MHC
Coimisiún Meabhair-Shláinte | Mental Health Commission

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



National Standards for the **Conduct of Reviews of Patient Safety Incidents**

2017

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.

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Key terms used in this document

This section includes the key terms which apply across the standards. A full list of relevant definitions is included in the glossary section of this document.

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 Organization, 2009). Where the term patient is used to describe 'patient safety incident', 'quality and patient safety committees' or 'patient safety data', it is intended to encompass all definitions of people who use healthcare (including mental health) services, such as service users in both acute and community healthcare 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: a 'service user' refers to a person who uses healthcare (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 service 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.) Family involvement is in line with the expressed wishes of the service user.

Service: a 'service' is used to describe any acute hospital or mental health service where care is provided to adults and or children.

Service provider: a 'service provider' is used to describe any organisation or part of an organisation, including its workforce, delivering acute hospital and mental health services to adults and or children.

Service-wide: at all levels within the overall organisational structure, including national, hospital group/community health organisation and service delivery levels.

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 organisation, or nationally.

Pseudonymisation: is the technical process of replacing service user labels (that is to say, 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, National Health Service (NHS); 2009).

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 near 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 for conducting reviews of patient safety incidents. These roles may exist at various governance levels within the service such as service delivery, hospital group, community health organisation and national level and may have a broader remit in the management of patient safety incidents.

Senior accountable officer: this person has overall executive accountability for the management of patient safety incidents at the relevant governance level. In relation to the review of patient safety incidents, they ensure that the appropriate review into patient safety incidents is conducted in an effective and timely manner. The senior accountable officer is impartial and sufficiently removed from the incident.

Incident management team: the incident management team is an established standing group and includes senior staff who are responsible for overseeing the management of patient safety incidents and reporting into the relevant senior accountable officer at regular intervals to update on the progress of the review. Members of the incident management team are impartial and sufficiently removed from the incident.

Incident review team: the incident review team is responsible for reviewing patient safety incidents. Membership of the incident review team is determined by the incident management team in the context of the incident under review, and reviewers are impartial and sufficiently removed from the incident. The lead reviewer reports into the incident management team.

Service-user liaison: this person is a contact point at service delivery level for the service user involved in a patient safety incident. The service-user liaison may facilitate feedback between the service user and the incident management team and or incident review team, as appropriate during the review process. They may also facilitate access to support services. The service-user liaison is impartial and sufficiently removed from the incident.

Staff liaison: this person is a contact point at service delivery level for the staff member involved in a patient safety incident. The staff liaison may facilitate communication between the staff member and the incident management team and or the incident review team, as appropriate during the review process. They may also facilitate access to support services. The staff liaison is impartial and sufficiently removed from the incident.

Quality and patient safety committees: these refer to standing committees that meet regularly and have responsibility for overseeing the implementation of recommendations and actions from patient safety incident reviews and monitor how the learning from reviews is being shared for improvement. Members of the quality and patient safety committee also evaluate training programmes on the conduct of reviews of patient safety incidents and report to the relevant senior accountable officer.

1. Introduction

Service users and members of the public expect to be safe when using health and mental health services. When the delivery of care falls below an acceptable standard and leads to a patient safety incident and or harm, people are entitled to openness. They are entitled to ask why an event has happened 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.

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, standardised 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) and Health Information and Quality Authority (HIQA) investigations[1] into the quality and safety of health services — and additionally in the 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 involved in these incidents. 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 relevant services throughout the review process.

These National Standards sit within the overarching framework of:

- HIQA's *National Standards for Safer Better Healthcare*, in particular Standard 3.3, which aims 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
- the 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.'

These Standards aim to promote 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 National 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*. This 2014 report had recommended developing national standards on the conduct of reviews of patient safety incidents, following the identification of shortfalls within the current system in Ireland. It had 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
- an insufficient procedure for unique anonymisation.

These National Standards cover reviews of patient safety incidents which fit into a service's overall incident management process; this includes reporting, open disclosure and notification to external bodies. Service providers need to fully and openly inform and support service users as soon as possible after a patient safety incident affecting them has occurred, or becomes known, and continue to provide information and support as needed in line with the national policy on open disclosure.

On a practical level, the Standards endorse setting up and implementing structures and procedures for conducting reviews of patient safety incidents. As the size and scope of healthcare 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.

Reviewing a patient safety incident can be a complex process and requires services to weigh up the outcome or potential outcome of the incident with the complexity of the incident to determine the appropriate level and method of review. Most patient safety incidents should continue to be managed at a service-delivery level, within a service's standing quality, safety and risk structures, and do not require involvement from the incident management team.

The role of the incident management team is to oversee the conduct of reviews of patient safety incidents. It will ensure, where appropriate, a review is commissioned to determine what happened during the incident and why it happened and determine what learning can be derived to improve patient safety.

The methods and time frames for reviews of patient safety incidents must be appropriate and proportionate to the nature, severity and complexity of the incident. Above all, reviews must be focused on learning and improvement for the future. These National Standards promote the timely review of patient safety incidents, and services must be aware 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 try 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, and ongoing communication on the review is provided to all parties as required.

Services should use these Standards to support their existing patient safety governance structures for the review of patient safety incidents. These National Standards support services to use all available information following an incident to determine the appropriate level of review and methodology, 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 healthcare 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, thereby sharing the learning between services to stop or reduce the likelihood of preventable incidents from reoccurring.

These National Standards build on a body of evidence-based policies and guidelines which have focused on patient safety incidents. The Standards were jointly developed by HIQA and the MHC, which together aim to promote a framework for best practice in the conduct of reviews of patient safety incidents and intend to set a standard for cohesive, person-centred reviews of such incidents.

2. Scope

The Department of Health requested that a phased approach be taken towards developing 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. Further standards will be developed to support a consistent national approach for the conduct of reviews of patient safety incidents across wider health and social care settings. Service providers may determine that the principles of these standards may be applied to other health and social care settings in the interim.

Designated centres for older people and people with disabilities under the Health Act 2007 are not within the scope of these Standards. These services should refer to the relevant HIQA Standards and regulations for information on conducting reviews of incidents in social care services.

The requirements in these Standards are separate from existing obligations on 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 under the Health Act 2007; or the Mental Health Commission under the Mental Health Act, 2001; and any other relevant legislation.

3. Themes

The *National Standards for the Conduct of Reviews of Patient Safety Incidents* are divided into five broad themes:

Theme 1: Governance and Accountability — The structures put in place by a service for accountability, decision-making, quality 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 service 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 and 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 time frames to review incidents and how they implement recommendations from reviews of patient safety incidents.

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

4. Standards and features

These National 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 identifies the Standard and describes the high-level outcome required to deliver high-quality and effective management of patient safety incidents.

Underneath each standard statement is the list of features that a provider may have in place to meet each standard. These features are not an exhaustive list and service providers may meet the requirements of the Standards in different ways.

5. How the National Standards were developed

HIQA and the MHC carried out a focused desktop review of international and national literature to inform the development of the 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. Members included service users, healthcare 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 Standards Advisory Group was to advise HIQA and the MHC during the development of the standards and on an appropriate public consultation process. Both regulatory organisations 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 also participated in and ran 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 National Standards should address. HIQA and the MHC would like to acknowledge with gratitude all those who participated for taking the time to attend the sessions and contributing to the standards development process in such a meaningful way.

A national six-week public consultation on the published draft national standards ran from 26 September until 4 November 2016. Arising from the public consultation, 47 detailed submissions on the draft national standards were received by HIQA and the MHC, which considered these submissions and revised the Standards as appropriate. A summary of these submissions is available to read in a Statement of Outcomes document on **www.hiqa.ie** and **www.mhcirl.ie**

The National Standards

Theme 1: **Governance and Accountability**

Patient safety depends 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 for, and work together towards, achieving a common vision.

Effective governance structures and accountability arrangements for patient safety are fundamental prerequisites for the sustainable conduct of timely and effective reviews of patient safety incidents service-wide. 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. The formalised governance arrangements at national, hospital group and or community health organisation level and service-delivery level ensure that there are clear lines of accountability so that everyone working in the service is aware of his or her responsibilities and accountability.

Services that have good governance structures and accountability arrangements will monitor performance to ensure consistency and quality so that they review patient safety incidents in a timely manner with minimal variation in such reviews service-wide.

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 at national, hospital group and or community health organisation and service delivery levels to ensure all information, including personal information, is handled securely, efficiently, effectively and in line with legislation. Information governance 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 in the review of patient safety incidents.

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, including their rights in relation to the management and review of patient safety incidents.

1.2 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.

1.3 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.

1.4 Service providers communicate authentically, compassionately and respectfully with service users, families and staff involved in patient safety incidents, and they ensure open disclosure happens in line with national policy. Each person's voice is heard and his or her views are listened to and are taken into account in the review of patient safety incidents.

1.5 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.

1.6 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 service-wide 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, minimises the risk of harm to service users and implements actions and learning from reviews of patient safety incidents.

2.2 Governance structures promote patient safety as a collective goal within the service to support 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 (or equivalent)
- design and delivery of services
- code of governance (or equivalent)
- allocation of resources and training
- and monitoring and evaluation processes.

2.5 Service providers have a standardised approach to the conduct of reviews of patient safety incidents service-wide in the following areas:

- governance structures
- reporting and escalation process
- arrangements for feedback
- staff skills and experience
- workforce planning, including capacity building and protected time
- training and induction of staff
- peer support and mentoring of staff
- access to specialist expertise and support

- tools to assist the decision-making process on the level and method of review required
- taxonomy
- pseudonymisation of personal information
- implementation of recommendations from reviews
- sharing the learning for improvement.

2.6 Governance structures are in place to assess service-wide performance and proactively monitor, analyse (including historical and trend analysis) and respond to information relevant to the review of patient safety incidents. This information includes:

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

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

2.8 Service providers have governance structures in place for positive and cooperative relationships with other agencies, as appropriate, to support the effective review of patient safety incidents; this includes procedures on information sharing and interagency working.

Standard 3

Service providers have clear lines of accountability in place service-wide 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 clear lines of accountability for the review of patient safety incidents by having:

- a senior accountable officer at the highest governance level with overall executive accountability, responsibility and authority for the conduct of reviews of patient safety incidents
- identified individuals at hospital group/community health organisation level who have delegated accountability, responsibility and authority, from the senior accountable officer, for the reviews of patient safety incidents, through the relevant governance structures
- identified senior individuals at service delivery level who have delegated accountability, responsibility and authority, from the senior accountable officer, for the reviews of patient safety incidents, through the relevant governance structures.

3.2 The availability of an up-to-date, publicly available, organisational chart detailing the lines of accountability of individuals and groups involved in the conduct of reviews of patient safety incidents at national, hospital group/community health organisation and service delivery levels.

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 service-wide 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 adherence with relevant national policy, standards and guidelines.

4.2 Service providers publish an annual overview report on the conduct of reviews of patient safety incidents. This should include adherence to time frames for reviews and how actions and recommendations from reviews are being implemented in the service.

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

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

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

4.6 Service providers evaluate the incident review process and incident review reports to identify opportunities for improvement for implementation service-wide.

4.7 Service providers, in consultation 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.

Standard 5

Service providers have effective information governance structures in place service-wide 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 comply with relevant legislation[3] and ensures:

- information used by the service is of a high quality[4]
- 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 and publish 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[5] 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 unauthorised access.

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

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. Where appropriate, action is taken to address areas for improvement.

3 For example, Freedom of Information Act, 2014 and the Data Protection Acts, 1988 and 2003.

4 Health Information and Quality Authority. *What you should know about Data Quality: A Guide for Health and Social Care Staff* (2012)

5 See Standard 14 on pseudonymisation.

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 open disclosure, 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. Service providers respect service users' expressed preferences in relation to communication with family members.

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 developing a relationship based on trust. Providing a service-user liaison to communicate with service users and their families during the incident management and review process supports the flow of timely and accessible information and acts as 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 service users at the centre of all that 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 are made aware of their rights, have their rights protected and their views respected and responded to by service providers in the conduct of reviews of patient safety incidents. This includes respecting a service user's right not to engage in the review process.

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 during the review process and are informed of key developments as the review progresses.

6.4 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.

6.5 Service users and their families are advised of support and advocacy services available to them.

Standard 7

Service users and families involved in a patient safety incident are appointed a service-user liaison to facilitate communication with the incident management/review team and access to support.

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

7.1 Service providers identify a service-user liaison, with the necessary skills and experience, to act as a point of contact between the service user[6] and their family and the incident management/review team.

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

- are provided with information as soon as possible and in an accessible format
- meet with a member of the incident management team to highlight issues they may wish to see addressed in the review
- have an opportunity to engage with the review team, in accordance with their wishes
- receive regular updates on the progress of the review, including where there are delays
- can review and provide feedback on the terms of reference, chronology of events and any findings or recommendations prior to submission of the final draft review report for sign off by the senior accountable officer
- receive a copy of the final report and advance notification of publication
- are facilitated to raise any concerns with the review process with the senior accountable officer
- and are facilitated to access support and advocacy services, where requested.

7.3 Service providers ensure that service-user liaisons have access to protected time, if required, and training to meet the requirements of the role.

6 In some circumstances, for example in the event of the death of a service user, the liaison will consult and liaise 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 an accessible format, 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 and understand information on the conduct of reviews of patient safety incidents, in accordance with their wishes.

8.3 Service users and their families are facilitated to access their personal health information.

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 to carry out its roles and responsibilities through the organisation's safety culture. 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 assisting staff involved in patient safety incidents by actively listening to their views and providing a staff liaison throughout the incident-review process for staff members who are involved in patient safety incidents. The staff liaison is a point of contact between the individual staff member and the incident management or review team.

Standard 9

A staff liaison is appointed to facilitate communication with the incident management/review team and access to support for staff.

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

9.1 Service providers identify a staff liaison with the necessary skills and experience to act as a point of contact between the staff member involved in the patient safety incident and the incident management/review team.

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:

- is provided with information as soon as possible and in an accessible format
- has an opportunity to meet with a member of the incident management team to highlight issues they may wish to see addressed in the review
- receives regular updates on the progress of the review, including where there are delays
- can review and provide feedback on the chronology of events and any findings or recommendations prior to submission of the final draft review report for sign off by the senior accountable officer
- receives a copy of the final report and advance notification of publication
- is facilitated to raise any concerns with the review process with the senior accountable officer
- and is facilitated to access support services, where requested.

9.3 Service providers ensure that staff liaisons have access to protected time, if required, and training to meet the requirements of the role.

Standard 10

Service providers establish a standing incident management team[7] to oversee the management and review of patient safety incidents.

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

10.1 Service providers ensure they have a standing incident management team in place to oversee the management and review of patient safety incidents.

10.2 The incident management team provides oversight of the incident management 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 the appointment of service-user liaisons and staff liaisons
- ensuring 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
- ensuring that the risk of harm to other persons arising from the incident is minimised
- overseeing the preliminary assessment of the incident and deciding on the response required.

7 Most patient safety incidents should continue to be managed at a service-delivery level, within a service's standing quality, safety and risk structures, and do not require involvement from the incident management team.

10.3 The incident management team provides oversight of the review process by:

- determining the appropriate level and method of review required
- establishing a process for the provision of updates on the review's progress
- establishing a process for the receipt and consideration of feedback on the terms of reference, draft review report and review process
- determining the terms of reference for a review
- overseeing of the time frames for completion of a review
- determining the review team members and reporting arrangements
- receiving and considering the review report
- ensuring the completion of the review process
- establishing the arrangements for the sharing of the learning from the review.

10.4 The membership of the incident management team is multidisciplinary and may include representation from the following areas, where relevant and appropriate:

- senior accountable officer
- senior clinicians and or managers
- service-user leads
- risk management
- complaints officer
- human resources
- other appropriate personnel.

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

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

10.7 Service providers facilitate access to any specialist supports, expertise or advice required to support the incident management team.

Standard 11

Service providers have a skilled and experienced 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 roles, responsibilities, skills and experience for all staff involved in the review of patient safety incidents.

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

11.3 Service providers engage in workforce planning to build capacity in conducting reviews of patient safety incidents and expertise at all levels.

11.4 Service providers facilitate access to peer support and or mentoring for staff conducting reviews of patient safety incidents, where required.

11.5 Service providers facilitate protected time for staff to conduct reviews of patient safety incidents.

11.6 Service providers facilitate access to any specialist supports, expertise or advice required to support the incident review team.

Standard 12

Service providers ensure that training is delivered to staff on 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 on conducting reviews of patient safety incidents.

12.2 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 incidents.

12.3 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.

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

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

12.6 A training needs analysis is undertaken annually, by the service provider, to identify opportunities to improve the training programmes on conducting reviews of patient safety incidents.

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, commissioned by the incident management team.

This is best done through:

- classifying patient safety incidents using an agreed standardised taxonomy
- providing tools to assist staff in identifying the most appropriate level of and method of review for the different types of patient safety incidents
- and completing the reviews within specified time frames.

Services also 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.

Services promote the effective review of incidents through determining the level of review and using the appropriate methods, using standardised decision-making tools.

Services use the appropriate methods to conduct the review and report on what happened during the patient safety incident and why it happened. They take prompt action on recommendations and action plans for implementation in the service to prevent reoccurrence and to promote improvements in patient safety.

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

Standard 13

Service providers classify patient safety incidents using an agreed standardised taxonomy that is applied service-wide.

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 standardised taxonomy, derived from the World Health Organization (WHO) Conceptual Framework for the International Classification of Patient Safety.[8]

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

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

8 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[9] 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 service-wide policy and procedure in place for the pseudonymisation of personal information relevant 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.

9 Pseudonymisation refers to the technical process of replacing labels 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, National Health Service (NHS); 2009).

Standard 15

Service providers ensure a preliminary 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 in place detailing the process used to determine the appropriate level of review required for different categories of patient safety incidents.

15.2 Serious incidents[10] are notified to the Senior Accountable Officer within 24 hours of their identification.

15.3 The Senior Accountable Officer ensures that a preliminary assessment of the incident is undertaken to determine the appropriate level of review required, in line with the service's policy and procedure.

15.4 The preliminary assessment is completed within five working days following notification of the incident to the Senior Accountable Officer.

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

15.6 Service providers determine the level of review required for patient safety incidents, taking into account:

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

10 Serious incidents that require notification to the Senior Accountable Officer in line with the service's policy and procedure.

15.7 The levels[11] of review for patient safety incidents are determined by the level of severity of the incident and the potential for learning and improvement and include:

- concise internal reviews[12]
- comprehensive internal reviews[13]
- external independent reviews.[14]

15.8 The level of review may be revised in light of information received during the review process. Decisions relating to the appropriate level of review required and the time frame for the commencement of the review are based on the findings of the preliminary assessment and are documented by the service.

15.9 Where the decision is made by the incident management team that a review is not appropriate, such incidents are subject to periodic aggregate analysis to identify trends and opportunities for learning, risk reduction and quality improvement.

11 Adapted from the National Health Service (NHS) England. *NHS England Serious Incident Framework*. London: National Health Service England; 2015.

12 These reviews are suited to less complex incidents and can be managed by individuals or a small team at a local level.

13 These reviews are suited to more complex incidents and may involve a multidisciplinary team at either a local or national level.

14 These reviews may be commissioned externally by the service where the objectivity or integrity of an internal review maybe challenged or for particularly complex incidents which involve multiple services.

Standard 16

Reviews of patient safety incidents are conducted using appropriate and proportionate 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 and 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[15] used to conduct reviews of patient safety incidents include but are not limited to:

- after-action review
- aggregate review
- human factors analysis
- review of care against policies, procedures and guidelines
- systems analysis.

16.3 The review is conducted using the appropriate methodology and will identify, where relevant, the:

- chronology of events leading up to the patient safety incident
- what happened
- why it happened
- incidental findings
- recommendations for action to reduce risk and improve quality and safety.

16.4 Where reviews of patient safety incidents are being conducted in parallel with other external[16] investigations by statutory bodies, the incident management team must engage with the relevant agency to inform them that the review is underway.

15 A description of each of these review methods is included in Appendix 1.

16 External investigations can include those conducted by the State Claims Agency, Health Information and Quality Authority, Mental Health Commission, An Garda Síochána, 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 time frames for reviews of patient safety incidents are implemented by the service:

- concise internal reviews are completed no later than 60 calendar days after the decision to review has been made
- comprehensive internal reviews are completed no later than 120 calendar days after the decision to review has been made
- external independent reviews, commissioned by the service, are completed no later than 120 calendar days after the decision to review has been made.

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

17.3 As soon as a delay is identified, the reasons for the delay and the revised time frame 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 report[17] is produced, which accurately describes what happened and why it happened 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 Depending on the level and method of review, review reports may contain:

- the terms of reference
- the membership of the review team
- the methodology applied to the review process and the rationale for why the decision to use this methodology was made
- a summary of the background to the incident
- any actions taken immediately following identification of the incident and during the review process
- what happened during the incident or incidents
- why it happened
- any incidental findings
- an apology or expression of regret to all those affected
- the recommendations and actions 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.

17 Review reports are developed for concise internal, comprehensive internal and external independent reviews.

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

18.4 All parties involved in the patient safety incident have an opportunity to review and provide feedback on the findings and recommendations of the report, in advance of it being finalised.

18.5 The review team prepares and quality assures the report and checks for consistency, factual accuracy and readability prior to submission to the senior accountable officer.

18.6 The final draft report is presented to the incident management team and the senior accountable officer for sign off to ensure that the terms of reference of the review have been met.

18.7 Service providers have arrangements in place for meeting with relevant staff to brief them on the report in advance of wider circulation of the report.

18.8 The service-user liaison ensures that the service user involved in the incident receives a copy of the final report and advance notice of the publication date, once confirmed.

18.9 The staff liaison ensures that the staff member involved in the incident receives a copy of the final report and advance notice of the publication date, once confirmed.

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 the patient safety incident-review report. The plan outlines the actions to be taken, responsible person or people, time frames and the resources required to implement each action. Actions in the implementation plan should be SMART.[18]

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 service-wide.

19.3 Quality and patient safety committees oversee the implementation of recommendations and actions required from reviews of patient safety incidents and have assurance processes in place to 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.

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

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 of a similar incident. Discussion on the learning from reviews of patient safety incidents should be actively promoted within the service to encourage a positive safety culture.

Service providers should develop an implementation plan that uses a range of approaches for sharing the learning, to best fit the needs of the particular 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 promote improvements in patient safety.

Standard 20

Service providers have structures in place to actively share the learning from reviews of patient safety incidents service-wide.

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

20.1 Service providers implement a plan to share learning from reviews of patient safety incidents service-wide. This plan should identify responsibilities of staff involved in sharing the learning and the range of mechanisms that will be used. This includes but is not limited to summary reports of incident reviews, safety alerts, seminars and online modules.

20.2 Quality and patient safety committees oversee the implementation of sharing the learning from reviews of patient safety incidents.

20.3 Service providers actively promote discussion on the learning from reviews of patient safety incidents to promote a positive safety culture service-wide.

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

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

20.6 Service providers work in partnership with external bodies, as appropriate, to share the learning from reviews of patient safety incidents.

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Glossary of terms in the context of these standards

Accountability: being answerable to another person or organisation 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 or mental health service.

Best practices: clinical, scientific or professional practices that are recognised 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 organisational 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 organised or analysed.

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 desired 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. (Adapted from the definition of a connected person as per the *General Scheme on Open Disclosure-Periodic Payment Orders 2015*.) Family involvement is in line with the expressed wishes of the service user.

Features: these, taken together, will enable progress towards achieving the 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 have been 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 World Health Organization's *Conceptual Framework for the International Classification of Patient Safety*, 2009.)

Health information: information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present or 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 healthcare system.

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

Information governance: the arrangements that service providers have in place to manage information to support their immediate and future regulatory, legal, risk, environmental and operational requirements.

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.

Mental health service: a service that provides care and treatment to persons suffering from a mental illness or a mental disorder under the clinical direction of a consultant psychiatrist (Mental Health Act, 2001).

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: 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.

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 reoccurrence of the adverse event.

Patient safety: 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 Organization, 2009). Where the term patient is used to describe 'patient safety incident', 'quality and patient safety committees' or 'patient safety data', it is intended to encompass all definitions of people who use healthcare (including mental health) services, such as service users in both acute and community healthcare settings.

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 (that is to say, 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).

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 organisation, or nationally.

Risk: Risk is the effect of uncertainty on objectives. It is measured in terms of consequences and likelihood.

Risk management: Coordinated activities to direct and control an organisation with regard to risk.

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

Service: a 'service' is used to describe any acute hospital or mental health service where care is provided to adults and or children.

Service provider: a 'service provider' is used to describe any organisation or part of an organisation, including its workforce, delivering acute hospital and mental health services to adults and or children.

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

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

Service-wide: at all levels within the overall organisational structure, including national, hospital group/community health organisation and service delivery levels.

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

Taxonomy: a system for naming and organising 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 review. Some of the review types include but are not limited to:

After-action review: an after-action review is a discussion of an event that enables the individuals involved to learn for themselves what happened, why it happened, what went well, what needs improvement and the lessons learnt. The after-action review seeks to understand the expectations of all those involved and provides insight into events and behaviours in a timely way with the learning leading to personal awareness and action.

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

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.

Systems analysis investigation of an incident: 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.

The aim is to establish the chronology of events that lead up to the incident, identifying the key causal factors that the investigator or investigators considered had an effect on the eventual adverse outcome. It also aims to determine the contributory factors, and recommended control actions to address these in order 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 (HSE), Quality Improvement Division
Ann Duffy	State Claims Agency
Aoife Lenihan	Health Information and Quality Authority (HIQA)
Barbara Foley	HIQA
Clare O'Neill	HSE, Mental Health Division
Cornelia Stuart	HSE, Quality Assurance and Verification Division
Deirdre Hyland	Mental Health Commission (Joint Project Lead)
Emma Balmaine	Private Hospitals Association of Ireland
Kara Madden	World Health Organization Patients for Patient Safety
Kathleen Mac Lellan[20]	Department of Health, National Patient Safety Office
Margaret Brennan	HSE, Acute Hospitals Division
Marie Kehoe O'Sullivan	HIQA (Co-Chairperson)
Oliver Mernagh	HSE, St James's Hospital
Patrick Lynch	HSE, Quality Assurance and Verification Division
Patsy Fitzsimons	Office of the Ombudsman
Sarah Murphy	HIQA (Joint Project Lead)
Roisin O'Leary	Patient Focus
Rosemary Smyth	Mental Health Commission (Co-Chairperson)

20 Ms Susan Reilly attended two meetings on behalf of Dr Kathleen Mac Lellan.

Standards Development Project Team

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	Kate Frowein, Quality Assurance and Regulatory Officer

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