to what was expected.

What should have happened? Normal System/process	What did happen?	What are the identified gaps/ issues?

4.2 Understanding why these occurred

System factors analysis:

Once the gaps/issues with the patient's care have been identified then within this section discuss why these occurred. What were the barriers and systems that could have prevented the incident from occurring? Are actions required that could be implemented to provide or strengthen controls to prevent recurrence?

4.2.1 System Analysis	
External context factors	
Organisational and strategic factors	
Operational management factors	
Workplace factors	
Equipment and technology factors	
Team and social factors	
Task factors	
Individual patient factors	
Individual staff factors	

Appendix 1 Duty of Candour

Duty of Candour				
Requirement	Yes/No Date	Name and designation of registered person completing requirement	Date recorded in health record	Comments
<p>Has the patient or the relevant person lawfully acting on the patient's behalf been provided with:</p> <ul style="list-style-type: none"> - An appropriate, meaningful face to face apology? - An explanation of the facts known at the time of the event? - The type of review/investigation that is taking place? 				
<p>Has the patient or the relevant person lawfully acting on the patient's behalf had the opportunity to:</p> <ul style="list-style-type: none"> - Ask any relevant questions to be included in the investigation? - Notified of how they can be involved in this or service improvements? 				

Appendix 2: Glossary/acronyms used in Report

Acronyms should be kept to a minimum to avoid making the report difficult to read for those unfamiliar with technical or medical terminology. Add or delete rows to the table below as applicable

Acronym/Term	Explanation

Appendix 4: Supporting Staff

Supporting Staff	
Specify available support offered to staff involved in the incident in line with the Staff Support and Being Open Policy:	
Individual debrief	
Team debrief	
Support from line manager: for individuals	
Support from line manager: for team	
Support from supervisor/mentor	
Support from professional body/union representative	
External support (including via Occupational Health)	

Appendix 5: Version Control

Version	Status	Date	Person responsible	Comments
1.0	First draft for comment by contributors	dd/mm/yyyy	Report author	N/A
2.0	Second draft amended in response to contributors comments			Factual accuracy amendment to Appendix1. Clarification of why xxxx happened Addition of relevant literature.
3.0	Final draft with Clinical Quality sign off		Report sign off by HoCGR or DoC &CNO	
4.0	Objective Quality assurance check patient safety team		Report sign off by patient safety team.	Addressing use of abbreviations Removal of inadvertently left in patient's name Clarification of analysis section

5.0	Report sent to Exec Lead prior to sending to CCG		Report initial sign off by Exec lead.	
6.0	Review by Patient Safety Group dd/mm/yyyy		Report signed off by PSG group	None
Final	Executive final sign off following CCG and PSG amendments.		Report signed off at Exec review.	
	Report presented at CQSC		Report signed off by CQSC	

Appendix 5: References

Appendix 6: System Analysis (Patient Safety Incident Response Framework, contributory and mitigating factors classification – See Appendix 9)

Appendix 7: Patient Safety Incident Investigation Closure Checklist

Stage	Component	Yes / No	Comment
Commissioning the investigation	Do the focus and findings of this investigation reflect the questions asked in the terms of reference at the commencement of this investigation?		
Person affected & family	Have all Duty of Candour been completed in the PSII and the Clinical Notes		
	Have the Patient and Family been given an opportunity to participate in the investigation and does the investigation reflect the questions that the family wished addressed?		
	Is the patient/family/identity protected throughout?		
Staff involved or affected	Is there evidence that staff were offered appropriate support		
	Is staff identity protected throughout? Are there no references to names, only job titles to differentiate those involved		
Gathering data	Were all suitable information sources used to gather the data e.g. <ul style="list-style-type: none"> • Patient and/or their family/ significant other. • Patient clinical records • People involved • Procedural documentation • The site of incident • Other sources (e.g. equipment records) 		

Stage	Component	Yes / No	Comment
	<ul style="list-style-type: none"> Current relevant policies, SOP's and procedural guidance. 		
Mapping the data	Is there a clear description of the incident that has occurred, the events that are relevant that have led up to the incident and the outcome / impact of this incident on the patient?		
	Is the Chronology Clear? <ul style="list-style-type: none"> Time (HH:MM) Date Event description Information source 		
Analysing Information	Does the analysis answer the questions outlined in the terms of reference set for this investigation?		
	Have all the questions that the patient/ family asked been clearly answered?		
	Has a systems approach been undertaken when analysing the investigations findings?		
Generating Solutions	Are the investigation recommendations consistent with the findings in the investigation analysis? Have clear, numbered recommendations been made that flow logically and realistically.		
	Are recommendations consistent with the terms of reference		
	Are all recommendations relevant		
	Are these recommendations realistic		
Governance Effectiveness and internal consistency of the report Report housekeeping standards	Has a report distribution list been set out?		
	Are all sections of the PSII report complete?		
	Has the suitable governance groups been identified to develop and monitor the action plan that arise from the investigation recommendations?		
	Is there any content in different sections that is inconsistent or contradictory (dates, times, different wording for the same event)?		
	Are there any typos, spelling, punctuation or grammatical errors?		
	Are any abbreviations used written in full the first time with the abbreviations in brackets		
	<ul style="list-style-type: none"> Are times stated using 24-hour clock in the format hh:mm? 		
	Is the font size and type consistent throughout?		

Stage	Component	Yes / No	Comment
Effectiveness and internal consistency of the report	Is the formatting consistent throughout the report? Use of		
	Is the general presentation professional?		
Tone and style		For Reflection and comment	
	Does the report use plain English with a simple and direct style; use short sentences and avoid complicated constructions or unnecessary clinical terms?		
	Is the patient/family referred to in a respectful way within the report?		
	Does the report come across as open and honest, with empathy for all individuals involved?		

APPENDIX 6: THEMATIC REVIEW TEMPLATE

What is this for?

A themed review may be useful in understanding common links, themes, or issues within a cluster of investigations or incidents. It will seek to understand key barriers or facilitators to safety using reference cases (e.g. individual InPhase incidents or previous investigations).

What may benefit a themed review?

Grouped incidents, for example from the same portfolio like radiation protection incidents, falls or deteriorating patient, may benefit from a themed review because they take the same safety concern and identify different reference cases and contexts. This helps the organisation make sense of the safety concern at different points of the system and with different aspects of variability e.g. staffing issues, multiple radiation incidents. This is important, because safety incidents may occur when systems are 'pushed' or 'pressurised' and therefore our view of safety needs to be flexible to the variability around the context.

What should the output of a themed review be?

Themed reviews may identify fallibilities of the components of a safety system. For example, it may be that across all the reference cases a risk assessment was completed but the preventative measures were not actioned. Outputs of themed reviews can highlight these problems and identify safety recommendations. Themed reviews may provoke more questions than answers, and therefore may be best placed to link in to a quality improvement project for ongoing monitoring. A themed review should be viewed as a diagnostic tool to help diagnose problems in the system, and therefore doing a themed review should **always** result in some improvement efforts after this diagnosis.

What are the stages of a thematic review?

Stage 1: Description of the reference cases

Stage 2: Description of the safety system

Stage 3: Relevant context to each reference case and key problems

Stage 4: Common themes across the reference cases – narrative analysis

Stage 5: Safety recommendations and future work

Use Appendix 7 as an Action Plan Template

E.g. System of safety for deteriorating patient:

- Patient identified as being at risk of deterioration (clinical notes/observations)
- Clinical task of collecting observation data and calculating (NEWS2 score)
- Preventative/clinical measures put in place (e.g. increased observations/sepsis bundle)
- Senior review of deteriorating patient

Stage 3: Relevant context to each reference case and key problems

This stage refers to contributory factors (as classified by the contributory and mitigating factors classification here: [https://www.england.nhs.uk/wp-content/uploads/2020/08/PSII Contributory and Mitigation Factors Classification.pdf](https://www.england.nhs.uk/wp-content/uploads/2020/08/PSII_Contributory_and_Mitigation_Factors_Classification.pdf))

Mark the factors that affected each reference case based on the description above:

Causal Factors	Domain	Components	Contributory, Causal and Mitigating Factors Analysis – for identified PROBLEMS/WEAKNESSES and STRENGTHS										
			1	2	3	4	5	6	7	8	9	10	
Incident numbers			1	2	3	4	5	6	7	8	9	10	
CONTRIBUTORY and MITIGATING FACTORS Described as they relate to the PROBLEMS/WEAKNESSES and STRENGTHS identified (NB: There may be none, one or more CF/MF in each category)	External Contextual Factors	National guidelines and policies											
		Economic and regulatory context											
		Societal factors											
		Total											
	Organisational Strategic Factors	Structure											
		Priorities/resource											
		Safety culture											
		Policies, standards, and goals											
	Total												
	Operational Management Factors	Safety focus											
		Work planning and delivering											
		Staffing levels and skill mix											
		Workload, shift pattern, hours of work											
		Training											
		Staff supervision											
		Staff competence											
	Total												
	Workplace Factors	Environment factors											
		Design of physical environment											

	<i>Administrative factors</i>																				
	Total																				
Equipment & Technology Factors	<i>Display</i>																				
	<i>Integrity and maintenance</i>																				
	<i>Positioning and availability</i>																				
	<i>Usability/design</i>																				
	Total																				
Team & Social Factors	<i>Culture</i>																				
	<i>Team structure and consistency</i>																				
	<i>Leadership</i>																				
	<i>Communication management</i>																				
	<i>Verbal communication</i>																				
	<i>Written communication</i>																				
	<i>Non-verbal communication</i>																				
	Total																				
Task Factors	<i>Clinical condition</i>																				
	<i>Plans/policies/procedures in place for task</i>																				
	<i>Decision making aids</i>																				
	<i>Procedural or task design and clarity</i>																				
	Total																				
Individual Patient Factors	<i>Physical factors</i>																				
	<i>Social factors</i>																				
	<i>Psychological factors</i>																				
	Total																				
Individual Staff Factors	<i>Physical health</i>																				
	<i>Psychological factors</i>																				
	<i>Social/domestic factors</i>																				
	<i>Personality factors</i>																				
	<i>Social factors</i>																				
	<i>Cognitive factors</i>																				
Incident numbers		1	2	3	4	5	6	7	8	9	10										

Stage 4: Common themes across the reference cases - Narrative analysis

Use the space below to compile narrative data surrounding the above sections. For example, if 2 or more incidents have a X by the group, then clarify the similarities/differences in the boxes below:

External Contextual Factors	<i>E.g., How did national guidelines affect the reference cases?</i>
Organisational Strategic Factors	<i>E.g., How did local guidelines/organisational resource affect the reference cases?</i>
Operational Management Factors	<i>E.g., How did local organisational level factors (e.g. staffing, skill mix, training, and staff supervision) affect the reference cases?</i>
Workplace Factors	<i>E.g., How did environment factors/design of workplace affect the reference cases?</i>
Equipment & Technology Factors	<i>E.g., How did equipment/technology affect the reference cases?</i>
Team & Social Factors	<i>E.g., How did local team dynamics/team culture/leadership/communication affect the reference cases?</i>
Task Factors	<i>E.g., How did task clarity/decision-making prompts affect the reference cases?</i>
Individual Patient Factors	<i>E.g. How did individual patient factors (e.g. acuity/clinical/psychological) affect the reference cases?</i>

Individual Staff Factors	<p><i>E.g. How did individual staff factors (e.g. social/psychological) affect the reference cases?</i></p>

Stage 5: Safety recommendations

In this section, linking to the sections above, list the safety recommendations based on this thematic review.

Different types of safety recommendations:

Category	Definition	Example
Fix	Resolve problems in reliably doing what we said we would do. These were usually issues that could be resolved with rapid operational changes.	Linear or more 'simple' things you can do to help the process. E.g., if you identify that there are conflicting local policies which meant a clinician was confused with the task, then the fix would be to resolve the confusion by rewriting the policy
Improvements	Find better ways of delivering standard care; improve what is currently being done.	Where improvement need to be made in an already defined process. This may be linked to a Quality Improvement (QI) project and should involve metrics to measure improvements.
Changes	Significant changes in clinical or operational practice.	Where a system, process, or pathway needs to change. N.b. this should be based on multiple cases of evidence, rather than being linked to one case. Where change is needed, an output may be a task and finish group, and this will involve multiple stakeholders.
Further insight	Where investigations have resulted in more questions relating to a safety issue, it may be appropriate for a safety recommendation to involve gaining more insight	If you do an investigation for a particular safety risk but are not sure of the scale of the problem or the mechanism of action then collecting further data may then help identify safety recommendations later.

Safety recommendation	Category (Fix/improvement/change/further insight)	Date Due	Evidence	Owner

APPENDIX 7: PATIENT SAFETY INCIDENT INVESTIGATION ACTION PLAN

Version: Date:

Action Plan in response to recommendations arising from the investigation relating to:

Patient Safety Investigation Number:	N/A if not applicable
InPhase incident number:	
Incident date:	
Type of incident:	
Action plan sign off by Service	
Action Plan Owner	
Management Committee monitoring implementation:	

Recommendation	Action required to deliver recommendation	Owner	Target Date	Governance group responsible for monitoring action	Evidence that will be provided to demonstrate completion of action	How will this make a difference
If patient/family have requested, then provide feedback to patient/family on incident investigation outcome following Governance sign off.	See recommendation	Director of Clinical Quality and Chief Nursing officer/ SCGR BP	Date the meeting is undertaken, or report sent to the family	Governance Committee	Date of the meeting entered into Duty of Candour fields on InPhase and/ or progress notes on InPhase to evidence that the report has been sent to the family.	Ensure compliance with the Regulation 20 – Duty of Candour

APPENDIX 8- EXTERNALLY REPORTABLE EVENTS ROLES AND RESPONSIBILITIES

This document aims to provide guidance to managers and staff about the actions required prior to the submission of a report of an adverse event within InHealth to an external body. Should you require any assistance or guidance regarding any element of external reporting please contact

EXTERNAL BODY	RESPONSIBILITY FOR SUBMISSION	REPORT DISCUSSION/ REVIEW PRIOR TO SUBMISSION	APPROVAL PRIOR TO SUBMISSION
MHRA/ BNF yellow card system	Location manager	Location manager (if not submitting directly)	Not required
Health and Safety Executive – RIDDOR Incidents	CQC Registered Manager/ Service Manager	SCGR BP, Health and Safety Competent Person	Legal team and Director of Clinical Quality and Chief Nursing Officer
Care Quality Commission (CQC)	CQC registered Manager	Clinical Quality Team	Director of Clinical Quality and Chief Nursing Officer
Commissioning Body	Service/ contract manager	Service/ contract manager if not submitting directly	Legal team OR Director of Clinical Quality and Chief Nursing Officer OR Chief People Officer
LFPSE/ Commissioning Body- Serious Incident	Service manager/ CQC registered manager	Clinical Quality Team Legal team	Legal team and Director of Clinical Quality and Chief Nursing Officer
Information Commissioner's Office (ICO)	Clinical Quality Team	Caldicott Guardian, Data Protection Officer and Senior Information Risk Officer (SIRO)	Legal team and SIRO
Environment Agency (EA)	Location Manager	Sustainability Steering Group	Legal team and Sustainability Executive Sponsor

APPENDIX 9 - NPSA CONTRIBUTORY FACTORS CLASSIFICATION FRAMEWORK

Contributory Factors Classification Framework

Patient Factors	Components
Clinical condition	<input type="checkbox"/> Pre-existing co-morbidity <input type="checkbox"/> Complexity of condition <input type="checkbox"/> Seriousness of condition <input type="checkbox"/> Limited options available to treat condition <input type="checkbox"/> Disability
Physical Factors	<input type="checkbox"/> Poor general physical state <input type="checkbox"/> Malnourished <input type="checkbox"/> Dehydrated <input type="checkbox"/> Age related issues <input type="checkbox"/> Obese <input type="checkbox"/> Poor sleep pattern
Social Factors	<input type="checkbox"/> Cultural / religious beliefs <input type="checkbox"/> Language <input type="checkbox"/> Lifestyle (smoking/ drinking/ drugs/diet) <input type="checkbox"/> Sub-standard living accommodation (e.g. dilapidated) <input type="checkbox"/> Life events <input type="checkbox"/> Lack of support networks / (social protective factors -Mental Health Services) <input type="checkbox"/> Engaging in high risk activity
Mental/ Psychological Factors	<input type="checkbox"/> Motivation issue <input type="checkbox"/> Stress / Trauma <input type="checkbox"/> Existing mental health disorder <input type="checkbox"/> Lack of intent (Mental Health Services) <input type="checkbox"/> Lack of mental capacity <input type="checkbox"/> Learning Disability
Interpersonal relationships	<input type="checkbox"/> Staff to patient and patient to staff <input type="checkbox"/> Patient engagement with services <input type="checkbox"/> Staff to family and family to staff <input type="checkbox"/> Patient to patient <input type="checkbox"/> Family to patient or patient to family <input type="checkbox"/> Family to family (Siblings, parents, children)

Staff Factors	Components
Physical issues	<input type="checkbox"/> Poor general health (e.g. nutrition, hydration, diet, exercise, fitness) <input type="checkbox"/> Disability (e.g. eyesight problems, dyslexia) <input type="checkbox"/> Fatigue <input type="checkbox"/> Infected Healthcare worker
Psychological Issues	<input type="checkbox"/> Stress (e.g. distraction / preoccupation) <input type="checkbox"/> Specific mental illness (e.g. depression) <input type="checkbox"/> Mental impairment (e.g. illness, drugs, alcohol, pain) <input type="checkbox"/> Lack of motivation (e.g. boredom, complacency, low job satisfaction)
Social Domestic	<input type="checkbox"/> Domestic problems (e.g. family related issues) <input type="checkbox"/> Lifestyle problems (e.g. financial/housing issues) <input type="checkbox"/> Cultural beliefs <input type="checkbox"/> Language
Personality Issues	<input type="checkbox"/> Low self-confidence / over confidence (e.g. Gregarious, reclusive, interactive) <input type="checkbox"/> Risk averse / risk taker <input type="checkbox"/> Bogus Healthcare worker

Cognitive factors	<input type="checkbox"/> Preoccupation / narrowed focus (Situational awareness problems) <input type="checkbox"/> Perception/viewpoint affected by info. or mindset (Expectation/Confirmation bias) <input type="checkbox"/> Inadequate decision/action caused by Group influence <input type="checkbox"/> Distraction / Attention deficit <input type="checkbox"/> Overload <input type="checkbox"/> Boredom
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Task Factors	Components
Guidelines, Policies and Procedures	<input type="checkbox"/> Not up-to-date <input type="checkbox"/> Unavailable at appropriate location (e.g. Lost/missing/non-existent/not accessible when needed) <input type="checkbox"/> Unclear/not useable (Ambiguous; complex; irrelevant, incorrect) <input type="checkbox"/> Not adhered to / not followed <input type="checkbox"/> Not monitored / reviewed <input type="checkbox"/> Inappropriately targeted/focused (i.e. not aimed at right audience) <input type="checkbox"/> Inadequate task disaster plans and drills
Decision making aids	<input type="checkbox"/> Aids not available (e.g. CTG machine; checklist; risk assessment tool; fax machine to enable remote assessment of results) <input type="checkbox"/> Aids not working (e.g. CTG machine, risk assessment tool, fax machine) <input type="checkbox"/> Difficulties in accessing senior / specialist advice <input type="checkbox"/> Lack of easy access to technical information, flow charts and diagrams <input type="checkbox"/> Lack of prioritisation of guidelines <input type="checkbox"/> Incomplete information (test results, patient history)
Procedural or Task Design	<input type="checkbox"/> Poorly designed (i.e. too complex; too much info.; difficult to conceive or remember) <input type="checkbox"/> Guidelines do not enable one to carry out the task in a timely manner <input type="checkbox"/> Too many tasks to perform at the same time <input type="checkbox"/> Contradicting tasks <input type="checkbox"/> Staff do not agree with the 'task/procedure design' <input type="checkbox"/> Stages of the task not designed so that each step can realistically be carried out <input type="checkbox"/> Lack of direct or understandable feedback from the task <input type="checkbox"/> Misrepresentation of information <input type="checkbox"/> Inappropriate transfer of processes from other situations <input type="checkbox"/> Inadequate Audit, Quality control, Quality Assurance built into the task design <input type="checkbox"/> Insufficient opportunity to influence task/outcome where necessary <input type="checkbox"/> Appropriate automation not available

Communication	Components
Verbal communication	<input type="checkbox"/> Inappropriate tone of voice and style of delivery for situation <input type="checkbox"/> Ambiguous verbal commands / directions <input type="checkbox"/> Incorrect use of language <input type="checkbox"/> Made to inappropriate person(s) <input type="checkbox"/> Incorrect communication channels used
Written communication	<input type="checkbox"/> Inadequate patient identification <input type="checkbox"/> Records difficult to read <input type="checkbox"/> All relevant records not stored together and accessible when required <input type="checkbox"/> Records incomplete or not contemporaneous (e.g. unavailability of patient management plans, patient risk assessments, etc) <input type="checkbox"/> Written information not circulated to all team members <input type="checkbox"/> Communication not received <input type="checkbox"/> Communications directed to the wrong people <input type="checkbox"/> Lack of information to patients <input type="checkbox"/> Lack of effective communication to staff of risks (Alerts systems etc)
Non-verbal communication	<input type="checkbox"/> Body Language issues (closed, open, body movement, gestures, facial expression)

Communication Management	<input type="checkbox"/> Communication strategy and policy not defined / documented <input type="checkbox"/> Ineffective involvement of patient/carer in treatment and decisions <input type="checkbox"/> Lack of effective communication to patients/relatives/carers of risks <input type="checkbox"/> Lack of effective communication to patients about incidents (being open) <input type="checkbox"/> Information from patient/carer disregarded <input type="checkbox"/> Ineffective communication flow to staff up, down and across <input type="checkbox"/> Ineffective interface for communicating with other agencies (partnership working) <input type="checkbox"/> Lack of measures for monitoring communication
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Equipment	Components
Displays	<input type="checkbox"/> Incorrect information / feedback available <input type="checkbox"/> Inconsistent or unclear information <input type="checkbox"/> Illegible information <input type="checkbox"/> Interference/unclear equipment display
Integrity	<input type="checkbox"/> Poor working order <input type="checkbox"/> Inappropriate size <input type="checkbox"/> Unreliable <input type="checkbox"/> Ineffective safety features / not designed to fail safe <input type="checkbox"/> Poor maintenance programme <input type="checkbox"/> Failure of general services (power supply, water, piped gases etc.)
Positioning	<input type="checkbox"/> Correct equipment not available <input type="checkbox"/> Insufficient equipment / emergency backup equipment <input type="checkbox"/> Incorrectly placed for use <input type="checkbox"/> Incorrectly stored
Usability	<input type="checkbox"/> Unclear controls <input type="checkbox"/> Not intuitive in design <input type="checkbox"/> Confusing use of colour or symbols <input type="checkbox"/> Lack of or poor-quality user manual <input type="checkbox"/> Not designed to make detection of problems obvious <input type="checkbox"/> Use of items which have similar names or packaging <input type="checkbox"/> Problems of compatibility

Work Environment	Components
Administrative factors	<input type="checkbox"/> Unreliable or ineffective general administrative systems (Please specify e.g.: Bookings, Patient identification, ordering, requests, referrals, appointments) <input type="checkbox"/> Unreliable or ineffective admin infrastructure (e.g. Phones, bleep systems etc.) <input type="checkbox"/> Unreliable or ineffective administrative support
Design of physical environment	<input type="checkbox"/> Poor or inappropriate office design (computer chairs, height of tables, anti-glare screens, security screens, panic buttons, placing of filing cabinets, storage facilities, etc.) <input type="checkbox"/> Poor or inappropriate area design (length, shape, visibility, provision of space) <input type="checkbox"/> Inadequate security provision <input type="checkbox"/> Lack of secure outside space <input type="checkbox"/> Inadequate lines of sight <input type="checkbox"/> Inadequate/inappropriate use of colour contrast/patterns (walls/doors/flooring etc.)
Environment	<input type="checkbox"/> Facility not available (failure or lack of capacity) <input type="checkbox"/> Fixture or fitting not available (failure or lack of capacity) <input type="checkbox"/> Single sex accommodation limitation/breach <input type="checkbox"/> Ligature/anchor points <input type="checkbox"/> Housekeeping issues – lack of cleanliness <input type="checkbox"/> Temperature too high/low <input type="checkbox"/> Lighting too dim or bright, or lack of <input type="checkbox"/> Noise levels too high or low <input type="checkbox"/> Distractions

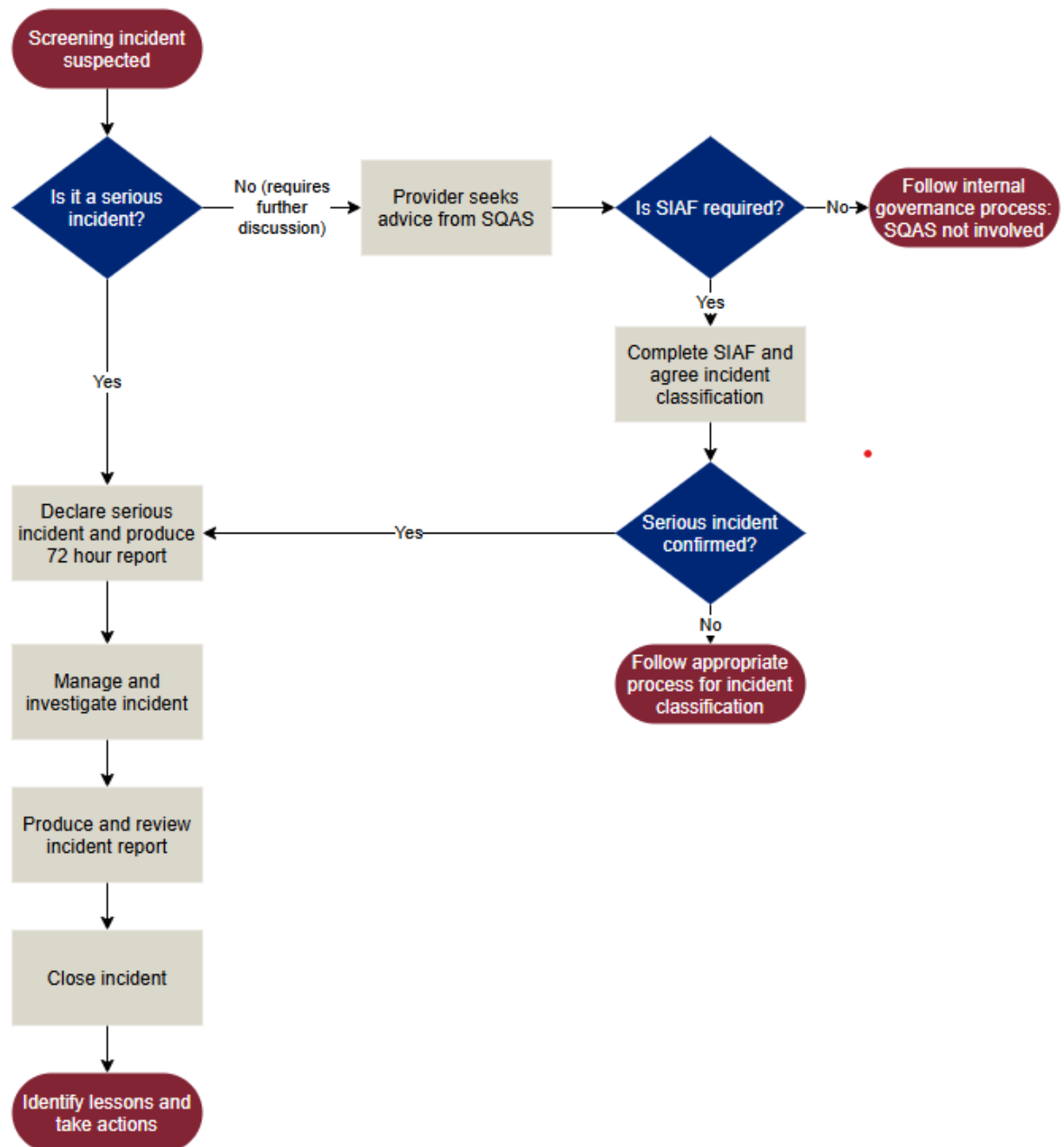
Staffing	<input type="checkbox"/> Inappropriate skill mix (e.g. Lack of senior staff; Trained staff; Approp. trained staff) <input type="checkbox"/> Low staff to patient ratio <input type="checkbox"/> No / inaccurate workload / dependency assessment <input type="checkbox"/> Use of temporary staff <input type="checkbox"/> High staff turnover
Workload and hours of work	<input type="checkbox"/> Shift related fatigue <input type="checkbox"/> Excessive working hours <input type="checkbox"/> Lack of breaks during work hours <input type="checkbox"/> Excessive of extraneous tasks <input type="checkbox"/> Lack of social relaxation, rest and recuperation
Time	<input type="checkbox"/> Delays caused by system failure or design <input type="checkbox"/> Time pressure

Organisational	Components
Organisational structure	<input type="checkbox"/> Hierarchical structure/Governance structure not conducive to discussion, problem sharing, etc. <input type="checkbox"/> Tight boundaries for accountability and responsibility <input type="checkbox"/> Professional isolation <input type="checkbox"/> Clinical versus the managerial model <input type="checkbox"/> Inadequate maintenance <input type="checkbox"/> Lack of robust Service level agreements/contractual arrangements <input type="checkbox"/> Inadequate safety terms and conditions of contracts
Priorities	<input type="checkbox"/> Not safety driven <input type="checkbox"/> External assessment driven e.g. Annual Health checks <input type="checkbox"/> Financial balance focused
Externally imported risks	<input type="checkbox"/> Unexpected adverse impact of national policy/guidance (from Department of Health / Health authorities /Professional colleges) <input type="checkbox"/> Locum / Agency policy and usage <input type="checkbox"/> Contractors related problem <input type="checkbox"/> Equipment loan related problem <input type="checkbox"/> Lack of service provision <input type="checkbox"/> Bed Occupancy levels (Unplanned bed opening/closures) <input type="checkbox"/> PFI related problems (Private Finance Initiative)
Safety culture	<input type="checkbox"/> Inappropriate safety / efficiency balance <input type="checkbox"/> Poor rule compliance <input type="checkbox"/> Lack of risk management plans <input type="checkbox"/> Inadequate leadership example (e.g. visible evidence of commitment to safety) <input type="checkbox"/> Inadequately open culture to allow appropriate communication <input type="checkbox"/> Inadequate learning from past incidents <input type="checkbox"/> Incentives for 'at risk'/'risk taking' behaviours <input type="checkbox"/> Acceptance/toleration of inadequate adherence to current practice <input type="checkbox"/> Ignorance/poor awareness of inadequate adherence to current practice <input type="checkbox"/> Disempowerment of staff to escalate issues or take action

Education and Training	Components
Competence	<ul style="list-style-type: none"> <input type="checkbox"/> Lack of knowledge <input type="checkbox"/> Lack of skills <input type="checkbox"/> Inexperience <input type="checkbox"/> Inappropriate experience or lack of quality experience <input type="checkbox"/> Unfamiliar task <input type="checkbox"/> Lack of testing and assessment
Supervision	<ul style="list-style-type: none"> <input type="checkbox"/> Inadequate supervision <input type="checkbox"/> Lack of / inadequate mentorship <input type="checkbox"/> Training results not monitored/acted upon
Availability / accessibility	<ul style="list-style-type: none"> <input type="checkbox"/> Training needs analysis not conducted/acted upon <input type="checkbox"/> On the job training unavailable or inaccessible <input type="checkbox"/> Emergency Training unavailable or inaccessible <input type="checkbox"/> Team training unavailable or inaccessible <input type="checkbox"/> Core skills training unavailable or inaccessible <input type="checkbox"/> Refresher courses unavailable or inaccessible
Appropriateness	<ul style="list-style-type: none"> <input type="checkbox"/> Inappropriate content <input type="checkbox"/> Inappropriate target audience <input type="checkbox"/> Inappropriate style of delivery <input type="checkbox"/> Time of day provided inappropriate

Team Factors	Components
Role Congruence	<ul style="list-style-type: none"> <input type="checkbox"/> Lack of shared understanding <input type="checkbox"/> Role + responsibility definitions misunderstood/not clearly defined
Leadership	<ul style="list-style-type: none"> <input type="checkbox"/> Ineffective leadership – clinically <input type="checkbox"/> Ineffective leadership – managerially <input type="checkbox"/> Lack of decision making <input type="checkbox"/> Inappropriate decision making <input type="checkbox"/> Untimely decision making (delayed) <input type="checkbox"/> Leader poorly respected
Support and cultural factors	<ul style="list-style-type: none"> <input type="checkbox"/> Lack of support networks for staff <input type="checkbox"/> Inappropriate level of assertiveness <input type="checkbox"/> Negative team reaction(s) to adverse events <input type="checkbox"/> Negative team reaction to conflict <input type="checkbox"/> Negative team reaction to newcomers <input type="checkbox"/> Routine violation of rules/regulations <input type="checkbox"/> Lack of team openness/communication with colleagues <input type="checkbox"/> Inadequate inter-professional challenge <input type="checkbox"/> Failure to seek support <input type="checkbox"/> Failure to address/manage issues of competence (whistle blowing)

APPENDIX 10 – Reporting and Managing screening incidents



APPENDIX 11: JUST CULTURE GUIDE



A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to 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.

Please note:

- A just culture guide is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A just culture guide can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- A just culture guide does not replace HR advice and should be used in conjunction with organisational policy.
- The guide can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - **Q1. deliberate harm test**

1a. Was there any intention to cause harm?



Yes

Recommendation: Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual.

END HERE

No go to next question - **Q2. health test**

2a. Are there indications of substance abuse?



Yes

Recommendation: Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier.

END HERE

2b. Are there indications of physical ill health?



Yes

Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

END HERE

2c. Are there indications of mental ill health?

if No to all go to next question - **Q3. foresight test**

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?



If No to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

if Yes to all go to next question - **Q4. substitution test**

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?



If Yes to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

if No to all go to next question - **Q5. mitigating circumstances**

5a. Were there any significant mitigating circumstances?



Yes

Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

if No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

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