MHC
Coimisiún Meabhair-Shláinte | Mental Health Commission

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

DRAFT NATIONAL STANDARDS FOR THE CONDUCT OF REVIEWS OF PATIENT SAFETY INCIDENTS

26 September 2016

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services.

Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services —** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation —** Registering and inspecting designated centres.
- **Monitoring Children's Services —** Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality —** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment —** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information —** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

About the Mental Health Commission

The Mental Health Commission (MHC) was established under the Mental Health Act 2001 to promote, encourage, and foster the establishment and maintenance of high standards and good practices in the delivery of mental health services in Ireland.

The MHC's remit includes the broad spectrum of mental health services including general adult mental health services, as well as mental health services for children and adolescents, older people, people with intellectual disabilities and forensic mental health services.

The MHC's role is to regulate and inspect mental health services, support continuous quality improvement and to protect the interests of those who are involuntarily admitted and detained under the Mental Health Act 2001. Legislation focuses the MHC's core activities into regulation and independent reviews.

Regulation:

- Registration and enforcement — registering approved centres and enforcing associated statutory powers e.g. attaching registration conditions.
- Inspection — inspecting approved centres and community mental health services and reporting on regulatory compliance and the quality of care.
- Quality improvement — developing and reviewing rules under the Mental Health Act 2001. Developing standards, codes of practice and good practice guidelines. Monitoring the quality of service provision in approved centres and community services through inspection and reporting. Using our enforcement powers to maintain high quality mental health services.

Independent reviews:

- Mental Health Tribunal Reviews — administering the independent review system of involuntary admissions. Safeguarding the rights of those detained under the Mental Health Act 2001.
- Legal Aid Scheme — administering of the mental health legal aid scheme.

Table of Contents **Page Number**

Summary of the Draft National Standards

Theme 1: Governance and Accountability	
Standard 1	Service providers support a culture of patient safety that promotes trust, openness, empathy and respect.
Standard 2	Service providers have formal governance structures in place for assuring timely and effective reviews of patient safety incidents.
Standard 3	Service providers have clear lines of accountability in place for the conduct of reviews of patient safety incidents.
Standard 4	Service providers implement a system to monitor and evaluate the effectiveness of reviews of patient safety incidents.
Standard 5	Service providers have effective information governance structures in place for the management of information related to reviews of patient safety incidents.

Theme 2: Person-Centred Approach to the Review of Patient Safety Incidents	
Standard 6	Service users and their families are actively engaged with as part of the review of patient safety incidents and their views are listened to, respected and responded to in a timely manner.
Standard 7	Service users and families involved in a patient safety incident are supported by a service user liaison for the duration of the review process.
Standard 8	Service users and their families have access to relevant information related to the reviews of patient safety incidents and this information is provided in an accessible format.

Theme 3: Workforce

Standard 9	A staff liaison is appointed to communicate with and support staff involved in a patient safety incident for the duration of the review process.
Standard 10	Service providers convene a competent and skilled serious incident management team to oversee the conduct of reviews of patient safety incidents.
Standard 11	Service providers have a competent and skilled workforce in place to review patient safety incidents.
Standard 12	Service providers ensure that training is delivered to staff involved in the conduct of reviews of patient safety incidents.

Theme 4: Reviews of Patient Safety Incidents

Standard 13	Service providers classify patient safety incidents using an agreed standardized taxonomy.
Standard 14	Personal information used in conducting reviews of patient safety incidents is pseudonymised using unique reference codes to protect confidentiality.
Standard 15	Service providers ensure an initial assessment of the patient safety incident takes place and the decision on the appropriate level of review required is clearly documented.
Standard 16	Reviews of patient safety incidents are conducted using appropriate methods, in line with the service's policy and procedures.

Theme 4: Reviews of Patient Safety Incidents

Standard 17	Reviews of patient safety incidents are conducted in a timely manner, in line with the service's policy and procedures.
Standard 18	Service providers ensure that a timely, comprehensive and accessible review report is produced, which accurately describes identified key causal and contributing factors to the incident and makes recommendations to reduce risk and improve patient safety and service quality.
Standard 19	Service providers implement the recommendations and actions from patient safety incident review reports.

Theme 5: Sharing the Learning for Improvement

Standard 20	Service providers have structures in place to actively share the learning from reviews of patient safety incidents, both locally and nationally.

Key terms used in this document

This section includes the key terms which are used in the standards. A full list of relevant definitions is included in the glossary section.

Patient safety: is 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). Where the term patient is used to describe 'patient safety incident' or 'patient safety governance committees' or 'patient safety data', it is intended to encompass all definitions of people who use health care services e.g. service users and patients in both acute and community health care settings

Patient Safety Incident: As defined in the Health Information and Patient Safety Bill Revised General Scheme (2015) a 'patient safety incident' means:

a) any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service,

b) an event that occurred when providing a health service to a service user that did not result in actual injury or harm but there are reasonable grounds to believe that the event concerned placed the service user at risk of unintended or unanticipated injury or harm,

c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user.

Service user: 'Service user' refers to a person who uses health (including mental health) services.

Family: An individual who is a parent, guardian, son, daughter, spouse or civil partner of the service user, is cohabiting with the service user, or has been expressly identified by the service user to the health services provider as an individual to whom clinical information in relation to the service user may be disclosed (Adapted from the definition of a *connected person* as per the *General Scheme on Open Disclosure-Periodic Payment Orders 2015*).

Service: 'Service' is used to describe any location where health (including mental health) care is provided.

Service provider: 'Service provider' is used to describe any person, organization or part of an organization delivering health (including mental health) services.

Review of a patient safety incident: Reviews of patient safety incidents involve a structured analysis and are conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organization, or nationally.

Standard: Describes the high-level outcome required to achieve a quality, safe service.

Features: These, taken together, will enable progress towards achieving the standard.

A full glossary of terms can be found at the end of the document.

Key roles and responsibilities for conducting reviews of patient safety incidents

For the purpose of these standards, described below are some of the key roles and responsibilities in services for conducting reviews of patient safety incidents. These roles may already exist under a different name within each service.

Patient safety governance committees: These refer to standing governance structures that meet regularly and have responsibility for the oversight of the conduct of reviews of patient safety incidents within the service. This may include but are not limited to quality, patient safety and risk committees, clinical governance committees, serious incident management teams, and programme quality assurance departments.

Service user liaison: This person is the key contact person for the service user and, or family involved in a patient safety incident during the review process to share information and update on progress of the review and may act as a conduit between the service user and the serious incident management team/review team, as appropriate. The service user liaison should be independent of the review process and where possible, should be someone who is known to the service user and, or their family; for example, a nurse dealing with their care or a key worker. The preferences of the service user are taken into account when appointing the service user liaison.

Staff liaison: This person is the key contact person for the staff member involved in a patient safety incident during the review process to share information and update on the progress of the review and may act as a conduit between the staff member and the serious incident management team/review team, as appropriate. The staff liaison should be independent from the review process and where possible should be known to the staff member; for example, a colleague.

Senior accountable officer: This is the person within the service who has overall executive accountability for the review of patient safety incidents. They have a key role in ensuring that appropriate reviews are commissioned. For example, this may be the Chief Executive of a public hospital or a registered proprietor of an inpatient mental health facility.

Serious incident management team: The serious incident management team is responsible for immediate actions following a patient safety incident and overseeing the conduct of reviews of patient safety incidents, based on an assessment of the incident. They are responsible for determining the terms of reference for the review,

advising on appropriate methods and appointing members of the review team and quality assuring the review report.

1. Introduction

Service users and members of the public expect to be safe when using our health and mental health services. When the delivery of care falls below that quality, they are entitled to openness, to ask why and to be assured that measures have been taken to protect them and others from similar harm in the future. Services must have effective systems in place to understand what went wrong, why it went wrong and what can be done to lessen the likelihood of a similar incident happening again in the future.

Patient safety incidents must be managed in an open culture that learns from errors and takes corrective action to improve patient safety. When things go wrong, services need to act in a transparent, standardized and systematic way to review the incident and learn from it. As highlighted in the *Report of the Commission on Patient Safety and Quality Assurance (2008)*, recent Health Information and Quality Authority (HIQA) investigations[1] into the quality and safety of health services and the recent Mental Health Commission (MHC) Targeted Intervention[2] over the safety of mental health services, safety and quality is everyone's responsibility.

Patient safety incidents can also have a significant and serious effect on the health and wellbeing of staff. Services need to recognise the potential effects of an incident and the subsequent burden of a review on staff and provide them with support and services throughout the review process.

These standards sit within the overarching framework of HIQA's *National Standards for Safer Better Healthcare,* in particular, Standard 3.3 "to ensure that patient safety incidents are managed and reported in a timely manner in line with national legislation, policy, guidelines, and guidance where these exist", and MHC's *Quality Framework for Mental Health Services in Ireland,* in particular " Theme 8: systematic evaluation and review of mental health services underpinned by best practice, will enable providers to deliver quality services", with the aim of promoting improvements in how services conduct reviews of patient safety incidents.

[1] *Investigation into the safety, quality and standards of services provided by the Health Service Executive to service users, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar* (2013) *and the Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to service users in the Midland Regional Hospital, Portlaoise* (2015).

[2] *Report of the Targeted Intervention by the Office of Inspector of Mental Health Services, Mental Health Commission into the Carlow/Kilkenny/South Tipperary Mental Health Services* (2015).

These standards were commissioned by the Department of Health and are underpinned by findings from the Chief Medical Officer's 2014 *Report on Perinatal Deaths in HSE Midland Regional Hospital Portlaoise*, which recommended the development of national standards on the conduct of reviews of patient safety incidents, following the identification of shortfalls with the current system in Ireland. It highlighted that there was:

- confusion regarding incident classification and method of review required
- inconsistency in the time taken to conduct and complete reviews
- variable quality of reviews
- insufficient procedures for unique anonymisation.

These standards cover the conduct of reviews of patient safety incidents which fits into a service's overall incident management process which includes reporting, open disclosure and notification to external bodies On a practical level, the standards endorse the establishment and implementation of structures and procedures for conducting reviews of patient safety incidents. As the size and scope of health and mental health services differ across the country, a one-size-fits-all approach does not recognise the diverse nature of incidents, the context in which they could occur and the range of approaches that may be undertaken to conduct reviews of patient safety incidents.

Conducting a review of a patient safety incident is a complex process which requires services to weigh the outcome or potential outcome of the incident with the complexity of the incident. An incident which resulted in severe harm or death may have a very clear root cause and not require a comprehensive review. Similarly an incident with lower level of harm may have occurred on a repeat basis with no clear reason; this may require a comprehensive systems analysis. The standards also recognise that incidents may not be detected at the point of occurrence, but may become apparent sometime later, for example, during a look-back review.

The circumstances surrounding each incident will vary in terms of:

• degrees of harm

• numbers of people involved

• risk exposure

• financial loss

• media interest, and

• the need to involve other stakeholders.

The majority of patient safety incidents should continue to be managed at a local level, within the standing quality, safety and risk structures, and do not require a formal review or involvement from the serious incident management team. The serious incident management team will oversee the management of incidents requiring a formal review. They will ensure a review is commissioned to determine the identified key contributory and causal factors and determine what learning can be derived to improve patient safety.

The methods and timeframes for reviews of patient safety incidents must be appropriate to the nature, severity and complexity of the incident but above all, reviews must be focused on learning and improvement for the future. These standards promote the timely review of patient safety incidents and services must be cognisant of the need for a timely review of the evidence and their duty of care to respond to those involved in the incident. The review of some incidents may be delayed due to factors outside of the service provider's control; however services should endeavour to respect the integrity of the review process. Any delays should be communicated to all parties involved in the incident as soon as the delay becomes apparent.

Services should use these standards to support their existing patient safety governance structures for the review of patient safety incidents. The standards support services to use all available information following an incident to determine the appropriate review type and method, as well as ensuring that the staff managing and undertaking reviews have the time and resources they need to carry out their functions effectively and efficiently.

The public has a vested interest in the quality and safety of health and mental health services provided to them, their families and their communities. It is important that incidents are reviewed in a transparent, objective and standardised way; sharing the learning between services to stop preventable incidents from reoccurring.

These standards were jointly developed by HIQA and the MHC. Together HIQA and MHC aim to promote a framework for best practice in the conduct of reviews of patient safety incidents. These standards build on a body of evidence-based policies and guidelines which have focused on patient safety incidents. The standards do not replace any national policies, standards or guidelines, but instead intend to set a standard for cohesive, person-centred reviews of patient safety incidents.

2. Scope

The Department of Health requested that a phased approach be taken towards the development of these standards with an initial focus on service specific standards for acute hospitals under HIQA's remit and mental health services under the remit of the MHC.

Designated centres for older people, people with disabilities and children under the Health Act, 2007 are not within the scope of these standards and should refer to the relevant HIQA standards and regulations for information on conducting reviews of incidents in social care services. The principles in these standards can be applied to all care settings and further standards will be developed to support a consistent national approach to the management of patient safety incidents across health and social care settings.

Requirements in these standards also supplement existing obligations by providers to report adverse incidents to the State Claims Agency, in line with the National Treasury Management (Amendment) Act 2000 or by providers to the Chief Inspector of Social Services or the Mental Health Commission, arising from the Health Act, 2007 and the Mental Health Act, 2001.

3. Themes

The standards are divided into five broad themes:

Theme 1: Governance and Accountability – The structures put in place by a service for accountability, decision-making, and risk management in relation to patient safety as well as meeting its strategic and statutory obligations.

Theme 2: Person-Centred Approach to the Review of Patient Safety Incidents– How services place service users and their families at the centre of the review process, ensuring that services users and their families are well informed and supported at all times.

Theme 3: Workforce – How services provide resources and protect the time of staff involved in reviews of patient safety incidents. Services also support the welfare of staff affected by and involved in patient safety incidents.

Theme 4: Reviews of Patient Safety Incidents – How services protect personal information used in the review of incidents, how they classify and define

categories of patient safety incidents, use appropriate methods and timeframes to review incidents and how they implement recommendations from reviews of patient safety incidents.

Theme 5: Sharing the Learning for Improvement – Services actively monitor, evaluate and improve the review of patient safety incidents through the implementation and sharing of learning from reviews of patient safety incidents.

4. Standards and Features

These standards are outcome based which means that each standard provides a specific outcome for the service to meet. This outcome is described in the 'standard statement'. The standard statement describes the high-level outcome required to deliver high-quality and effective management of patient safety incidents.

The list of features provided under each standard statement heading is not an exhaustive list and service providers may meet the requirements of the standards in different ways.

5. How the draft national standards were developed

A focused desktop review of international and national literature was undertaken and used to inform the development of the draft national standards. This review took account of published research, investigations and reviews of patient safety incidents in Ireland and guidelines relating to the review of patient safety incidents in Ireland and other countries.

HIQA and the MHC convened a Standards Advisory Group made up of a diverse range of interested and informed parties, including service users, healthcare (including mental health) professionals, and representatives from the Department of Health, the Health Service Executive (HSE), the State Claims Agency, the Office of the Ombudsman and the Private Hospitals Association of Ireland.

The function of the group was to advise HIQA and the MHC, during the development of the standards and on an appropriate public consultation process. HIQA and the MHC would like to acknowledge with gratitude the effort and commitment of the Standards Advisory Group. Membership of this group is listed in Appendix 2.

HIQA and the MHC participated in and undertook a series of focus groups with service users, staff and management involved in patient safety incidents. These groups discussed the experience of reviews of patient safety incidents and obtained opinions as to what issues the draft national standards should address. HIQA and

the MHC would like to acknowledge with gratitude those who participated for taking the time to attend the sessions and contributing to the standards development process in such a meaningful way.

6. Public Consultation Process

These draft national standards are available for public consultation for a six-week period. During this time, service users, their families, service providers and the public will have the opportunity to provide feedback and become involved in the standards development process. We invite all interested parties to submit their views on the draft national standards.

A number of consultation questions have been prepared for your consideration when reviewing the standards. These questions are not intended in any way to limit feedback, and other comments are welcome. Please note that any information you provide will be shared between HIQA and the MHC as these are a collaborative set of standards. Submissions should be made to either HIQA or the MHC; it is not required to submit to both organisations.

How to make a submission

Your comments can be submitted by downloading and completing the consultation feedback form available from www.hiqa.ie and www.mhcirl.ie and emailing your completed forms to standards@hiqa.ie or standards@mhcirl.ie. You can print off a copy of the feedback form from our website and post it to us at the either of the addresses below. There are several ways to tell us what you think.

	Mental Health Commission	Health Information and Quality Authority
By email	standards@mhcirl.ie	standards@hiqa.ie
By post	Mental Health Commission National Standards for the Conduct of Reviews of Patient Safety Incidents Consultation St Martin's House Waterloo Road Dublin 4 D04 E5W7	Health Information and Quality Authority National Standards for the Conduct of Reviews of Patient Safety Incidents Consultation George's Court George's Lane Smithfield Dublin 7 D07 E98Y
By electronic submission	www.mhcirl.ie	www.hiqa.ie

For further information or if you have any questions, you can talk to a member of the team by calling 01 814 7400.

DRAFT NATIONAL STANDARDS

Theme 1: Governance and Accountability

Patient safety is dependent on the culture of a service. Individual and collective leadership builds support for a culture of patient safety and inspires individuals and teams to strive and work together to achieve a common vision.

Effective governance and accountability for patient safety are fundamental prerequisites for the sustainable conduct of timely and effective reviews of patient safety incidents. A well-governed service is clear about what it does, how it does it, and is accountable to its stakeholders. It is unambiguous about who has overall executive accountability and formalised governance arrangements ensure that there are clear lines of accountability at individual, team and service levels so that everyone working in the service are aware of their responsibilities and accountability.

Services that have good governance structures and accountability arrangements will monitor performance to ensure consistency and quality so that it reviews patient safety incidents in a timely manner with minimal variation in how services review incidents across the system.

Information governance provides a framework to bring together all the legislation, guidance and best available evidence that applies to the handling of information used in the conduct of reviews of patient safety incidents. It provides a consistent approach for services to ensure all information including personal information is handled securely, efficiently, effectively and in line with legislation and ensures that service providers protect and manage personal information in a sensitive and responsible manner.

Standard 1

Service providers support a culture of patient safety that promotes trust, openness, empathy and respect.

Features of a service meeting this standard are likely to include the following:

1.1 Service providers have a charter in place which clearly outlines the rights of service users and the service's responsibilities to service users and their families in relation to conducting reviews of patient safety incidents.

1.2 Service providers promote respect for each person as an individual within services. Service providers ensure that service users are listened to and treated with kindness and respect at all times when conducting reviews of patient safety incidents.

1.3 Service providers promote a culture of mutual respect and trust between service users, families and healthcare professionals and between healthcare professionals, managers and other staff.

1.4 Service providers promote a culture of welcoming feedback, compliments, complaints and concerns in relation to conducting reviews of patient safety incidents. This information is used effectively to improve safety and promote learning throughout the service.

1.5 Service providers communicate authentically and compassionately with service users, families and staff involved in patient safety incidents. Each person's voice has equal weight and their views are listened to and are taken into account in the review of patient safety incidents.

1.6 Service providers implement a communications strategy which promotes the importance of trust, openness, empathy and respect for service users, families and staff involved in patient safety incidents.

1.7 Service providers consult with service users, families and staff in the development of policy and guideline documents for conducting reviews of patient safety incidents. Documents are updated as and when required.

Standard 2

Service providers have formal governance structures in place for assuring timely and effective reviews of patient safety incidents.

Features of a service meeting this standard are likely to include the following:

2.1 Governance structures are in place, which ensure the service effectively reviews patient safety incidents, minimising the risk of harm to service users and implementing actions and learning from reviews of patient safety incidents.

2.2 Governance structures promote patient safety as a collective goal within the service which supports the timely and effective review of patient safety incidents, including adherence to due process and fair procedure.

2.3 Service providers have integrated corporate and clinical governance structures which define roles, accountability and responsibilities throughout the service for conducting reviews of patient safety incidents.

2.4 Service providers demonstrate visible leadership in promoting a just culture of openness, quality and safety in the review of patient safety incidents through the service's statement of purpose, design and delivery of services, code of governance (or equivalent), allocation of resources and training, and monitoring and evaluation processes.

2.5 Governance structures are in place to proactively monitor, analyse and respond to information relevant to the review of patient safety incidents. This information includes:

- complaints and concerns
- patient safety data
- findings from risk assessments
- legal claims
- audits; including clinical audits
- surveys; including experience surveys and patient safety culture surveys
- findings and recommendations from local, national and international reviews and investigations
- casemix, activity and performance data.

2.6 Governance structures enable the oversight of reviews of patient safety incidents, including the review process, implementation of recommendations and dissemination of learning from reviews of patient safety incidents.

2.7 Service providers publicly report annually on the conduct of reviews of patient safety incidents and how actions and recommendations from reviews are being implemented in the service.

2.8 Service providers have governance structures in place for positive and co-operative relationships with other agencies to support the effective review of patient safety incidents; this includes procedures on information sharing and inter-agency working.

Standard 3

Service providers have clear lines of accountability in place for the conduct of reviews of patient safety incidents.

Features of a service meeting this standard are likely to include the following:

3.1 Service providers demonstrate accountability for the review of patient safety incidents by having:

- a senior accountable officer with overall executive accountability, responsibility and authority for the conduct of reviews of patient safety incidents.
- identified individuals and teams, at an appropriate level, within the service who are accountable for the reviews of patient safety incidents, through the relevant governance structures.

3.2 The availability of an up-to-date, publicly available, organization chart detailing individuals' role and responsibility in relation to conducting reviews of patient safety incidents.

3.3 All staff are aware of their role and responsibilities in relation to reviews of patient safety incidents and adhere to the service's policy and procedure in relation to the conduct of reviews of patient safety incidents.

Standard 4

Service providers implement a system to monitor and evaluate the effectiveness of reviews of patient safety incidents.

Features of a service meeting this standard are likely to include the following:

4.1 Service providers monitor the conduct of reviews of patient safety incidents on a monthly basis in line with national policy, standards and guidelines.

4.2 Service providers have a patient safety governance committee in place to ensure that any recommendations or actions required from the review of a patient safety incident are implemented.

4.3 Service providers evaluate the findings of reviews of patient safety incidents and any actions required and communicate relevant learning locally and nationally to improve the quality and safety of the service.

4.4 Service providers, in conjunction with service users and staff, develop and implement quality improvement programmes to actively improve services based on the learning from reviews of patient safety incidents. These programmes are evaluated annually.

4.5 Service providers evaluate the effectiveness of systems for the monitoring of the conduct of reviews of patient safety incidents, on an annual basis.

Standard 5

Service providers have effective information governance structures in place for the management of information related to reviews of patient safety incidents.

Features of a service meeting this standard are likely to include the following:

5.1 Service providers ensure that the service complies with relevant legislation, uses information ethically and uses national standards and guidelines to protect personal information used in the review of patient safety incidents.

5.2 There are procedures in place for information governance for conducting reviews of patient safety incidents which ensures:

- information used by the service is of a high quality[3],
- the sharing of relevant personal information within and outside of the service protects the security of information, privacy and confidentiality of individuals,
- consent to access personal health information, is sought in line with national policy, legislation and guidelines,
- service users and their records are identified using a unique identification code to avoid duplication and misidentification.

5.3 Information, in both paper and electronic formats, relating to the review of patient safety incidents is held securely by the service and is protected from unauthorized access.

5.4 Service providers adhere to the relevant legislation, national standards and guidelines for the creation, use, protection, storage and disposal of personal information relating to the review of patient safety incidents.

5.5 There is an annual evaluation of the service's record management practices and systems for information related to the review of patient safety incidents, and, where appropriate, action is taken to address areas for improvement.

[3] Health Information and Quality Authority. *What you should know about Data Quality A guide for health and social care staff* (2012)

Theme 2: Person-Centred Approach to the Review of Patient Safety Incidents

A person-centred approach to patient safety places service users at the centre of all that the service does. It does this by protecting their rights, respecting their values, and actively supporting and involving them in the review of patient safety incidents. Services that are person-centred promote kindness, openness, consideration; compassion and respect in how they engage with service users and their families involved in patient safety incidents. Service providers promote a culture of active listening, supporting and actively engaging with service users and their families throughout the review process and having a review process that is informed by the experience of service users.

Good service user experiences are an important outcome for all healthcare and mental health services. Being person centred means service providers communicate in a manner that supports the development of a relationship based on trust. The provision of a service user liaison to communicate with service users and their families during the review process supports the provision of timely and accessible information and acts a link between the service user and the incident management or review team.

Services providing person-centred care recognise the potential impact that patient safety incidents can have on individuals and their families. People are supported throughout the incident review process so that they experience a person-centred service that responds in a manner that places the service users at the centre of all it does.

Standard 6

Service users and their families are actively engaged with as part of the review of patient safety incidents and their views are listened to, respected and responded to in a timely manner.

Features of a service meeting this standard are likely to include the following:

6.1 Service users and their families have their rights protected and their views respected and responded to by service providers in the conduct of reviews of patient safety incidents.

6.2 Service users and their families involved in the review of patient safety incidents experience empathy, kindness, dignity and respect in their communication and interaction with service providers.

6.3 Service users and their families are actively engaged with by service providers at all stages of the review process.

6.4 Service users and their families are actively involved in the review process and are informed of all key developments as the review progresses.

6.5 Service users and their families are facilitated to provide feedback on their experience of the review process. Where areas for improvement are identified, the service provider takes action to address the issues raised.

Standard 7

Service users and families involved in a patient safety incident are supported by a service user liaison for the duration of the review process.

Features of a service meeting this standard are likely to include the following:

7.1 Service providers identify a competent person to act as a service user liaison to engage with the service user[4] and their family, articulate their views to the serious incident management/review team and provide regular updates during the review process. The service user liaison is independent of the review process.

7.2 The service user liaison is the main point of contact for the service user and their family and ensures that that the service user involved in the incident and their family:

- receive co-ordinated care and support, which may include medical and/or psychological care, as required,
- are provided with information in a timely manner,
- have an opportunity to be involved in the review process and to meet with the review team to highlight issues they may wish to see addressed,
- receive regular updates on the progress of the review, including where there are delays,
- can review and comment on the terms of reference and the findings or recommendations of any draft review report prior to submission for final sign-off by the senior accountable officer,
- are facilitated to raise any concerns with the review process with the senior accountable officer
- and, are facilitated to access independent advocacy services, where requested.

[4] In some circumstances, for example in the event of the death of a service user, the liaison will link in with the service user's family.

Standard 8

Service users and their families have access to relevant information related to the reviews of patient safety incidents and this information is provided in an accessible format.

Features of a service meeting this standard are likely to include the following:

8.1 Service users and their families are given information on how reviews are conducted in a format and language they can understand, for example, in an information leaflet. Information includes how services determine the appropriate type of review of a patient safety incident.

8.2 Service users and their families are provided with assistance and support to access information on the conduct of reviews of patient safety incidents, including advocacy services, in accordance with their wishes.

8.3 Service users and their families are facilitated to access their personal health information in a timely manner during the review of a patient safety incident.

Theme 3: Workforce

The workforce consists of all the people who work in, for, or with the service provider and they are all integral to the delivery of patient safety. The individual members of a workforce must be skilled and competent and the workforce as a whole must be planned and managed to achieve these objectives.

The workforce has a key role in patient safety and should be supported in doing this. Effective recruitment of competent staff and workforce planning ensure that staff members involved in the oversight and conduct of reviews of patient safety incidents have the necessary skills and experience to undertake their role. Services also need to facilitate staff to have access to the right training to be able to carry out their role effectively.

Supporting the workforce includes service providers providing support to staff involved in patient safety incidents by actively listening to their views and providing a staff liaison to support staff members who are involved in patient safety incidents throughout the incident review process and who can act as a link between the individual staff member and the incident management or review team.

Standard 9

A staff liaison is appointed to communicate with and support staff involved in a patient safety incident for the duration of the review process.

Features of a service meeting this standard are likely to include the following:

9.1 Service providers identify a competent person to act as a staff liaison to engage with staff involved in a patient safety incident, articulate their views to the serious incident management/review team and provide regular updates during the review process. The staff liaison is independent of the review process.

9.2 The staff liaison is the main point of contact for staff involved in a patient safety incident and ensures that the member of staff involved in the incident:

- receives co-ordinated care and support, which may include medical and/or psychological care, as required,
- is provided with information in a timely manner,
- has an opportunity to be involved in the review process and to meet with the review team to highlight issues they may wish to see addressed,
- receives regular updates on the progress of the review, including where there are delays,
- can review and comment on the terms of reference and the findings or recommendations of any draft review report prior to submission for final sign-off by the senior accountable officer,
- and, is facilitated to raise any concerns with the review process with the senior accountable officer.

Standard 10

Service providers convene a competent and skilled serious incident management team to oversee the conduct of reviews of patient safety incidents.

Features of a service meeting this standard are likely to include the following:

10.1 Service providers ensure that there is a framework in place which details the competencies, roles and responsibilities of the serious incident management team in relation to conducting reviews of patient safety incidents as well as their circumstances, their purpose and how they may be convened.

10.2 The role of the serious incident management team is to provide oversight of the review process by:

- assuring the immediate response to the incident was appropriate
- ensuring all immediate care needs of the service user have been met,
- assuring the safety and wellbeing of service users, families and staff involved in the incident
- ensuring all equipment or medication involved in a patient safety incident is retained, labelled and isolated, and relevant documentation is copied and secured to preserve evidence and facilitate review and learning,
- overseeing the initial assessment of the incident and decide on the response required
- overseeing the appointment of service user liaisons and staff liaisons
- establishing a process for the exchange of information between the review team and the service user or staff liaison
- determining the terms of reference for a review,
- determining the appropriate method of review required,
- overseeing of the timeframes for completion of a review,
- determining the review team members,
- and, determining the reporting arrangements for the review team.

10.3 The membership of the serious incident management team is multidisciplinary, meets the requirements of the framework and should include representation from the following areas, where relevant:

- senior accountable officer

- relevant senior clinicians and/or line managers
- risk management
- complaints officer
- human resources
- other appropriate personnel for example, legal, communications.

10.4 Service providers facilitate access to peer support/mentoring for all members of the serious incident management team, where required.

10.5 Service providers facilitate protected time for the serious incident management team to oversee the conduct of reviews of patient safety incidents.

10.6 Any specialist supports required to support the serious incident management team are identified and requested through the appropriate channels.

Standard 11

Service providers have a competent and skilled workforce in place to review patient safety incidents.

Features of a service meeting this standard are likely to include the following:

11.1 Service providers have a framework in place which details the competencies, roles, responsibilities and training requirements for all staff involved in the review of patient safety incidents.

11.2 Service providers facilitate protected time for staff to conduct reviews of patient safety incidents and provide access to peer support/mentoring, where required.

11.3 Service providers ensure that there are trained personnel available to conduct reviews of patient safety incidents in the service.

11.4 Service providers engage in workforce planning to build capacity and expertise in conducting reviews of patient safety incidents.

Standard 12

Service providers ensure that training is delivered to staff involved in the conduct of reviews of patient safety incidents.

Features of a service meeting this standard are likely to include the following:

12.1 Staff, appropriate to their role, receive induction and ongoing training in conducting reviews of patient safety incidents.

12.2 A training needs analysis is undertaken annually, by the service provider, with all staff involved in conducting reviews of patient safety incidents, and relevant training is provided, appropriate to their role.

12.3 Staff receive training, appropriate to their role, in how to communicate with and provide support to service users, family and staff involved in reviews of patient safety incident.

12.4 Training methods make use of a variety of approaches including case studies and participation from service users, families and staff who have been involved in reviews of patient safety incidents.

12.5 Service providers ensure that training programmes clearly identify the intended learning outcomes for both the participants and the service.

12.6 Training programmes are regularly evaluated by the relevant patient safety governance committee using feedback from staff who participate in the training and feedback from the trainer and content is revised accordingly.

Theme 4: Reviews of Patient Safety Incidents

Services with a strong patient safety culture ensure that there are effective arrangements in place for the timely completion of reviews of patient safety incidents. This is best done through classifying patient safety incidents, providing tools to assist staff in identifying the most appropriate method to review the different types of patient safety incidents and completing reviews within a timely manner.

Services communicate regularly with service users and staff through the relevant liaison to ensure that they are regularly updated and informed of the progress of the review and how actions/recommendations are being implemented, once the review report has been finalised.

Services promote the effective review of incidents by reporting on the findings from reviews, identifying the key contributory factors to the incident and action plans for implementation in the service to prevent reoccurrence and drive improvements in patient safety.

Pseudonymization of personal information of service users, families and staff involved in the reviews of incidents protects confidentiality and ensures a structured method of unique identification is implemented.

Standard 13

Service providers classify patient safety incidents using an agreed standardized taxonomy.

Features of a service meeting this standard are likely to include the following:

13.1 Patient safety incidents are clearly defined within the service using an agreed standardized taxonomy, for example, the World Health Organization (WHO) standardized taxonomy, as outlined in the International Classification of Patient Safety.[5]

13.2 All policies and procedures related to the conduct of reviews of patient safety incidents use an agreed, standardized taxonomy and have clear definitions in place for patient safety incidents.

13.3 Staff use an agreed, standardized taxonomy when conducting reviews of patient safety incidents and have clear definitions for the different types of patient safety incidents.

[5] World Health Organization. *Conceptual Framework for the International Classification for Patient Safety*. 2009.

Standard 14

Personal information used in conducting reviews of patient safety incidents is pseudonymised using unique reference codes to protect confidentiality.

Features of a service meeting this standard are likely to include the following:

14.1 There is a policy and procedure in place for the pseudonymisation of personal information pertaining to service users, families and staff involved in reviews of patient safety incidents.

14.2 A standardised, agreed system of unique identification codes is used in the service to protect the confidentiality of service users, families and staff involved in patient safety incidents.

14.3 Personal information is pseudonymised by the service provider in the publication of any incident review reports.

Standard 15

Service providers ensure an initial assessment of the patient safety incident takes place and the decision on the appropriate level of review required is clearly documented.

Features of a service meeting this standard are likely to include the following:

15.1 Service providers have a policy and procedure(s) in place detailing the assessment process to determine the appropriate level of review required for different categories of patient safety incidents which have been escalated to the serious incident management team in line with the service's policy, or through the incident management system.

15.2 Following the management of immediate safety concerns, an initial assessment of the incident is undertaken to determine the level of risk and the appropriate level of review required, in line with the service's policy and procedure.

15.3 Service providers have standardized tools in place to assist staff in determining the appropriate type of review required for each type of incident.

15.4 Service providers determine the level of review required for patient safety incidents, taking into account at a minimum:

- the impact or potential impact of harm on service users,
- risk of recurrence,
- the outcome of the incident,
- the complexity of the incident,
- characteristics of the incident,
- the nature of the care setting,
- and the potential for learning.

15.5 The levels of review of for patient safety incidents are determined by the level of severity of the incident and the potential for learning and improvement and include:

- Concise[6] internal reviews
- Comprehensive[7] internal reviews
- External independent[8] investigations.

15.6 Decisions relating to the appropriate level of review required are based on the findings of the initial assessment and are documented by the service.

15.7 Where the decision is made that a detailed review to identify contributory factors/root causes is not appropriate, such incidents are subject to periodic aggregate reviews to identify trends and opportunities for learning, risk reduction and quality improvement.

[6] These reviews are suited to less complex issues and can be managed by individuals or a small team at a local level

[7] These reviews are for more complex issues and will often involve a multidisciplinary team at either a local or national level

[8] These reviews may be required where the objectivity or integrity of an internal review may be challenged or for particularly complex incidents which involve multiple services.

Standard 16

Reviews of patient safety incidents are conducted using appropriate methods, in line with the service's policy and procedures.

Features of a service meeting this standard are likely to include the following:

16.1 Service providers have a policy, procedures and guideline documents that outline the methods to be used for the review of patient safety incidents, appropriate to the care setting. These documents are developed in line with best practice.

16.2 The methods[9] used to conduct reviews of patient safety incidents include, but are not limited to:

- after action review
- aggregate review
- clinical audit
- human factors analysis
- look back review
- review of care against policies, procedures and guidelines
- systems analysis or root cause analysis.

16.3 The review is conducted using the appropriate methodology to identify the:

- chronology of events leading up to the patient safety incident,
- key causal factors,
- incidental findings,
- key contributory factors, and
- the recommendations for action to reduce risk and improve quality and safety.

[9] A description of each of these review methods is included in Appendix 1.

16.4 Where reviews of patient safety incidents are being conducted in parallel with other external[10] investigations, the serious incident management team must link-in with the relevant agency to inform them that the review is underway.

[10] External investigations can include those conducted by the State Claims Agency, Health Information and Quality Authority, Mental Health Commission, An Garda Siochána, Medical Council, CORU, Health and Safety Authority, Office of the Ombudsman and the Nursing and Midwifery Board of Ireland.

Standard 17

Reviews of patient safety incidents are conducted in a timely manner, in line with the service's policy and procedures.

Features of a service meeting this standard are likely to include the following:

17.1 The following timeframes for reviews of patient safety incidents are implemented by the service:

- concise internal reviews are completed no later than 60 working days after the review process has commenced.
- comprehensive internal reviews are completed no later than 120 working days after the review process has commenced
- independent investigations are completed no later than 120 working days after the review process has commenced.

17.2 Where there are delays to the review timeframes, these are documented by the review team, considered by the serious incident management team and an action plan put in place.

17.3 As soon as delay is identified, the reasons for the delay are communicated verbally and in writing to the service user and staff member through the appropriate liaison (service user or staff).

Standard 18

Service providers ensure that a timely, comprehensive and accessible review[11] report is produced, which accurately describes identified key causal and contributing factors to the incident and makes recommendations to reduce risk and improve patient safety and service quality.

Features of a service meeting this standard are likely to include the following:

18.1 The service provider has a policy, procedure and guideline document on the structure, content and language to be used in the reporting of reviews of patient safety incidents to ensure quality and consistency in all review reports.

18.2 Review reports will contain at a minimum:

- a collective apology to all those affected,
- a summary of the background to the incident,
- any actions taken immediately following identification of the incident and during the review process,
- the methodology applied to the review process and the rationale for why the decision to use this methodology was made,
- a list of identified key causal and contributory factors relating to the incident or incidents,
- the analysis and findings relating to the identified factors,
- the recommendations and actions[12] identified for implementation,
- a section relating to responsibility for implementing recommendations and arrangements for sharing the learning with other services nationally,
- and, a glossary of key terms used in the report.

18.3 Review reports are written in clear simple language which is accessible and easy to understand, and avoid the use of jargon.

18.4 The review team assure the draft report for consistency, quality, factual accuracy and readability prior to submission by the senior accountable officer.

[11] Review reports are developed for concise, comprehensive and external reviews.

[12] Actions should be specific, measurable, achievable, realistic and time-bound (SMART).

18.5 The service user liaison meets with the individual service user in advance of the report being finalised to review and comment on the findings and recommendations.

18.6 The staff liaison meets with the individual staff member in advance of the report being finalised to review and comment on the findings and recommendations.

18.7 The final report is presented to the serious incident management team for review and to the senior accountable officer for review and sign off.

18.8 A summary report is completed by the relevant patient safety governance committee for wider dissemination to staff.

18.9 Service providers have arrangements in place for meeting with relevant staff to debrief them on the report in advance of wider dissemination.

Standard 19

Service providers implement the recommendations and actions from patient safety incident review reports.

Features of a service meeting this standard are likely to include the following:

19.1 Services develop an implementation plan, based on the recommendations from patient safety incident review report(s) that outlines the actions to be taken, responsible person(s), timeframes and the resources required to implement each action.

19.2 Service users and staff involved in patient safety incidents are informed of the implementation plan, how it will be monitored and how the learning is being shared within the service.

19.3 Patient safety governance committees oversee the implementation of recommendations and actions required from reviews of patient safety incidents and monitor the effectiveness of the actions taken.

19.4 The effectiveness of the plan for implementing recommendations from reviews of patient safety incidents is evaluated at regular intervals by the service and any necessary actions for improvement are initiated.

Theme 5: Sharing the Learning for Improvement

Following a review of a patient safety incident, it is essential that any learning identified from the review is shared locally and nationally to drive improvements in patient safety and to prevent reoccurrence. Discussion on the learning from reviews of patient safety incidents should be actively promoted within the service to support the development of a positive safety culture.

Service providers should develop an implementation plan that makes use of a range of approaches for sharing the learning, to best fit the needs of the service. A service that is effective at sharing the learning should also use any learning to inform other areas of development such as training, policy and workforce planning.

Working in partnership with external bodies to share the learning from reviews of patient safety incidents can also drive improvements in patient safety.

Standard 20

Service providers have structures in place to actively share the learning from reviews of patient safety incidents, both locally and nationally.

Features of a service meeting this standard are likely to include the following:

20.1 Service providers have a framework in place which details roles and responsibilities for all staff involved in sharing the learning for improvement.

20.2 Service providers implement a plan to share learning from reviews of patient safety incidents. This plan should identify the range of mechanisms that will be used to share the learning.

20.3 Patient safety governance committees oversee the implementation of sharing the learning from reviews of patient safety incidents.

20.4 Service providers actively promote discussion on the learning from reviews of patient safety incidents to promote a positive safety culture.

20.5 Learning from reviews of patient safety incidents are used to inform training for staff, policy development, workforce planning and service planning, where relevant.

20.6 The effectiveness of the plan for sharing the learning is evaluated by the service and any necessary actions to improve the process are initiated.

20.7 Service providers work in partnership with external bodies to share the learning from reviews of patient safety incidents.

Resources

Commission on Patient Safety and Quality Assurance. *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance*. Dublin: The Stationery Office; 2008.

Danish Society for Patient Safety (Patientsikkerhed). *Root Cause Analysis. Compendium for use by Patient Safety Officers and others responsible for conducting root cause analysis of adverse events*. Copenhagen: Danish Society for Patient Safety (Patientsikkerhed); 2004.

Department of Health*. Report on Perinatal Deaths in HSE Midland Regional Hospital Portlaoise*. Dublin: Department of Health; 2014.

Department of Health (UK). *Changing Culture in the NHS, Applying the lessons of the Francis Inquiries*. Department of Health: London; 2015.

Doupi P. *National Reporting Systems for Patient Safety Incidents, a review of the situation in Europe*. Helsinki: National Institute for Health and Welfare (THL); Report No.: 13. 2009.

Health Information and Quality Authority*. 'As is' analysis of patient safety intelligence systems and structures in Ireland.* Dublin: Health Information and Quality Authority; 2016.

Health Information and Quality Authority*. International review of patient safety surveillance systems*. Dublin: Health Information and Quality Authority; 2016.

Health Information and Quality Authority. *Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration and as reflected in the care and treatment provided to Savita Halappanavar.* Dublin: Health Information and Quality Authority; 2013.

Health Information and Quality Authority. *Linking learning to National Standards: How recommendations from previous HIQA investigation, statutory inquiry and review reports (2009–2015) relate to specific National Standards for Safer Better Healthcare*. Dublin: Health Information and Quality Authority; 2015.

Health Information and Quality Authority*. Recommendations on the coordination of patient safety intelligence in Ireland*. Dublin: Health Information and Quality Authority; 2016.

Health Information and Quality Authority. *Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise*. Dublin: Health Information and Quality Authority; 2015.

Health Information and Quality Authority. *Report of the investigation into the quality, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) for patients who require acute admission.* Dublin: Health Information and Quality Authority; 2012.

General Scheme of the Health Information and Patient Safety Bill, 2015

Health Quality and Safety Commission. *New Zealand Health and Disability Services: National Reportable Events Policy*. Wellington: Health Quality and Safety Commission; 2012.

Health Service Executive. *Final Report of the investigation of Incident 50278, from the time of the patient's self referral to hospital on the 21st of October 2012, to the patient's death on the 28th of October, 2012.* Dublin: Health Service Executive; 2012.

Health Service Executive. *Guideline for Systems Analysis: Investigation of Incidents and Complaints*. Dublin: Health Service Executive; 2015.

Health Service Executive. *HSE Standards and Recommended Practice for Healthcare Records Management V3.0.* Dublin: Health Service Executive; 2011.

Health Service Executive. *Midland Hospital Portlaoise Systems Analysis Review Report: Review of Care of Shauna Keyes.* Dublin: Health Service Executive; 2016.

Health Service Executive. *Safety Incident Management Policy.* Dublin: Health Service Executive; 2014.

Health Service Executive. Special Report: Serious Reportable Events. Dublin: Health Service Executive; 2015.

Health Service Executive. *Systems Analysis Review into the death of Baby Mark Molloy.* Dublin: Health Service Executive; 2015.
Health Service Executive. *National Consent Policy.* Dublin: Health Service Executive; 2014.

Health Service Executive and the State Claims Agency. *Open Disclosure: National Guidelines – Communicating with service users and their families following adverse events in healthcare*. Dublin: Health Service Executive and the State Claims Agency; 2013.

Health Service Executive and the State Claims Agency. *Open Disclosure: National Policy*. Dublin: Health Service Executive and the State Claims Agency; 2013.

Healthcare Improvement Scotland. *Learning from adverse events: Learning and improvement summary*. Edinburgh: Healthcare Improvement Scotland; 2016.

Healthcare Improvement Scotland. *Learning from adverse events through reporting and review: A national framework for NHS Scotland*. Edinburgh: Healthcare Improvement Scotland; 2015.

Healthcare Safety Investigation Branch Expert Advisory Group. *Improving safety investigations in healthcare.* London: Department of Health; 2016.

House of Commons Public Administration Select Committee. *Investigating clinical incidents in the NHS*. London; The Stationery Office; 2015.

Mental Health Commission. *Quality Framework for Mental Health Services in Ireland*. Dublin: Mental Health Commission; 2007.

Mental Health Commission. *Report of the Targeted Intervention by the Office of Inspector of Mental Health Services, Mental Health Commission into the Carlow/Kilkenny/South Tipperary Mental Health Services.* Dublin. Mental Health Commission, 2015.

National Advisory Group on the Safety of Patients in England. *A promise to learn, a commitment to act: Improving the safety of patients in England*. National Advisory Group on the Safety of Patients in England: London; 2013.

National Health Service England. *NHS England Serious Incident Framework*. London: National Health Service England; 2015.

National Health Service England. The Caldicott Guardian-Edition 10. London: National Health Service; 2009.

National Patient Safety Agency. *Three Levels of RCA Investigation-Guidance*. London: National Patient Safety Agency; 2008.

Northern Ireland Health and Social Care Board. *Procedure for the Reporting and Follow-Up of Serious Adverse Incidents*. Belfast: Northern Ireland Health and Social Care Board; 2013.

Provincial Health Services Authority*. Patient Safety Event Management and Review Policy*. British Columbia, CA: Provincial Health Services Authority; 2013.

Provincial Health Services Authority*. Critical Patient Safety Event Review Toolkit*. British Columbia, CA: Provincial Health Services Authority; 2013.

Rafter N, Hickey A, Condell S, Conroy R, O' Connor P, Vaughan D, Walsh, G, Williams, D. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study. *British Medical Journal of Quality and Safety*. Downloaded from http://qualitysafety.bmj.com/ on February 10, 2016.

Rafter N, Hickey A, Condell S, Conroy R, O' Connor P, Vaughan D, Williams, D. *Adverse Events in Healthcare: learning from mistakes*. Quarterly Journal of Medicine; 30 July 2014.

State Claims Agency. *Clinical Incident and Claims Report in Maternity and Gynaecology Services – A Five Year Review 2010 – 2014.* Dublin: The State Claims Agency; 2015.

World Health Organization. Conceptual Framework for the International Classification for Patient Safety. 2009.

Glossary of terms

Accountability: being answerable to another person or organization for decisions, behaviour and any consequences.

Advocacy: the practice of an individual (advocate) acting independently of the service provider on behalf of, and in the interests of, a service user who may feel unable to represent themselves.

Apology: means an expression of regret in respect of a patient safety incident.

Audit: the assessment of performance against any standards and criteria (clinical and non-clinical) in a health, mental health or social care service.

Best practices: Clinical, scientific or professional practices that are recognized by a majority of professionals in a particular field. These practices are typically evidence based and consensus-driven.

Clinical audit: a quality improvement process that seeks to improve care and outcomes through systematic review of care against explicit criteria and the implementation of change.

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.

Competence: The knowledge, skills, abilities, behaviours, experience and expertise to be able to perform a particular task and activity.

Confidentiality: the right of individuals to keep information about themselves from being disclosed.

Corporate governance: the system by which the service directs and controls its functions in order to achieve organizational objectives, manage business processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Culture: the shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

Data: data are numbers, symbols, words, images, graphics that have yet to be organized or analyzed.

Degree of harm: the severity and duration of harm, and the treatment implications, that results from an incident.

Effective: a measure of the extent to which a specific intervention, procedure, treatment, or service, when delivered, does what it is intended to do for a specific population.

Evaluation: a formal process to determine the extent to which the planned or desire outcomes of an intervention are achieved.

Evidence: the consistent and systematic identification, analysis and selection of data and information to evaluate options and make decisions in relation to a specific question.

Family: an individual who is a parent, guardian, son, daughter, spouse or civil partner of the service user, is cohabiting with the service user, or has been expressly identified by the service user to the service provider as an individual to whom clinical information in relation to the service user may be disclosed

Features: these, taken together, will enable progress towards achieving a standard.

Harm: impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm, and the treatment implications, that result from a patient safety incident. Degrees or levels of harm include:

- None – service user outcome is not symptomatic or no symptoms detected and no treatment is required.
- Mild – service user outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short-term, and no or minimal intervention (for example, extra observation, investigation, review or minor treatment) is required.
- Moderate – service user outcome is symptomatic, requiring intervention (for example, additional operative procedure or additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function.
- Severe – service user outcome is symptomatic, requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function.
- Death – on balance of probabilities, death was caused or brought forward in the short-term by the incident.

(As adapted from the WHO, *Conceptual Framework for the International Classification of Patient Safety*, 2009)

Health information: information, recorded in any form, which is created or communicated by an organization or individual relating to the past, present of

future, physical or mental health or social care of an individual (also referred to as a cohort). Health information also includes information relating to the management of the health and social care system.

Incident type: A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.

Informed consent: the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication in which the service user has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention or service.

Just culture: an environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action.

Monitoring: systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.

Near miss: a deviation from best practice in healthcare delivery that would have led to unwanted harm to the service user or to the mission of the organization, but was prevented through planned or unplanned actions.

No harm incident: An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.

Open Disclosure: an open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.

Patient safety: freedom, for a service user, from unnecessary harm or potential harm associated with health and social care and the reduction of risk of unnecessary harm to an acceptable minimum.

Patient safety data: the broad and heterogeneous information that includes, but is not limited to, the description of incidents with medical errors or near misses, their causes, the follow-up corrective actions, interventions that reduce future risk, and patient safety hazards.

Patient Safety Incident: As defined in the Health Information and Patient Safety Bill Revised General Scheme (2015) a 'patient safety incident' means:

a) any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service,

b) an event that occurred when providing a health service to a service user that did not result in actual injury or harm but there are reasonable grounds to believe that the event concerned placed the service user at risk of unintended or unanticipated injury or harm,

c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user.

Policy: a written operational statement of intent which helps staff make appropriate decisions and take actions, consistent with the aims of the service provider and in the best interest of service users.

Pseudonymisation: is the technical process of replacing service user labels (ie data items which identify service users, such as name, date of birth) in a dataset with other values (pseudonyms), from which the identities of individuals cannot be intrinsically inferred (adapted from Caldicott Guardian, NHS; 2009).

Risk: the probability that an incident will occur. The combination of the probability of occurrence of harm and the severity of that harm.

Risk Management: one of a number of organizational systems or processes aimed at improving the quality of health care, but one that is primarily concerned with creating and maintaining safe systems of care.

Safety culture: an integrated pattern of individual and organizational behaviour, based upon shared beliefs and values, which continuously seeks to minimize service user harm which may result from the processes of care delivery.

Service user: a person who receives or has received a healthcare or mental health service.

Service user outcome: The impact upon a service user which is wholly or partially attributable to an incident.

Staff: the people who work in healthcare and mental health services, including but not limited to healthcare professionals, care assistants, laboratory staff, administrative staff, catering staff, cleaning staff and security staff.

Standard: in the context of this document, a standard is a statement which describes the high-level outcome required to achieve a quality, safe service.

Taxonomy: a system for naming and organizing items into groups that share similar characteristics.

Appendices:

Appendix 1: Types of reviews of patient safety incidents

There are a number of types of reviews of patient safety incidents which make use of high quality, consistent and systematic methods. Depending on the type of patient safety incident, a multi-method approach may be required to conduct a robust review. Some of the review types include but are not limited to:

After action review: a facilitated discussion that allows those who were involved in patient safety incidents to review what happened, track progress, correct unintended effects and capture recommendations for the future.

Aggregate review: An aggregate review is a type of root cause analysis of multiple occurrences of the same type of incident.

Clinical audit: a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

Human factors analysis: a review to identify the role of human factors in patient safety incidents, in terms of the type and nature of human factors involvement in safety-related incidents and how they interact with other causes.

Look back: a 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.

Systems analysis investigation of an incident (previously known as root cause analysis): A methodical investigation of an incident which involves collection of data from the literature, records (general records in the case of non clinical incidents and healthcare records in the case of clinical incidents), individual interviews with those involved where the incident occurred and analysis of this data to establish the chronology of events that lead up to the incident, identifying the Key Causal Factors that the investigator(s) considered had an effect on the eventual adverse outcome, the Contributory Factors, and recommended control actions to address the Contributory Factors to prevent future harm arising as far as is reasonably practicable.

Appendix 2: Membership of the Standards Advisory Group

Member	Representing
Angela Tysall	Health Service Executive, Quality Improvement Division
Ann Duffy	State Claims Agency
Aoife Lenihan	Health Information and Quality Authority (HIQA)
Barbara Foley	HIQA
Carmel Sheridan	Health Service Executive, Ireland East Hospital Group
Clare O'Neill	Heath Service Executive, Mental Health Division
Cornelia Stuart	Health Service Executive, Quality Assurance and Verification Division
Deirdre Hyland	Mental Health Commission (Project Lead)
Emma Balmaine	Private Hospitals Association of Ireland
Kara Madden	World Health Organization Patients for Patient Safety
Dr Kathleen Mac Lellan	Department of Health, Office of the Chief Medical Officer
Margaret Brennan	Health Service Executive, Acute Hospitals Division
Marie Kehoe O'Sullivan	HIQA (Co-Chair)
Oliver Mernagh	Health Service Executive, St. James' Hospital
Patrick Lynch	Health Service Executive, Quality Assurance and Verification Division
Patsy Fitzsimons	Office of the Ombudsman
Sarah Murphy	HIQA (Project Lead)
Roisin O'Leary	Patient Focus
Rosemary Smyth	Mental Health Commission (Co-Chair)
Suzanne Keenan	Health Service Executive, Social Care Division