Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

SAI Redesign Project

Framework for Learning and Improvement from Patient Safety Incidents

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Contents

1.0 Introduction

In Northern Ireland, people reasonably expect Health and Social Care (HSC) to be safe and to be delivered to a high standard. When that care fails to meet an acceptable standard and a Patient Safety Incident[1] occurs, they are entitled to openness, to understand/ask why the Patient Safety Incident occurred and how the system can learn and improve to prevent such reoccurrence in the future.

This Regional Framework for Learning and Improvement from Patient Safety Incidents[2] delivers a more streamlined and simplified process for reviewing Patient Safety Incidents. This will help ensure that learning reviews are of a high quality, are concluded in a timelier manner, with a focus on understanding how and why the Patient Safety incident has occurred, and that there is system wide learning[3] leading to demonstrable and sustainable improvements in care.

This is best achieved by placing All those Affected[4] by a Patient Safety Incident at the heart of the learning review process. Securing their involvement, at a level which is in line with their wishes, enables/delivers a more complete and authentic learning review and allows their unique perspective and 'lived experience' to be taken into account when undertaking the review of a Patient Safety Incident.

The Framework also aims to best support our staff - who provide high quality, safe, and effective care in complex and demanding environments - by implementing a systems-based approach[5] to reviewing Patient Safety Incidents.

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[1] See definition of a Patient Safety Incident in key terms and definitions section.
[2] Hereinafter referred to as the Framework
[3] In order to improve patient safety, system wide learning involves everyone learning together and improving together.
[4] One of the earliest steps in the Patient Safety Incident Learning Review process is to consider and identify in a structured way who 'All those Affected' include. Organisations should consider service users, patients, families, carers, victims, victim's families, and visitors that may be affected by a Patient Safety Incident, when determining who All those Affected are.
[5] The focus of a system-based approach is examining the components of a system (e.g. person(s), tasks, tools and technology, the environment, the wider organisation) and understanding their interdependencies (i.e. how they influence each other) and how those interdependencies may contribute to patient safety. (*PSIRF NHS England*)

The Framework is firmly anchored to the HSC core values of working together, excellence, compassion, openness and honesty, and will fully align with and support the Department of Health's Being Open Framework.[6]

This Framework replaces the 'HSC Procedure for the Reporting and Follow up of Serious Adverse Incidents (SAI) - 2016' and represents a fundamental shift in how the HSC sector responds to Patient Safety Incidents by supporting a proportionate response and embedding learning reviews within a wider organisational system of learning and improvement.

2.0 Key terms and definitions

A full list of terms and definitions used in the Framework can be found in the accompanying glossary (**Annex 1**). Key definitions include:

Patient

For the purpose of this Framework the single term *patient* is used for simplicity and is defined as 'a person who is receiving, or has received, care provided by, or on behalf of, an HSC body'.[7]

Patient Safety Incident

A Patient Safety Incident is an incident or circumstance (including omissions) which could have resulted or did result in harm to a patient or group of patients, and which provides an opportunity for system learning.[8]

Patient Safety Incident Learning Review

A Patient Safety Incident Learning Review:

- examines the events leading up to the incident;
- analyses what happened and why;

[6] The Department's Being Open Framework is currently in draft pending the outcome of public consultation.
[7] Health and Social Care Complaints Directions (NI) 2009
[8] Definition adapted from the WHO patient safety curriculum guide 2011.

- specifically identifies factors in the system, using systems-based methodologies, that contributed to the incident and what needs to change to prevent it from occurring again; and
- indicates how learning will be disseminated and embedded in future practice and systems, and how resulting enhanced practice and learning will be evidenced and verified.

To ensure a balance between review and delivering safety improvements where necessary, HSC organisations are expected to take a proportionate approach to Patient Safety Incident Learning Reviews. HSC organisations are expected to consider a number of factors when deciding on the appropriate type of review for example, the circumstances and complexity of the incident, the level of risk of harm and the impact of the incident on All those Affected and the organisation.

The Framework recognises three types of review: Concise (which may take the form of: an; an After-Action Review, Structured Judgement Review or a Specific Review Tool); a Thematic Review or a Comprehensive Review. All the review methods:

- will analyse what happened and why;
- will align with the Principles for engaging, involving and supporting All those Affected and Staff Affected;
- aim to understand all the systems factors that may have contributed to the Patient Safety Incident;
- enable delivery of the five key themes described in this Framework;
- derive learning to improve patient safety; and
- will be supported by robust and effective organisational governance and oversight arrangements.

There are however some instances listed below where a comprehensive review of a Patient Safety Incident will be mandated:

- Never Events[9];

[9] doh-letter-to-chief-exec-never-events.pdf (health-ni.gov.uk)

- Deaths of patients in police custody which have involved nurse led healthcare;
- Suspected Mental Health Related Homicides[10];
- Suspected Suicide in any HSC Facility; a suspected suicide during authorised/agreed leave or following unplanned leave from any HSC facility; a suspected suicide occurring within 3 months of a planned discharge from an HSC facility; and
- Unexpected/Unexplained deaths in any care setting where following review, an issue has been identified which requires further review to determine if it has been caused by the systems in place or care provided.

Where there is an existing robust and rigorous review process for the purpose of identifying learning in the context of certain incidents, then the principle of 'Do once and do well' will apply.[11] The principal will be considered and applied to Domestic Homicide Reviews[12], Perinatal Mortality Review Tools, Case Management reviews and those incidents investigated by the Northern Ireland Prison Ombudsman.

By following the principle of 'Do once and do well' duplication will be avoided which will ensure All those Affected and Staff Affected are not required to engage in two separate processes which may lead to confusion and re-traumatisation.

[10] When a homicide has been committed by a person who is or has been under the care, i.e. subject to a regular or enhanced care programme approach, of specialist mental health services in the six months prior to the event. (*Independent investigation of adverse events in mental health services – NHS England)*

[11] This is to avoid duplication and to optimise resource in identifying new learning. Each HSC organisations will decide the appropriateness of this approach given the individual circumstances of each Patient Safety Incident.

[12] Further detail on the Domestic Homicide Review Process can be found at https://www.justice-ni.gov.uk/publications/multi-agency-domestic-homicide-review-guidance. When there is a (suspected) domestic homicide of a person aged 16 years old or over, the Police Service of Northern Ireland (PSNI) will send a notification in writing to inform SOF of the death. If the death can reasonably be judged to fit the circumstances, the Senior Oversight Forum (SOF) should commission a DHR to review the circumstances of the death. If a DHR is not commissioned the HSC organisation must determine if a Patient Safety Incident Learning Review is required and notify accordingly.

3.0 Notification

For the purposes of regional governance, oversight and surveillance all Patient Safety Incidents must be reported to the Strategic Planning and Performance Group (SPPG), in line with performance management and future surveillance arrangements.

This Framework does not remove the requirement to report certain incidents to external agencies. These requirements will already be known to HSC professionals undertaking the Patient Safety Incident Learning Review and are outlined in **Annex 2.**

4.0 Purpose

The purpose of the Framework is to provide an overarching approach for HSC organisations to manage and respond to Patient Safety Incidents with a clear focus on understanding how and why the Patient Safety Incident has occurred and the identification, dissemination and effective embedding of learning in practice leading to the evidence of sustainable improvement in patient safety.

The Framework and supporting guidance documents which are detailed in **Annex 3** describe the different approaches to reviewing Patient Safety Incidents through a range of methods that are underpinned by an understanding and consideration of system based contributory factors (see Theme 3: Considered and Proportionate Response to Review of Patient Safety Incidents below).

The Framework encourages and supports a significant cultural shift towards systematic patient safety management by embedding Patient Safety Incident Learning Reviews within a wider organisational system of learning and improvement.

The Framework and supporting guidance documents do not describe the detail of what to review and when and how to respond to individual incidents (a marked change from the previous SAI procedure), rather it requires that HSC organisations determine a data driven response to Patient Safety Incidents, critiquing and analysing data in detail to identify themes, trends and patterns and taking account of where applicable wider relevant factors.

The continual improvement of existing data systems within the HSC now allows us to connect data relating to patient safety from multiple sources.[13] With this information, HSC organisations can improve patient safety by beginning to understand their own unique patient safety risk profile.

When analysing their overall patient safety risk profile, organisations should also consider information from other sources including but not limited to coroners, litigation, risk assessments, audits, case mix and performance data, Care Opinion, RQIA, any ongoing safety actions (for example, in response to recommendations from other reviews or investigations internally or externally, including public inquiries), and any ongoing Quality Improvement work. This holistic understanding will inform the decision regarding which approach/method of review is most appropriate to an individual Patient Safety Incident.

Patient Safety Incident Learning and Improvement Plan

HSC Organisations must develop, using a regional template and working closely and collaboratively with SPPG, a Patient Safety Incident Learning and Improvement Plan. The plan will:

- describe their overall approach to responding to and learning from Patient Safety Incidents;
- identify the systems and processes in place to integrate the five key themes of the Framework;
- describe how those affected by a Patient Safety Incident will be engaged with;
- describe the governance processes for oversight which are in place;
- specify the methods they intend to use to maximise learning, disseminate learning and evidence learning and improvement and how these will be applied to different Patient Safety Incidents; and

[13] For example, Datix web, Datix complaints module, ENCOMPASS.

- outline how Patient Safety Incident Learning Reviews integrate with other related activities such as Clinical Governance and Complaints Management and will be reviewed and agreed with SPPG.

HSC organisations will use their Patient Safety Incident Learning and Improvement Plan to describe how they will respond to Patient Safety Incidents taking account of the wider organisational learning and improvement and supporting data systems. These Plans will be reviewed and agreed in collaboration with SPPG, will be kept under regular review at least annually and will be expected to be 'live documents' responsive to any new risks arising for the organisation.

5.0 When does the Framework not apply?

If during the course of a Patient Safety Incident Learning Review an issue arises that should be managed by a separate process such as matters related to conduct or performance these elements should be immediately referred to the extant appropriate governance processes **(see Annex 4).** The Patient Safety Incident Learning Review should continue in order to identify relevant learning.

Any such decision to refer to a separate process must be transparent, documented by the HSC organisation and explained fully to All those Affected by the Patient Safety Incident, including Staff Affected.

This Framework does not change current local Adverse Incidents Policies.[14] The Framework sits within a wider patient safety system and should therefore be read alongside relevant extant statute, legislation and guidelines.

[14] During the early implementation phase of the Framework, the interface between the Framework and the Adverse Incident process will be monitored and evaluated further and refined as necessary.

6.0 Inequalities in Health and Social Care

The World Health Organization defines health equity as 'the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically or geographically'.[15]

However, it is widely recognised that people from certain ethnic groups, and those marginalised in society are more likely to experience inequalities in health and social care, and this can contribute to disproportionate Patient Safety Incidents in these populations.[16] Ethnic minority groups, for example, are more likely to contract hospital acquired infections, adverse drug reactions, and pressure ulcers.[17]

These inequalities need to be identified and understood by HSC organisations not only in terms of how Patient Safety Incidents occur, but in terms of the impact of such incidents and the effectiveness of any safety actions required as a result.

The potential for such inequalities should also be considered by HSC organisations when developing their Patient Safety Incident Learning and Improvement Plans.
By better addressing health and social care inequalities through Patient Safety Incident Learning Reviews this will ensure equality in the delivery of services and lead to better outcomes for everyone.

HSC organisations must also take into consideration how certain groups of staff may be disproportionately affected by Patient Safety Incidents and how best to support them as a result.[18]

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[15] World Health Organization. Social determinants of health: health equity.
Social determinants of health (who.int)
[16] Selvarajah S, Corona Maioli S, Deivanayagam TA, et al. Racism, xenophobia, and discrimination: mapping pathways to health outcomes. Lancet 2022; 400: 2109-24
[17] The safety of health care for ethnic minority patients: a systematic review. Int J Equity Health; v.19; 2020
[18] Dalton, B., 2022. Inequalities among staff harmed by patient safety incidents should also be tackled. *BMJ*, *379*.

7.0 Scope

The Framework is intended to cover all care provided by or on behalf of the HSC. This includes, but is not limited to:

- Acute and Community care;
- Social care;
- all HSC Arm's Length Bodies (ALBs);
- The Strategic Planning and Performance Group;
- Special Agencies;
- Independent/Community/Voluntary sector organisations;
- Employees and Independent Contractors; and
- Primary Care[19]

8.0 Framework Themes

The Framework will enable delivery of five key Themes (see also Figure 1). Delivery of these Themes is underpinned and enabled by supporting Regional Standards and Guidance (**see Annex 3**).

1. **Engagement, Involvement and Support of All those Affected**
   How HSC organisations engage with All those Affected by a Patient Safety Incident in a collaborative, person-centred way and listen to and involve them, as active partners in the process throughout, in line with their wishes.

[19] The overall principles described in this Framework will apply to Primary care. Subject to the outcomes of public consultation and the adoption of this Framework, implementation will proceed at pace in a phased way. The first phase will involve secondary care only. Primary care may wish to adopt the Framework but it is not a requirement at this time. Further exploration with primary care is required during implementation phase.

2. **Engagement, Involvement and Support of Staff Affected**

   How HSC organisations will apply **'just culture'** principles where Staff Affected by a Patient Safety Incident are treated fairly and openly and are supported through a constructive and learning focused system.[20]

3. **Considered and Proportionate Response to review of Patient Safety Incidents**

   How HSC organisations will identify and respond to Patient Safety Incidents in a proportionate manner – taking account of the potential for new learning and improvement or the addressing of ineffective/non embedded learning previously identified by other Patient Safety Incidents.

4. **Governance, Oversight and Accountability**

   How HSC organisations including those with Regional Oversight roles[21] put in place robust and rigorous governance structures, policies and procedures to ensure the consistency and effectiveness of Patient Safety Incident Learning Reviews.

5. **Learning and Improvement**

   How HSC organisations, including those with Regional Oversight roles will ensure and demonstrate the timely identification, dissemination and/implementation of learning within and across organisations to evidence sustainable improved patient safety.

[20] Just and Learning Charter and NHS Just Culture Guide.
https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf

[21] The role of Regional governance, oversight, and surveillance will be taken forward by SPPG, PHA and RQIA.

Figure 1 Framework for Learning and Improvement from Patient Safety Incidents Themes

Theme 1: **Engagement, Involvement and Support of All those Affected**

When a Patient Safety Incident is identified All those Affected should expect that they will be supported and involved in a compassionate, empathetic and meaningful manner. [22]

HSC organisations must acknowledge and offer an apology that an incident has occurred and advise All those Affected that a further review may be required to

[22] This is further defined in the Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident

understand the circumstances leading to the Patient Safety Incident, to understand what has happened and why.

It is essential that All those Affected have a single point of contact and support throughout the review process. This person must possess the appropriate knowledge, skills, values and regionally standardised training to carry out this role and any engagement and involvement must take account of their cultural sensitivities and any other needs.

All those Affected should be signposted to support services, to include those within the organisation where the Patient Safety Incident took place and also to independent advocacy services.

Any review process must include the unique perspective/questions of All those Affected and must be completed in a timely manner with the degree of involvement and timescales agreed with All those Affected from the outset. Where these are not met for any reason, this must be explained openly and honestly. At all stages, the Patient Safety Incident review team will take time to listen to and seek to address all reasonable questions raised in an open and honest way.

All those Affected should be offered a chance to provide information and concerns relevant to the Patient Safet Incident Learning Review that will help shape the Terms of Reference[23], and should have an opportunity to review the draft terms of reference, the draft report and the learning following the review. They should also be given the opportunity to provide feedback on the entire review process. This can be done in person or virtually at a time convenient to them.

Theme 2: **Engagement, Involvement, and Support of Staff Affected**

The safety culture in every HSC organisation should be based on trust, openness, and strong collective leadership across all levels of the organisation. Staff should be

[23] Terms of Reference will only be required for comprehensive reviews.

encouraged and supported to report and participate in Patient Safety Incidents by organisations creating a psychologically safe space for staff to engage openly in learning processes as part of an open and learning culture.

There should be a move away from blame culture, towards a more proportionate approach to accountability, where required. Just Culture principles[24] should be adhered to when taking forward Patient Safety Incident Learning Reviews.

Staff Affected should be provided with a single point of contact who sets the expectations for engagement and involvement with Staff Affected from the beginning of the process and keeps them updated throughout. They should be provided with the appropriate compassion and support and be signposted to relevant support organisations when required.
Staff Affected should also have the opportunity to provide information and perspectives relevant to the Patient Safety Incident Learning Review to help shape the Terms of Reference and to review the draft Terms of Reference, draft report and learning following the review.

HSC organisations should make the required time available for Staff Affected within normal working hours (if possible) to engage and participate in a Patient Safety Incident Learning Review.

Staff Affected should expect timely learning reviews, the opportunity to be involved in the development of safety actions, to be advised of demonstrable improvement outcomes, and to be given the opportunity to feedback on the entire review process.[25]

Staff Affected should be equipped with the right skills, knowledge, expertise, and regionally standardised training to support the aspects of the Framework relevant to their role. This includes communication and engagement with All those Affected in a way that is respectful, compassionate, and confident.

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[24] https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf
[25] This is further defined in the Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident

Theme 3: **Considered and Proportionate Response to Review of Patient Safety Incidents**

Within the parameters set out in this Framework and supporting Standards and Guidance, HSC organisations will have a degree of flexibility in how they respond to individual Patient Safety Incidents.

All Patient Safety Incidents should be subject to initial Local Review and Decision making to decide whether any further learning review action should be undertaken. Deciding which type of review is most appropriate to the individual Patient Safety Incident under review will be based on local insight and knowledge of the wider patient safety profile.[26] At this stage, consideration should be given to the requirement for and level of independence as part of the Patient Safety Incident Learning Review, supported by a set of guiding principles, with the decision clearly documented and explained to All those Affected and Staff Affected.

Patient Safety Incidents should be reviewed in a proportionate manner taking account of the potential for new learning and improvement. A range of methodologies, tools, and systems-based learning approaches should be considered depending on the circumstances. This will help support the most effective use of HSC resources with a focus in those areas that are likely to have the greatest impact on learning, improvement and system change.

Theme 4: **Governance, Oversight and Accountability**

Governance, accountability, and oversight roles and responsibilities are clearly defined for HSC organisations and regionally.

[26] This will be outlined in the organisations Patient Safety Incident Learning and Improvement Plan.

HSC Organisations

HSC organisations' Boards and Executive Teams will be responsible and accountable for ensuring that they have robust, rigorous and effective governance systems in place to implement the Framework and supporting Standards, and for ensuring that these arrangements are monitored and evaluated. This will include arrangements for assuring, for example, that the appropriate type and methodology of a Patient Safety Incident Learning Review has been undertaken, and to the required quality and standard; relevant learning has been identified, appropriately shared, implemented and has led to demonstrable improvement; and that the required standard for engagement and support of All those Affected by the Patient Safety Incident, including Staff Affected has been achieved.

Regional

The role of Regional governance, oversight, accountability and surveillance will be taken forward by SPPG, PHA and RQIA[27] and has been redefined and rebalanced '*in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures'*[28], and to compliment and support organisational roles.

The following principles should be adopted as part of this overall change:

1. Open and Transparent
2. Objective and independent
3. Proportionate and Effective
4. Collaborative and supportive
5. Clear accountability

[27] Further detail on the roles and responsibilities of HSC organisations with a regional oversight function will be set out in the roles and responsibilities guidance.

[28] A framework for measuring and monitoring safety – The health Foundation https://www.health.org.uk/publications/a-framework-for-measuring-and-monitoring-safety

The regional role will include a focus on assuring that the Framework and Standards are implemented as intended by HSC Organisations, by:

- working closely and collaboratively to understand, and agree their *Patient Safety Incident Learning and Improvement Plans*;
- seeking assurance that governance structures to support the Framework within organisations are fit for purpose;
- assessing that the principles for the engagement, involvement and support of All those Affected and Staff Affected are being applied as intended;
- ensuring that learning systems are operating effectively in practice across the region; and
- developing robust surveillance for identifying themes, trends and outliers.

Theme 5: **Learning and Improvement**

There should be a clear culture of learning from Patient Safety Incidents within and between HSC organisations where learning is supported/encouraged by leadership.

Learning must be timely, relevant and demonstrate a clear understanding of what can be done to prevent the occurrence of Patient Safety Incidents and must also assure and give confidence to All those Affected. HSC organisations must demonstrate that they are continually learning from Patient Safety Incidents and that this learning is leading to improved patient safety.

In order to effectively share learning from Patient Safety Incidents across the system, and with partners in other sectors, a range of different dissemination methods and innovations should be considered. There must be robust monitoring/evaluation of the learning to ensure that it has been implemented, embedded in practice and that the necessary improvements have been made. This information must also be communicated to All those Affected by a Patient Safety Incident.

Learning should also be closely aligned to and inform local and regional quality improvement projects where appropriate. Changes resulting from learning can thus be evaluated and, if successful, implemented more widely through the HSC system.

The coordination and communication needed to ensure system wide learning must be carried out by a regional body with the responsibility and accountability for this.

Annex 1

Glossary

Unless stated otherwise these definitions are from the 'Conceptual Framework for the International Classification for Patient Safety.

Term	Definition
All those Affected	One of the earliest steps in the Patient Safety Incident Learning Review process is to consider and identify in a structured way who 'All those Affected' include. Organisations should consider service users, patients, families, carers, victims, victim's families and visitors that may be affected by a Patient Safety Incident, when determining who All those Affected are. (Adapted from the Conceptual Framework for the International Classification for Patient Safety definition of Person Affected.)
Apology	'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'. (Compensation Act 2006) As soon as possible after you become aware something has gone wrong, you should seek out the patient and or their family and say sorry and acknowledge what has happened and tell them that you will find out more. (NHS Resolution)
Advocate	An individual speaking on behalf of an individual affected by a patient safety incident, and/or supporting them to speak for themselves when they can. (PSIRF)
Carer	A carer is someone who regularly provides a substantial amount of care to a family member, friend or neighbour who is ill, disabled or is an older person. Carers (also referred to as informal carers or family carers) generally provide unpaid care as opposed to care workers who work in care and support jobs (e.g. domiciliary care) (The Department of Health and Social Care - Carers | Department of Health)
Clinical Governance	A system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

Term	Definition
Contributory Factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Culture	The shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.
Family	Family refers to the person or patient (the individual) to whom the patient safety incident occurred, their family and close relationships. Family and close relations may include parents, partners, siblings, children, guardians, carers, and others who had a direct and close relationship with the individual to whom the incident happened. (PSIRF)
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or Psychological
Just Culture	Staff, patients, service users, their families and carers are treated fairly, with empathy and consideration when they have been involved in an adverse incident or have raised a safety issue.
Lookback Review	Review where a number of people may have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them. Look backs may result in a patient notification exercise or recall.
Near Miss	An incident or potential incident that was averted by chance or because it was intercepted.
Never Event	A list of serious, largely preventable patient safety incidents that would not have occurred if the available preventive measures had been implemented.
Openness	Being Open is a core value of the Health and Social care system in Northern Ireland. It is described as a commitment to 'being open and honest with each other and acting with integrity and candour'. (Regional Being Open Framework)
Patient	A person who is receiving, or has received, care provided by, or on behalf of, a HSC body. (The Health and Social Care Complaints Directions NI 2009)

Term	Definition
Patient safety	The term used nationally and internationally to describe the freedom from unnecessary harm or potential harm associated with healthcare services and the reduction of risk of unnecessary harm to an acceptable minimum (World Health Organisation, 2009).
Patient Safety Incident	A Patient Safety Incident is an incident or circumstance (including omissions) which could have resulted or did result in harm to a patient or group of patients, and which provides an opportunity for system learning. (Adapted from the WHO patient safety curriculum guide 2011.)
Patient safety risk profile	Assess all patient safety risks, identify what could cause harm, who it could harm and how, and what you will do to manage the risk deciding what the priorities are and identifying the biggest risks for the organisation. (Adapted from Managing from Health and Safety (HSG65) Health and Safety Executive 2013)
Person	This refers to individual people e.g. service users, patients, members of staff, carers, relevant person(s) and visitors.
Safety Culture	An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values, which continuously seeks to minimise service user harm which may result from the processes of care delivery.
Service User	The term “service user” in relation to a health services provider means a person to whom a health service is, or has been, provided.
Staff	Defined as anyone charged with carrying out the work of the HSC or sometimes on behalf of the HSC (ie working for, employed by or contracted to the HSC). (PSIRF)
Staff Affected	Staff Affected are those staff who have been directly involved in or impacted by a Patient Safety Incident. HSC organisations should at an early stage consider and identify in a structured way who all Staff Affected include. (Framework for Learning and Improvement from Patient Safety Incidents)
Standard	This describes the high-level outcome required to achieve a quality, safe service.
Victim	For the purpose of Patient Safety Incidents, a victim must be a close relative or someone acting lawfully on behalf of the “patient” and who witnessed the Patient Safety Incident or its immediate aftermath.

Annex 2

Notification/Reporting requirements to external bodies

The following must continue be notified/reported as before **including but not limited** to:

- All mental health and learning disability Patient Safety Incidents reportable to the **RQIA** under Article 86.2 of the Mental Health (NI) Order 1986.
- Any Patient Safety Incident within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation to the **RQIA.**
- a child has died or been significantly harmed to the **Safeguarding Board for Northern Ireland (SBNI)**
- deaths and injuries due to a work-related accident to the **Health and Safety Executive (HSE)** as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- incidents relating to blood and tissue to the **Medicines and Healthcare Products Regulatory Agency (MHRA)** as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive
- adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the **MHRA**
- any incidents or concerns about the use or management of controlled drugs (CDs) (without the need for immediate evidence) to be reported to the **Controlled Drugs Accountable Officer (CDAO)** as required by 'The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009'.
- knows or has reason to believe that an accident or unintended exposure has or may have occurred under **Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018**
- adverse incidents involving medical devices and estates and facilities equipment used within the healthcare environment across Northern Ireland to the **Northern Ireland Adverse Incidents Centre (NIAIC)**
- deaths which are required to be reported by law to the **Coroners Service Northern Ireland**

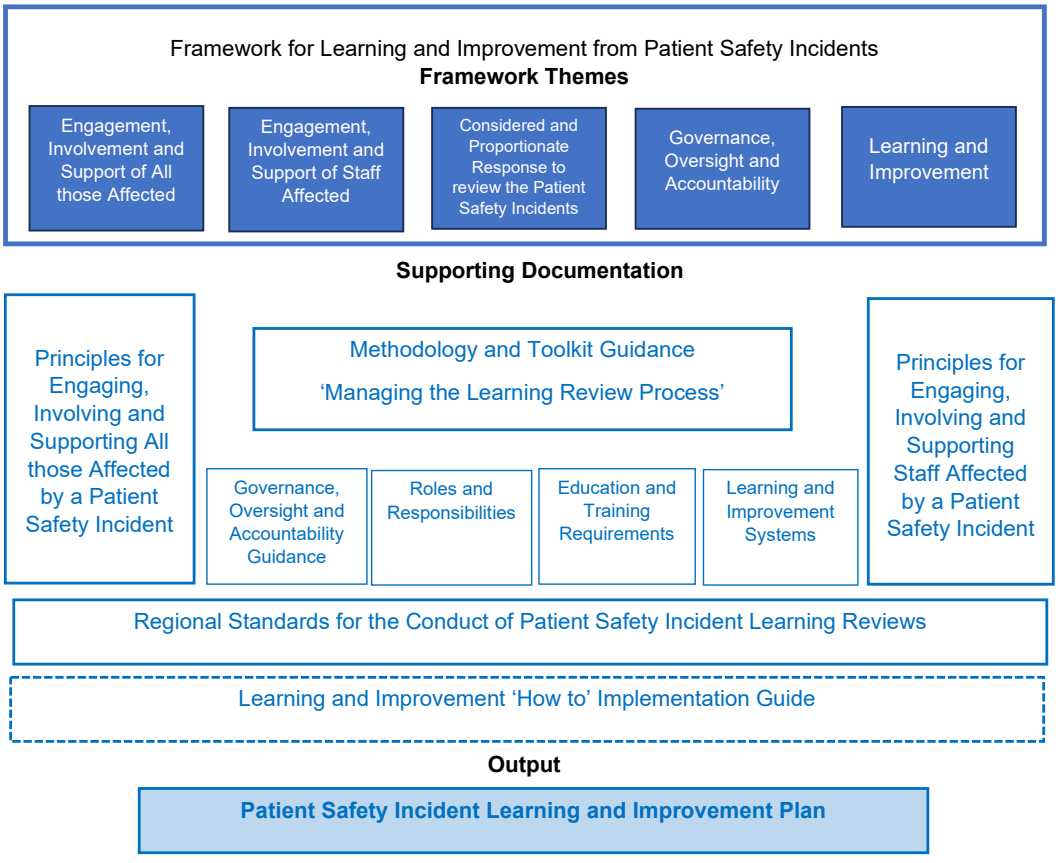
- in the case of a personal data breach the **Information Commissioners Office (ICO)**
- Potential screening incidents continue to be reported to the **Screening QA Service and Public Health Agency**
- outbreaks of HCAI's e.g. C difficile or pseudomonas to the **Public Health Agency**
- infection and environmental hazards to the **Health Protection Service**
- Issues related to fitness to practice notify professional regulators including **General Medical Council, Nursing & Midwifery Council etc.**
- Incidents relating to human tissues and organs to the **Human Tissue Authority (HTA)**
- any maternal, stillbirth, perinatal death and infant death (where there is a live born baby (born at 20+0 weeks gestation age or later) who die before 28 days after birth or any birth after 24 weeks gestation where the baby is stillborn) to Northern Ireland Maternal and Child Health (NIMACH) who will submit the data to **Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries – United Kingdom (MBRRACE-UK)**

Annex 3

Guidance - How to use the Framework

This Framework is supplemented by the following detailed guidance documents:

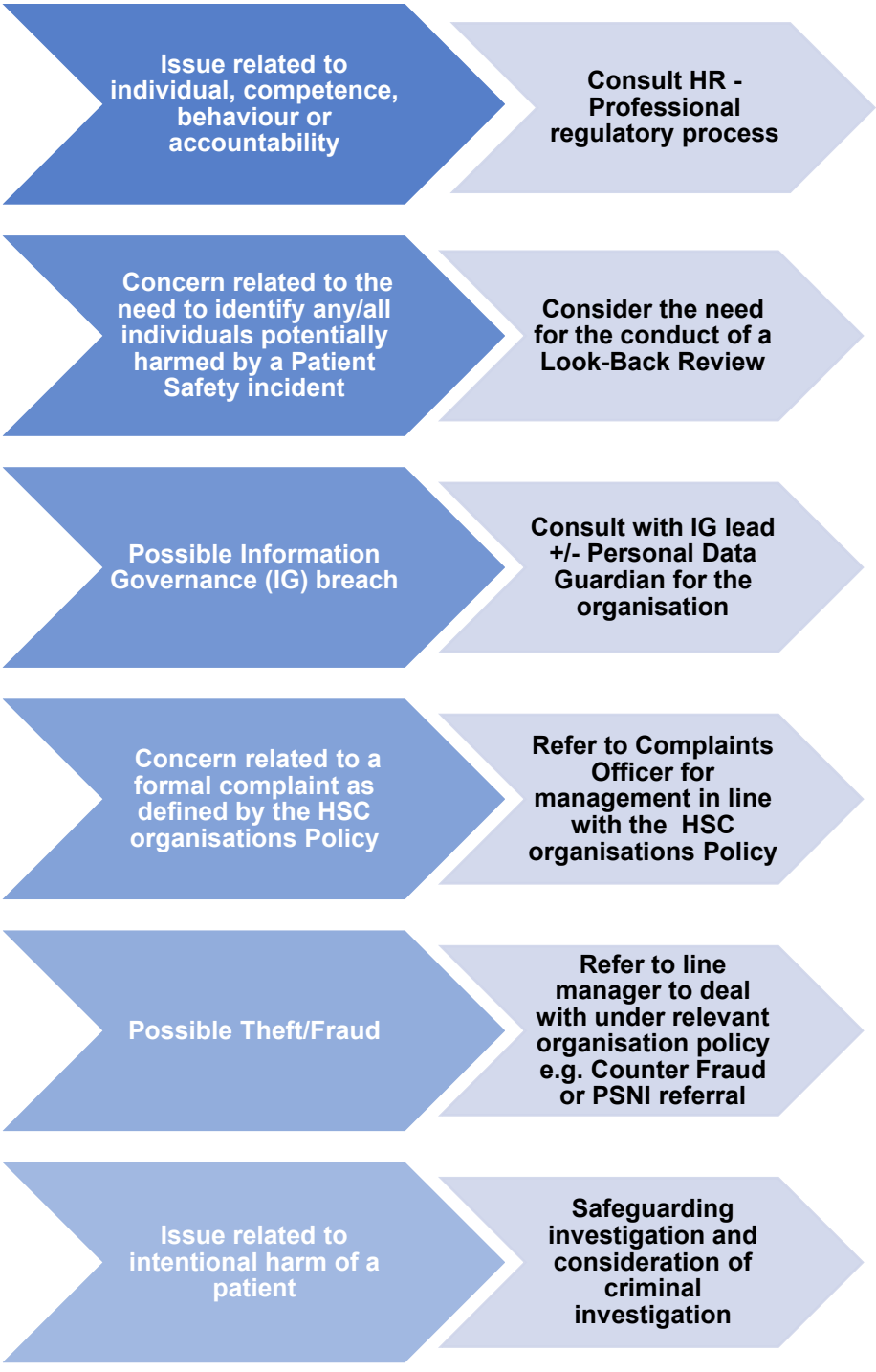
1. Regional Standards for the Conduct of Patient Safety Incident Learning Reviews which must be followed to assist in delivering regional consistency.
2. Principles for Engaging, Involving and Supporting All those Affected by a Patient Safety Incident.
3. Principles for Engaging, Involving and Supporting Staff Affected by a Patient Safety Incident.
4. Methodology and Toolkit guidance which will provide guidance on responding proportionately to a Patient Safety Incident and manging the review process.
5. Roles and Responsibilities.
6. Governance, Oversight and Accountability Guidance.
7. Guidance on education and training requirements.
8. Guidance of learning and improvement systems.
9. Implementation Guide to help and support HSC organisations to prepare for and implement the Framework.



Adapted from the NHS England Patient Safety Incident Response Framework (PSIRF)

Annex 4

Extant appropriate governance processes

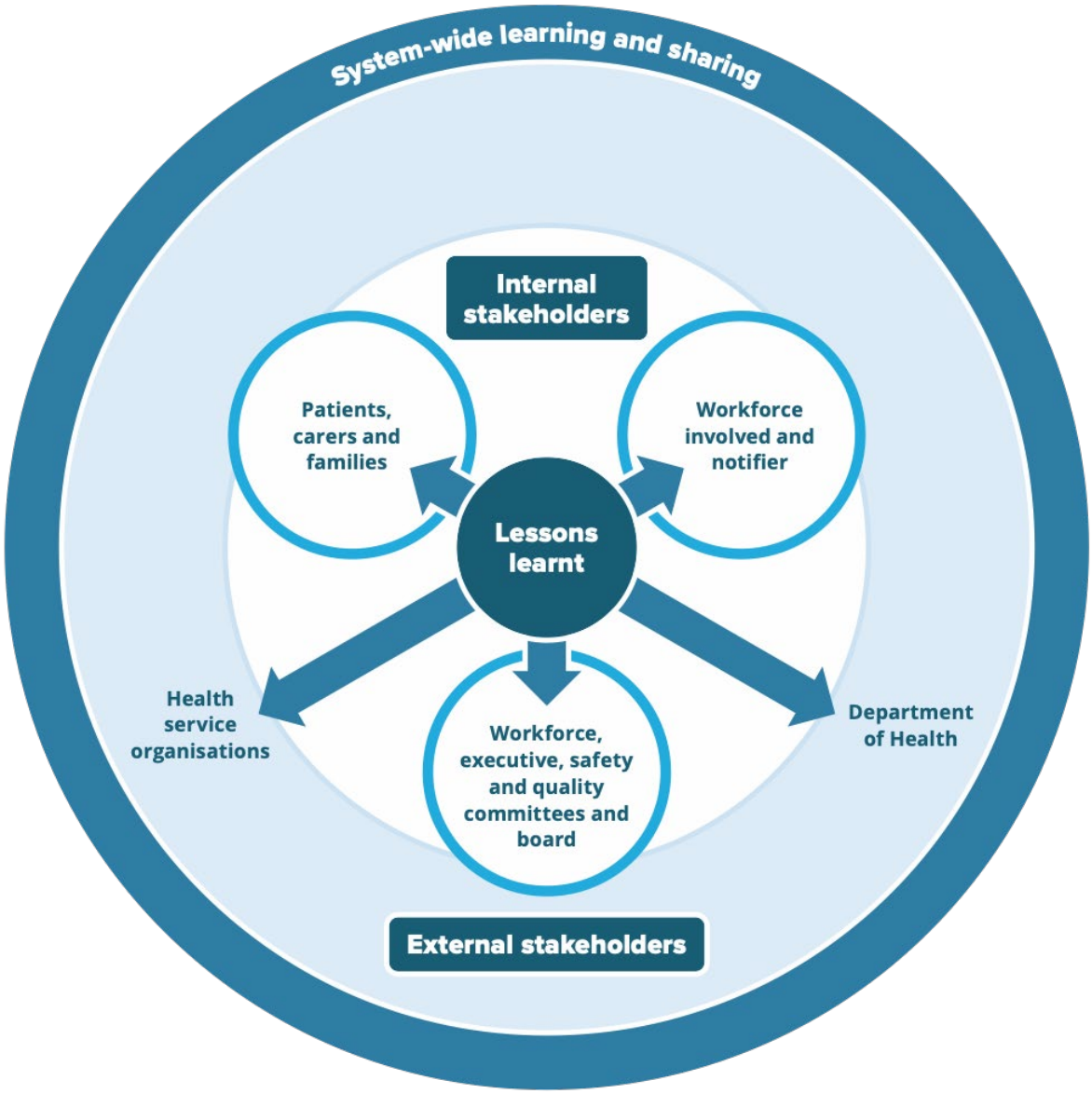


Adapted from HSE (Ireland) Incident Management Framework (2020)

* These are examples of links to other processes and should not be considered exhaustive

Annex 5

Feedback to stakeholders and System – wide learning



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Annex 6

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