Independent Patient Safety Council

Recommendations on Principles and Culture for Patient Safety Incident Management in Healthcare in Ireland

January 2024

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Foreword from the Chairperson

Dear Minister,

On behalf of the Independent Patient Safety Council, I am pleased to present you with our Recommendations on Principles and Culture for Patient Safety Incident Management in Healthcare in Ireland.

The ministerially appointed Council provides advice and guidance to inform policy direction in relation to patient safety policy and works in support of the promotion of a culture of patient safety throughout the health services.

As you requested, in carrying out this role the Independent Patient Safety Council has overseen the commissioning of research to identify the culture and values which should underpin a successful, patient-focused, patient safety incident management process and we have outlined the principles and cultural norms required to support policy and legislative development in this area.

The Council has produced this set of Recommendations on Principles and Culture for Patient Safety Incident Management in Healthcare in Ireland. The development of these recommendations has been based on the evidence provided in the Crowe report to the Independent Patient Safety Council (Crowe were appointed by the Council to carry out research on their behalf in this area) and the Council's subsequent deliberations on its findings. The Council engaged in a collaborative process of drafting and refining these recommendations.

We trust that you will find that these high-level principles and recommendations will support a coherent approach from which you and your department can progress policy and legislative development in the area of Patient Safety Incident Management in Healthcare in Ireland.

While the recommendations now furnished are those of the Council alone and come from the many perspectives of our expert members, our discussions benefitted substantially from the evidence and analysis gathered by Crowe and published in the report "Culture and Principles for Patient Safety Incident Management in Ireland", and we thank them for their assistance.

I would like to take this opportunity to thank my fellow members of the Independent Patient Safety Council for their hard work and commitment to this project. I would also like to thank the National Patient Safety Office in the Department of Health for their ongoing support. My thanks also to all those who contributed to discussions and requests for information.

Noeline Blackwell
Chair, Independent Patient Safety Council

January 2024

Introduction

A patient safety incident[1], or adverse event, is when something has gone wrong with patient or service user care, whether or not this results in a negative outcome for the patient or service user. In legislation, there is a definition in the Civil Liability Amendment Act, 2017:

> *"patient safety incident", in relation to the provision of a health service to a patient by a health services provider, means "an incident which occurs during the course of the provision of a health service" which:*
>
> *(a) has caused an unintended or unanticipated injury, or harm, to the Patient*
>
> *(b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm*
>
> *or*
>
> *(c) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented.*
>
> *Therefore, a patient safety incident includes harm events, no harm events and near miss events.*

The Minister for Health requested the Independent Patient Safety Council to oversee the commissioning of research to identify the culture and values which should underpin a successful, patient-focused, patient safety incident management process and outline the principles and cultural norms required to support policy and legislative development in this area.

It is important to distinguish between the principles and culture being considered here in reference to *patient safety incident management* and the overall *patient safety culture* in the healthcare system. These recommendations are focused on the response to and learning from patient safety incidents specifically. This is, of course, a critical feature of overall patient safety; nonetheless, the Council's recommendations are intended to support and improve patient safety incident pathways specifically, rather than seeking to address a broader patient safety remit.

The development of these draft recommendations has been based on the evidence provided in the Crowe report to the Independent Patient Safety Council and the Council's subsequent deliberations on its findings. The Council engaged in a collaborative process of drafting and refining recommendations.

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[1] These recommendations are intended to apply across the entire health system, which encompasses services whose users do not always use the term "patients", such as residents of nursing homes and other residential facilities, for example. For the purposes of this document, and in line with terminology used in legislation and in HSE documentation, the term "patient safety incident" is intended to encompass adverse events affecting, or which could have affected, all and any users of health services.

The term "family" should be taken to include designated support persons such as carers or friends.

The term "staff" should be taken to encompass healthcare professionals, whether employed or practicing independently, and non-professional staff in the healthcare system, such as managers, administration staff, and others.

Core Recommendation: Principles to Underpin the Culture of Patient Safety Incident Management

Overview

The core recommendation of the Council is a set of key principles that, in the considered collective opinion of the Council, should underpin patient safety incident management in the Irish healthcare system, and which form the basis for a positive culture supporting excellence in patient safety incident management as a key tool for improving patient safety.

The principles are closely aligned with those set out in the Health Service Executive (HSE*) Incident Management Framework*. This is because the Council considers the HSE principles well-chosen and reflective of the Council's conclusions in relation to patient safety incident management. These recommendations are intended to support what is positive about the current culture and practice both within the HSE and elsewhere in the health system, and to develop a whole-system approach to the culture of patient safety incident management.

The key principles on which the Council recommendations are based are as follows:

- Person-centred.
- Fair, consistent, and just.
- Nationally driven; locally led.
- Open, transparent, and accountable.

Focused on learning and improvement.

Principle 1: Person-Centred

It is of paramount importance that the people affected by the incident, who include patients, their families and support persons, and staff, are at the heart of the culture of patient safety incident management in Ireland.

This means:

- The people affected by the incident, who include patients, their families and support persons, and staff, have their needs prioritised throughout, from the time an incident is identified through to the outcome of any subsequent process or actions.
- There is an immediate, open, and clear response towards patients, families, and staff, which continues throughout the process of managing and responding to the incident.
- Patients, families, and staff receive communication and support in a timely manner via designated liaison persons.
- Access to patient advocacy services is available to patients and families when patient safety incidents are identified, with information provided about the right to have advocacy, facilitation of advocates to support patients and families, and promotion of a positive relationship between advocacy services and healthcare providers.
- Patients, families, and staff are kept informed and aware of the timeframe for and outcome of any investigations, reviews, and actions that ensue following a patient safety incident.

Principle 2: Fair, Consistent, and Just

Everyone involved in or affected by a patient safety incident must be treated in a fair, consistent, and just way, with appropriate, proportionate accountability to support improved safety and patient outcomes within a just culture.

This means:

- Patients, families, and staff feel listened to and informed, have opportunities to contribute to the design and operation of review processes, and are notified of the outcomes.
- Staff affected by patient safety incidents are treated fairly and justly, with proportionate accountability and responses from providers.
- Patients, families, and staff can expect consistent responses and processes in the event of patient safety incidents wherever in the health system they occur.
- Patient safety incident reporting and responses are perceived by staff as learning and improvement opportunities, rather than triggers to assign blame.

Principle 3: Nationally Driven; Locally Led

Patient safety incident management requires a national, whole-system approach and framework to support consistent outcomes and national system improvements in response to patient safety incidents. This however, must be led and championed at local level in order to become embedded in the culture of patient safety incident management across different healthcare settings.

This means:

- A robust governance structure is in place that allows consistency of evidence based and policy approach in the health regions. There is a seamless two-way flow of information that enables a consistent approach and provides the data, and intelligence required for national assurance.
- There is a national policy approach to the management of patient safety incidents, setting policy and standards and driving and supporting practice and procedure at local level.
- Patients, families, and staff can expect consistent responses and processes in the event of patient safety incidents wherever in the health system they occur.
- Healthcare providers and staff have access to and/or nominate local patient safety leads to support patient safety incident management within the framework of a national policy approach, but with flexibility to implement locally appropriate systems and processes.
- Healthcare providers outside the HSE have the framework, support, and tools to implement best practice patient safety incident management consistent with a national approach.

Principle 4: Open, Transparent, and Accountable

Patient safety incident responses must be open, transparent, and accountable. Patients, families, and staff affected by an incident must be aware of the incident, what is being done to identify what happened and how it happened, and what steps are being taken to learn from it.

This means:

- Open, clear, and honest communication to patients, families, and affected staff is initiated as soon as practicable after the incident has been identified.
- Open disclosure policies and procedures are in place and followed in all healthcare settings.
- Any review processes have been communicated to patients, families, and staff affected, with opportunities for them to ask questions, have input to the design of reviews, and be kept appraised of the progress and outcomes.
- Governance to assure the seamless flow of information between local and the national health care service which allows measurement, analysis and assurance.
- There is appropriate accountability from providers and staff, in a just and fair manner, without a blame culture that seeks to shift responsibility to individuals.

Principle 5: Focused on Learning and Improvement

Patient safety incidents must be considered by healthcare providers as opportunities to improve patient safety and outcomes. Patient safety incident management approaches should have explicit learning outcomes that are communicated to the wider health system to support learning.

This means:

- There is a range of tools and methods used to share learning from incidents at local, organisational, cross-service, and national levels.
- Patient safety incident data is collected, analysed, and reported on in a meaningful and utilisable way at local, service provider, and national levels.
- A clear objective of patient safety incident reporting is to share learning and drive improvement, and reporting systems at local and national level are designed to enable this.
- Patient safety incident responses can be directly linked to service improvements and to shared learning.

Specific Recommended Actions

Along with the principles described above, the Council recommends a number of specific initiatives and actions that will support improved patient safety incident culture and management in Ireland.

The Council recognises that much work has gone and continues to go into the approach and operation of patient safety incident management, both within the HSE and other healthcare providers and professionals. Nonetheless, the Council considers that further improvements will positively impact on the experience of and outcomes for patients, families, and staff when patient safety incidents occur.

The following actions are recommended:

Action		Principle(s)
1.	**Review of Factors Relating to the Psychological Safety of Staff Across the Health System:** It is accepted that for a positive culture of patient safety to be realised, each member of the care team must know from an individual perspective that if events go wrong and they speak up, they will be treated fairly and with compassion by their peers and the wider system. This is something that the evidence suggests is not currently the case. The psychological safety of staff requires value to be attached to diversity and is characterised by the respect of difference and how it benefits practice together with trust and inclusivity. A review of the factors affecting the psychological safety of healthcare staff across the health system in relation to patient safety incidents would be informative in identifying where culture change is required and how to address it.	✓ **Person-centred** ✓ **Fair, consistent, & just**
2.	**Access to the National Patient Advocacy Service:** The Council supports the proposed expansion of the remit of the Patient Advocacy Service to the private nursing home sector to support patients and families. Patients and families must have access to advocacy services and supports regardless of which healthcare provider is involved when a patient safety incident occurs.	✓ **Person-centred** ✓ **Open, transparent, & accountable**
3.	**Local Patient Safety Leads:** The Council recommends the development of clinical Patient Safety Leads in each healthcare provider organisation. This role requires defined protocols, communication and decision-making pathways, and policy support, to avoid “silo” working. The role should be at an appropriate level and sufficiently resourced. This role must not be seen as an avoidance of responsibility for staff involved in or managing a patient safety incident. In larger healthcare settings, each clinical area should consider a designated individual for patient safety leadership, co-ordinated with the clinical Patient Safety Lead in a hub-and-spoke model. The aim of this is to broaden patient safety leadership at local level, to support a positive culture for patient safety incident	✓ **Nationally driven; locally led** ✓ **Open, transparent, & accountable** ✓ **Fair, consistent, & just**

Action		Principle(s)
	management, and to support healthcare staff in responding to patient safety incidents. Within the HSE and other providers, existing quality and patient safety structures can be reviewed to identify where they can align with this recommended approach; the emphasis on patient safety is key.	
4.	**National Vision, Standards, and Protocols for the Management of Patient Safety Incidents:** The HSE has put considerable work into establishing standards, protocols, and pathways relating to patient safety incident management; however, these are not applicable to the healthcare services delivered outside the HSE, and within the organisation, local interpretation and application may be inconsistent. A national vision is required to set out what is wanted and what is to be achieved, supported by policy, standards, and guidance, and effectively communicated to all stakeholders.	✓ **Nationally driven; locally led** ✓ **Fair, consistent, & just**
5.	**Development of a National Network for Patient Safety:** The Council supports the creation of a national network, inclusive of healthcare providers throughout the healthcare system, to support the development of a positive culture of patient safety, with opportunities for shared learning, innovation, and changing awareness and attitudes towards the reporting and management of associated incidents. The Patient Safety Together platform in the HSE is a useful model to consider for a wider national network, which will require input and access across all aspects of the healthcare system and the wider population, and act as a mechanism for supporting consistent national policy and implementation, improving consistency, driving culture change, and sharing learning for system improvement.	✓ **Nationally driven; locally led** ✓ **Focused on learning and improvement**
6.	**National Patient Safety Incident Training Programme:** Considering the breadth of the healthcare system, ensuring that all healthcare providers and staff have access to appropriate and adequate training in relation to patient safety incident management to help to develop a positive culture and improved outcomes. An intelligence-led and multidisciplinary approach to training and education at both undergraduate and postgraduate levels is necessary. The Council recommends the development of a national plan for patient safety incident management training and education, with clear pathways and mapping of the required competencies and standards, together with the need for adaptability to different environments and challenges.	✓ **Nationally driven; locally led** ✓ **Focused on learning and improvement**
7.	**Accessible and Interactive Mechanism/Framework for the Reporting of Patient Safety Incidents:** To support shared learning and system improvement from patient safety incidents, effective reporting and data collection mechanisms must be in place. The existing National Incident Management	✓ **Nationally driven; locally led** ✓ **Focused on learning and improvement**

Action		Principle(s)
	System is a good example of how an electronic reporting system can support patient safety incident reporting. However, in the absence of appropriate data governance, there may be limitations on who can report to NIMS and how data may be accessed for the purpose of learning, to demonstrate that there is an opportunity to examine how national electronic patient safety incident reporting and data collection processes and the utilisation of NIMS can be improved. Key features of patient safety incident reporting systems include use by all healthcare providers, HSE and non-HSE; the capacity to disseminate learning; near-miss incident inclusion, ease of use by all healthcare staff, anonymous reporting capacity, and the collation of data that can be meaningfully analysed and shared. These features are supported by NIMS and may be better enabled with the appropriate processes, protocols, and governance. Patient safety incident reporting, data collection, and analysis must be adequately and appropriately resourced to deliver useful and improvement-focused outputs to the health system.	
8.	**Current Barriers to Reporting Incidents:** It is evident that there are barriers in some areas that prevent the effective and timely reporting of safety incidents, and differences between clinical specialities, areas, and disciplines across the system. An inclusive and comprehensive review, led by an independent body, should be undertaken to identify specific barriers, particularly culture-related, to patient safety incident reporting and management.	✓ **Fair, consistent, and just** ✓ **Nationally driven; locally led** ✓ **Focused on learning and improvement**