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Coimisiún Meabhair-Shláinte | Mental Health Commission

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

Background document to support the development of National Standards for the Conduct of Reviews of Patient Safety Incidents

October 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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Chapter 1 Background

1.0 Introduction

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. A recent report by the House of Commons into clinical incidents in the National Health Service (NHS) England highlighted the importance of investigations focusing on learning and improvement, supporting staff and having a "whole system" approach that does not rely on a singular method; for example, root cause analysis to conduct reviews [(1)].

Issues of timeliness, appropriate methods for reviewing patient safety incidents and the quality of reviews of patient safety incidents have been problematic in Ireland. The Health Service Executive's (HSE's) 2015 special report into serious reportable events (SRE) highlighted that 78% of reviews during the period March 2014 to September 2015 did not meet the target of four months for completing the review.[(2)] The 2014 *Report on Perinatal Deaths in HSE Midland Regional Hospital Portlaoise* by the Chief Medical Officer identified the following shortfalls with the current system in Ireland for conducting reviews of patient safety incidents:

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

The report also recommended the development of national standards on the conduct of reviews of patient safety incidents.[1(3)]

1.1 Purpose of the Standards

These outcome-based Standards were commissioned by the Department of Health and underpinned by findings from the Chief Medical Officer's 2014 *Report on*

[1] This report also recommended that the Health Information and Quality Authority (HIQA) develop recommendations on the co-ordination of patient safety intelligence in Ireland. This report should be read in conjunction with the following HIQA publications: *International Review of Patient Safety Surveillance Systems* (2016), *As-is Analysis of Patient Safety Intelligence Systems and Structures in Ireland* (2016) and *Recommendations for the Minister for Health on the co-ordination of patient safety intelligence in Ireland* (2016).

Perinatal Deaths in HSE Midland Regional Hospital Portlaoise, and have been jointly developed by the Health Information and Quality Authority (HIQA) and the Mental Health Commission (MHC). The Standards aim to establish a clear framework for acute hospitals and mental health services on how to conduct reviews of patient safety incidents and to promote improvements in patient safety and quality.

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 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 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.

1.2 Structure of this report

This document sets out the findings of the desktop research undertaken to inform the development of the draft national standards for public consultation. It includes:

- A review of policies and procedures, methods and time frames for conducting reviews of patient safety incidents in place in seven countries internationally.

- An overview of reviews and investigations of patient safety incidents in Ireland.

The findings from the documents reviewed informed the content of the standards and features within the individual themes, however where information was not readily available, or deficiencies within specific themes were identified, expert opinion and advice was sought through extensive engagement with stakeholders. HIQA and the MHC employed the following methods of engagement:

- HIQA and the MHC convened a standards advisory group which included service users, healthcare professionals (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.
- HIQA and the MHC conducted 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 undertook a six-week public consultation process from 26 September to 04 November 2016 and received 47 submissions as part of this process. All submissions were reviewed and considered when revising the draft standards.

Chapter 2 Review of policies and procedures for the conduct of reviews of patient safety incidents in seven countries

2.0 Overview

This section will examine the structures in place in Ireland, Northern Ireland, England, Scotland, Canada, Denmark and New Zealand for the conduct of reviews of patient safety incidents with a focus on the:

- classification of patient safety incidents
- levels of review, methods and time frames
- procedures for unique anonymisation
- sharing of learning from reviews of patient safety incidents.

These jurisdictions were chosen following a desktop review in November 2015 which identified relevant developments in the review of patient safety incidents in terms of recent policies, procedures and guidelines being developed.

2.1 Ireland[2]

Managing and learning from patient safety incidents in Ireland[3] are guided by the Health Service Executive (HSE) *Safety Incident Management Policy (2014)* , which is currently under review and the *Guidelines for Systems Analysis Investigations of Incidents (2016)*.[4,5] The policy and guideline highlight that following a review of incidents, management implements actions locally and learning is shared at a local and national level.

2.1.1 Classification of incidents

The policy defines an incident as 'an event or circumstance, which could have, or did lead to unintended and/or unnecessary harm'. Incidents include adverse events, near misses, and staff or service user complaints. Incidents can be clinical or non-clinical and may be associated with harm to patients, service users, staff and visitors and the HSE environment, systems and objectives. The policy refers to the World Health Organization *Conceptual Framework for the International Classification for*

[2] At the time of going to print, the HSE's Incident Management Policy is under review.
[3] The information provided for Ireland is reflective of policy in the HSE (the provider of the majority of health services). A small number of mental health services in Ireland are provided by independent service providers who have their own incident management policy and procedures.

Patient Safety (2009) for the classification of incidents and has a list of serious reportable events, which is reviewed annually [(6)].

All patient safety incidents, including serious reportable events and near misses are reported to a line manager and notified to the National Incident Management System (NIMS).

2.1.2 Levels of review, method and time frames

Once immediate safety concerns are managed, line managers assess the incident within 24 hours of its occurrence in terms of its impact[4] to determine the level of investigation required. Safety incidents that require investigation are managed by a safety incident management team (SIMT) led by a senior accountable officer from the service, division or care group. A SIMT must be convened for incidents of death or harm where the impact is rated as major or extreme.

There are three types of review specified in the guidance and the type of review undertaken will be based on the level of harm, type of incident and the risk assessment rating and may include:

1. Aggregate analysis – this is carried out for low impact safety incidents and summarises the key causal factors by type of incident, the contributory factors for each causal factor, and indentifies control measures and quality improvement plans to address the contributory factors identified.

2. Systems analysis – this is carried out for major or extreme impact safety incidents and involves collection of data from the literature, records, interviews with those involved in delivering the care or services where the incident occurred, and analysis of this data to establish the chronology of events that lead up to the incident, the care or service delivery problems that contributed to the incident, the contributory factors and recommended control actions to address the contributory factors to prevent future harm arising, as far as is reasonably practicable.

3. Look back review – this review is carried out where a number of people 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 those harmed.

[4] Level of impact of incidents can be rated as negligible, minor, moderate, major and extreme.

Providers must adhere to the following timelines:

- the policy states that all incidents are to be assessed within 24 hours to identify the impact of the incident
- the HSE's target for completion of an investigation report is 120 days.

When complete, review reports are submitted to the Investigation Commissioner[5] or the local Quality and Safety Committee.

2.1.3 Procedures for unique anonymisation

The policy and guidance makes reference to anonymisation of identifiable persons and location in the investigation report using codes, and some guidance is provided on how this is to be carried out.

2.1.4 Sharing of learning

Anonymised investigation reports are shared with the patient or his or her family or advocate (unless there are exceptional reasons why this cannot happen) and may also be disseminated to staff and other third parties such as health service managers and stakeholders (for example, the Department of Health or the State Claims Agency). The responsibility for the assessment, circulation, monitoring and implementation of recommendations from the review lies with the Investigation Commissioner or the local Quality and Safety Committee.

2.2 Northern Ireland

Reporting, follow-up and learning from serious adverse incidents in Northern Ireland are governed by the *Northern Ireland Health and Social Care Board Procedure for the Reporting and Follow-Up of Serious Adverse Incidents*.(7)

2.2.1 Classification of incidents

A serious adverse incident is defined by the Health and Social Care Board as 'any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation, arising during the course of the business of a Health and Social Care organisation / Special Agency or commissioned service'.(7) Criteria such as risk, serious injury or death to services users, staff or a member of the public are used to determine if the incident constitutes a serious

[5] The Commissioner of an investigation differs across the health system, but it is typically the senior accountable officer in a service, division or care group that commissions an investigation of a clinical or non-clinical safety incident.

adverse incident. Reporting and the investigation of serious adverse incidents are mandatory for all Health and Social Care organisations, special agencies or commissioned services.

2.2.2 Levels of review, method and time frames

The Health and Social Care Board use a regional risk-matrix tool to determine the level of seriousness and level of investigation to be undertaken. There are three categories of review prescribed for serious adverse incidents:

- Level 1: Significant event audit (to be completed within four to six weeks)
- Level 2: Root cause analysis (to be completed within 12 weeks)
- Level 3: Independent investigation (timelines to be agreed by reporting organisation and the designated review officer).

Level 1: Significant event audit (SEA)

Most serious adverse incident notifications enter the review process at level 1 and a significant event audit is immediately undertaken to assess what and why it has happened, agree follow-up actions and identify learning. Possible outcomes from the investigation may include:

- closed – no new learning,
- closed – with learning,
- or requires a Level 2 or 3 investigation.

If this level of review is deemed appropriate, a significant event audit report is completed and sent to the Health and Social Care Board within four weeks (six weeks by exception) of the incident being reported.

Level 2: Root cause analysis (RCA)

Whilst most serious adverse incidents will be subject to a Level 1 review, for some more complex serious adverse incidents, reporting organisations may instigate a Level 2 or 3 review immediately following the incident occurring. Where a Level 2 or Level 3 investigation is instigated following notification of a serious adverse incident, the reporting organisation informs the Health and Social Care Board (HSCB) within four weeks of the terms of reference and membership of the investigation team. The investigation is conducted to a high level of detail. It includes the use of appropriate analytical tools[6] by a multidisciplinary team (not directly involved in the incident),

[6]The National Patient Safety Agency's Seven Steps to Patient Safety and Root Cause Analysis Investigation Guidance are recommended in the guidance as useful investigation tools. On 1 June 2012 the the key functions and expertise for patient

and is chaired by someone independent to the incident (but not necessarily to the organisation). Where Level 2 root cause analysis (RCA) investigations involve two or more organisations, a lead organisation is identified and all parties contribute to and approve the final report. The final report must be submitted to the Health and Social Care Board within 12 weeks from the date the incident was discovered, or within 12 weeks from the date of the significant event audit.

Level 3: Independent investigation

Level 3 investigations are used for serious adverse incidents that are particularly complex; such as, involve multiple organisations, are technically complex and require independent expert advice or are very high profile, attracting a high level of media and public attention. The timescales for reporting the Chair and Membership of the investigation team are agreed by the Health and Social Care Board (HSCB)/Public Health Authority's (PHA) Dsignated Review Officer (DRO) at the outset. The format for Level 3 investigation reports is the same as for Level 2 investigations.

2.2.3 Procedures for unique anonymisation

The procedure makes reference to reports being anonymised but identifies no detailed procedure for how this is to be carried out.

2.2.4 Sharing of learning

Recommendations from the investigation of serious adverse incidents are monitored through the individual organisation's governance structure and learning is shared within the organisation. Where regional learning is identified, this is shared by the Health and Social Care Board or the Public Health Agency regional group.

2.3 England

The management of serious incidents in England is guided by the *NHS England Serious Incident Framework (2015)*.[8] The framework endorses the review of serious incidents to support learning and prevent reoccurrence. It details seven key principles for the management of serious incidents which promote investigations that are open and transparent, preventative, objective, timely and responsive, systems-based, proportionate and collaborative.

safety developed by the National Patient Safety Agency (NPSA) transferred to NHS Commissioning Board Special Health Authority.

2.3.1 Classification of Incidents

The framework defines a serious incident as an act or omission which occurred as part of National Health Service (NHS)-funded services resulting in:

- unexpected or avoidable death of one or more persons,
- unexpected or avoidable injury that has resulted in serious harm to one or more persons,
- unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent the death of or serious harm to a service,
- actual or alleged abuse where healthcare did not take appropriate action/intervention to safeguard against such abuse occurring or where abuse occurred during the provision of NHS-funded care,
- one of the core set of never events[7],
- an incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services,
- major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

The classification is different from the World Health Organization (WHO) International Classification for Patient Safety but is closely aligned.

2.3.2 Levels of review, methods and time frames

An initial review is completed within 72 hours of the serious incident being identified to identify any immediate action to be taken, assess the incident in detail and propose the relevant level of investigation. Within the NHS there are three levels of root cause analysis investigations: Level 1 (concise internal investigation), Level 2 (comprehensive internal investigation) and Level 3 (independent investigation). Detailed guidance[8] on each level of root cause analysis (RCA) is available for investigators.(9)

[7] Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at: http://www.england.nhs.uk/ourwork/patientsafety/never-events/

[8] The National Patient Safety Agency's Exploring Incidents – Improving Safety can be found here: https://report.nrls.nhs.uk/rcatoolkit/course/index.htm

The nature, severity and complexity of the serious incident will determine the level of review required. Concise internal investigations are suited to less complex issues and can be managed by individuals or a small team, while comprehensive internal investigations are required for more complex issues and will involve a multidisciplinary team. Independent investigations are commissioned where it is challenging for the organisation to conduct an objective investigation or where the integrity of an internal investigation may be challenged. Once the level of review is determined, providers must adhere to the following timelines:

- For a concise or comprehensive internal investigation, the provider organisation must submit a completed investigation within 60 working days of the incident being reported to the relevant commissioner of care as per the NHS policy.
- For an independent investigation, investigators must complete an investigation within six months of the investigation being commissioned.

2.3.3 Procedures for unique anonymisation

As reports are drafted on the basis that they may be published, the framework makes reference to investigation reports being anonymised and seeking consent for disclosure of personal information at the earliest opportunity, but does not identify a detailed procedure for how this is to be carried out. Each NHS organisation has a Caldicott Guardian whose responsibility is to protect the confidentiality of patient and service-user information and to facilitate appropriate information sharing. Investigators are encouraged to seek advice from the Caldicott Guardian regarding the disclosure of identifiable information.

2.3.1 Sharing of learning

Review reports must be shared with key stakeholders including the patient and their families. All NHS organisations with a responsibility for notifying or receiving details of serious incidents have a responsibility for the dissemination of learning. Organisations are to share findings with the National Reporting and Learning System and NHS Commissioning Board on a regular basis, who will disseminate the learning through relevant professional networks and bodies.

2.4 Scotland

Learning from Adverse Events through Reporting and Review: A National Framework for NHS Scotland 2nd Edition (2015) provides guidance on reporting and reviewing adverse events in Scotland.[10] It details seven key principles for the management of

adverse events, which promote investigations that: have an emphasis on learning and promoting best practice across Scotland; have a system approach; display openness about failures; support a just culture; promote a positive safety culture; take personal, professional and organisational accountability; and encourage teamwork.

2.4.1 Classification of incidents

Healthcare Improvement Scotland define an adverse event as an incident that could have caused (a near miss), or did result in, harm to people or groups of people. The framework advises that adverse events should be notified as soon as possible after the event occurs, in line with local notification and escalation procedures. Following receipt of the adverse event notification, adverse events are categorised following an initial assessment, using a decision-making tool such as a risk matrix.

The framework identifies three categories of adverse events, based on impact of harm:

- Category I – events that may have contributed to or resulted in permanent harm
- Category II – events that may have contributed to or resulted in temporary harm
- Category III – events that had the potential to cause harm but no harm occurred.

2.4.2 Levels of review, methods and time frames

The category of adverse event will determine the level of review required:

- Category I events require a comprehensive adverse event analysis using validated analysis tools and involves a full review team. The review is commenced within two weeks and is completed within three months of the incident being reported.
- Category II events require a local management review led by the service manager with multidisciplinary input. The review is commenced within two weeks of the incident being reported and is completed within six weeks.
- Category III events require a local review led by the line managers in consultation with staff . The review is commenced and is closed within two weeks of being reported.

Root cause analysis methods are used for the review of adverse events. However, some events, due to the complexity or the potential for learning, require a more

formal and extensive review making full use of all associated techniques to comprehensively examine the chronology, care delivery problems and contributory factors.

2.4.3 Procedures for unique anonymisation

The framework does not detail procedures for anonymisation but suggests that investigation reports are written in a format that reduces the need to redact person-identifiable information, meaning information can be more freely shared to enable appropriate learning, while also safeguarding patient, service user, family, carer, donor and staff confidentiality.

2.4.4 Sharing of learning

Scotland requires that Level I and Level II adverse event reviews develop an improvement plan based on the findings and recommendations from the review that highlights all actions required and identifies owners and timescales for completion. Improvement plans are shared with those who reported and were involved in the adverse event and are reviewed and updated regularly. Learning from adverse event reviews is disseminated across all services and the wider organisation.

2.5 British Columbia, Canada

In British Columbia, healthcare organisations report serious adverse events to the Minister of Health under the Hospitals Act 1996.[11] The legal framework requires that the administrator in a hospital and the licensee of a private hospital must report each serious adverse event to the Minister immediately after the adverse event occurs and in the form and manner specified by the Minister. Each health authority in British Columbia defines its own approach to managing adverse incidents, and each has its own incident management policy and review processes in place.

The Provincial Health Services Authority (PHSA) details procedures for the management and review of patient safety events in its *Critical and Non-Critical Patient Safety Event Management and Review Policy* (2013) and the accompanying *Critical Patient Safety Event Review Toolkit* (2013).[12,13]

2.5.1 Classification of Incidents

The Hospital Act (1996) and associated regulations establish definitions for serious adverse events and severe harm and the duty to report adverse events.[11]

According to the Act, a serious adverse event is an incident that:

- took place in a hospital or private hospital
- was the likely cause of, or likely significantly contributed to, severe harm to or the death of a patient
- was not expected or intended to occur, and
- was not caused by or related to an underlying medical condition of the patient.

The policy defines a critical patient safety event as an event resulting in serious harm or the significant risk of harm. Events are deemed to be critical when there is a need for immediate investigation and response. Critical patient safety event reviews are mandatory for 'never events[9]' or events where there is confirmed severe or catastrophic harm with a direct causal relationship.

2.5.2 Levels of review, methods and time frames

An initial investigation is carried out by local operational, clinical or quality and safety leaders using a risk assessment matrix to determine if a critical patient safety event review is required. Non-critical patient safety events may use the same process as critical events, but health authorities may also choose to deal with the issue via their own internal review processes. A critical patient safety event review is conducted to determine system-level weaknesses and uses systems analysis approach. The review comprises:

- a review team that includes people who are knowledgeable in the area, have management or decision making responsibility and is led by a chairperson or facilitator who is experienced in critical event analysis methods and in conducting reviews
- gathering relevant information to generate an understanding of what led to the critical patient safety event
- analysing the relevant information to determine the contributing factors that may have led to the adverse event. Tools suggested are Causal Chains, Ishikawa (Fishbone) Diagram, Contributing Factors Wheel and Constellation Diagram and Contributing Factors Triage Tool,
- developing recommendations and generating a report,
- evaluating the effectiveness of the critical patient safety event review process.

The timeline for a critical patient safety event review is four months, or sooner, from becoming aware of the event to implementing recommendations. The toolkit

[9] Never Events is a list of patient safety events that all PHSA Agencies have created and are deemed to be "must never happen" events. If an event on the list occurs, it must automatically be reviewed as a Critical Patient Safety Event.

suggests that a critical patient safety event review report is completed and submitted to the quality committee by day 60. By day 120 the recommendations from the report are implemented.

2.5.3 Procedures for unique anonymisation

The policy or review toolkit does not refer to information being confidential or detail procedures for anonymisation. However, it does state that all conversations and information discussed or presented during a critical patient safety event review are considered privilege under Section 51 of the Evidence Act (1996) and are prevented from being used as evidence in civil or court proceedings.[14]

2.5.4 Sharing of learning

All critical patient safety event reviews must have a patient safety learning summary completed and disseminated within the organisation. The organisation may also issue alerts in order to share learning on safety issues requiring immediate attention, to provide a summary of key findings to prevent reoccurrence, to communicate actions that have been implemented as a result of a critical patient safety event review, and to recommend best practice changes that other parts of the organisation may wish to adopt.

2.6 Denmark

The Danish Health Care Act (2010) provides for mandatory reporting of specified adverse events by frontline personnel in hospitals and in the primary care sector.[15] Patients and patients' relatives can also directly report an adverse event via their regional hospital administration. There are no standardised guidelines for the review of adverse events, but each hospital administration has the flexibility of organising the review system around existing local structures.

2.6.1 Classification of incidents

Adverse events are defined as "events resulting from treatment by, or stay in, a hospital and not from the illness of a patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events comprise events and error known and unknown." Denmark previously used a national customised version of the WHO's International Classification for Patient Safety.[6] In 2014, Denmark began to use a new customised Danish classification system that is similar to the WHO's

International Classification for Patient Safety, but with definitions that are more appropriate to the Danish context.

2.6.2 Levels of review, methods and time frames

In Denmark, patient safety incidents must be notified within seven days of the event occurring for local case handling and analysis. The head of the department where the adverse event has occurred usually performs analyses and risk assessments locally. Most regions use the Safety Assessment Code (SAC) Matrix[10] for determining the level of review required and more serious adverse events are analysed by staff from the National Agency for Patients' Rights and Complaints, who perform cluster and trend analysis and issue alerts where necessary. Adverse events or potential adverse events that score a 3 on the SAC Matrix automatically undergo a root cause analysis. Those with a SAC score of 2 undergo an aggregated root cause analysis and adverse events with a SAC score of 1 undergo a local review.

The Danish Society for Patient Safety has produced guidance on conducting a root cause analysis for adverse events.(16) The investigation team review whether contributory factors existed in relation to communication, training, scheduling, environment and equipment, rules/policies and procedures and barriers. The case handling and analysis must be completed within 90 days after the incident, and sent nationally for inclusion on the Danish Patient Safety Database.

2.6.3 Procedures for unique anonymisation

Personal identifiable information is redacted to protect confidentiality. There is both an automatic and manual filtering process in place to identify and remove patient names, dates of birth, case numbers, patient hospital numbers and staff names from reports.

2.6.4 Sharing of learning

The Health Act (2010) enables the sharing of reports on adverse events between agencies and the National Agency for Patients' Rights and Complaints is required to communicate learning nationally.(17) The National Agency publish learning from complaints and compensation cases, as well as systems and thematic reports on specific issues. The regions and municipalities also contribute to the development of thematic reports.

[10] Adapted from VA National Centre for Patient Safety https://www.patientsafety.va.gov/professionals/publications/matrix.asp

2.7 New Zealand

The *National Reportable Events Policy* 2012 in New Zealand was set by the Health Quality and Safety Commission.[18] Similar to Canada, each provider is required to develop their own local policies and processes for reporting and responding to incidents.

2.7.1 Classification of incidents

An adverse incident is defined in New Zealand as an incident 'which results in harm to a consumer'.

2.7.2 Levels of review, methods and time frames

The policy requires all providers to assign a severity assessment code (SAC) to each incident. These codes are assigned using a severity assessment code risk (SAC) matrix; SAC 1 to SAC 4. Providers must report all serious adverse events (SAC 1 or SAC 2) using a Reportable Events Brief (REB) document to the Health Quality and Safety Commission within 15 days, and submit a summary of the findings and recommendations of the review within 70 working days after that. The Health Quality and Safety Commission produces a summary report on events every year. A review of a less severe incident (SAC 3 or SAC 4) must be reported within 30 days.

The Health Quality and Safety Commission also provides detailed guidance[11] and templates for a root cause analysis. This includes templates which show how to select the team, how to conduct interviews, and how to structure finding statements. Finding statements should:

- clearly show the cause and effect relationship
- use specific and accurate descriptors for what occurred, rather than negative and vague words
- identify the preceding cause(s), not the human error
- identify the preceding cause(s) of procedure violations
- failure to act is only causal when there is a pre-existing duty to act.

2.7.3 Procedures for unique anonymisation

The policy does not refer to information being confidential or detail procedures for anonymisation.

[11] Root Cause Analysis For Clinical Incidents can be found here: https://www.hqsc.govt.nz/assets/Reportable-Events/Resources/RCA-clinical-incidents-May-2012.pdf

2.7.4 Sharing of learning

The policy states that all health and disability service providers are encouraged to consider notifying the central repository of near-miss incidents with a high potential SAC rating, or those adverse events rated as SAC 3 or SAC 4, where national learning can occur.

2.8 Summary

This review has focused on the existing measures in place for the conduct of reviews of patient safety incidents in seven jurisdictions, including Ireland, with a focus on how countries classify patient safety incidents, the levels, methods and time frames for reviewing patient safety incidents, the procedures in place for unique anonymisation of data and how countries share the learning following an adverse event.

Across the jurisdictions reviewed, there was some variation between the time frames and types of reviews conducted but there was similarity in terms of classification of incidents, use of risk assessment matrices to determine level of impact and also the use of systems analysis methods (root cause analysis) to conduct reviews.

Policies on patient safety incident management in Ireland and Denmark refer explicitly to the WHO's International Classification for Patient Safety, and Denmark has recently developed its own custom classification, based on the WHO framework. All jurisdictions have different terms to describe a patient safety incident for example, Northern Ireland refer to a 'serious adverse incident (SAI)' while it is an 'adverse event' in Denmark, or a 'serious incident' in England. However, all jurisdictions in their definition of a patient safety incident agree that it is an incident, which causes or has the potential to cause harm to a service user.

All jurisdictions use a form of root cause analysis methodology to conduct their reviews of patient safety incidents. However, jurisdictions varied in the level of reviews conducted (local, concise, comprehensive), constitution of the review team and time frames for the commencement and completion of the review. See Appendix 1 for an overview by country.

No polices or guidance in the jurisdictions reviewed referred to a detailed procedure on the anonymisation of data in investigation reports, but some did refer to identifiable information being redacted. However, all jurisdictions had mechanisms in place to share the learning within the system following a patient safety incident.

What this review demonstrates is that while there are both similarities and variances in how countries conduct reviews of patient safety incidents, there is no internationally agreed standardised approach to identify, analyse and report on patient safety incidents.[19] The lack of standardisation in how patient safety incidents are identified, reported and analysed can lead to errors in how policies and procedures are implemented locally. This was clearly seen in the findings of the Chief Medical Officer's *Report on Perinatal Deaths in HSE Midland Regional Hospital Portlaoise* (2014) which led to the recommendation for the development of national standards for the conduct of reviews of patient safety incidents.

Chapter 3: Reviews and investigations of patient safety incidents in Ireland

3.0 Overview

This chapter will provide an overview of the background and key findings of national investigations and reviews into patient safety incidents in Ireland, including HIQA and MHC investigations.

3.1 HIQA investigation reports

3.1.1 Investigation into the care received by Rebecca O'Malley, Symptomatic Breast Disease Services at the Mid Western Regional Hospital (MWRH) Limerick and the Pathology Services at Cork University Hospital (CUH), 2008[20]

This report outlines the findings of an investigation into the care received by Rebecca O'Malley following her presentation to the Mid Western Regional Hospital (MWRH) Limerick in 2005 with symptomatic breast disease. It also includes her pathway following re-presentation to the MWRH Limerick and subsequent diagnosis of breast cancer and treatment in 2006 and 2007.[20]

As a result of the concerns raised by Rebecca O'Malley and a request from the Health Service Executive (HSE), the Health Information and Quality Authority (HIQA) decided to instigate an investigation in 2007.[20] During the investigation various documents were reviewed including relevant strategic plans, policies and procedures and evaluations at the MWRH and Cork University Hospital (CUH), as well as correspondence relevant to Rebecca O'Malley's experience. Site visits and interviews were conducted with clinical and non-clinical staff, Rebecca O'Malley, her husband and another patient Ms X. The team also reviewed patient records, imaging material and pathological specimens as part of the investigation.

The scope of the investigation was to consider all aspects of Rebecca O'Malley's care, including the symptomatic breast disease service at the MWRH Limerick and the pathology service as it related to breast disease at CUH. In respect of Rebecca O'Malley's misdiagnosis, it was concluded that the primary error was made by a locum Consultant Pathologist at CUH.[20] However, the investigation found that this in itself might not have led to a delay in diagnosis for Rebecca O'Malley. If a fully functioning multidisciplinary review meeting about her case had been held at the MWRH, the opportunity to correct the error may not have been lost.

Some of the key findings from the investigation were as follows:

- Given the seriousness of the delays in responding to concerns raised, an urgent review by Corporate HSE of communications within its hospitals is required, to ensure that effective communications policies and procedures are in place to provide an efficient and co-ordinated response to the patient when a serious incident arises.
- Formal risk management policies were not effectively implemented and the management of risk was not fully embedded or consistently applied across the MWRH and CUH.
- Deficiencies were identified in the management of adverse clinical incidents at the MWRH Limerick. The specific responsibility for each element of the process was not clearly assigned to named post holders. No root cause analysis was undertaken and an integrated system-wide approach involving both managerial and clinical input was not initiated. In addition to this, an audit system that allowed for issues to be discussed and lessons learned was not in place.

3.1.2 Investigation into the Pathology Service and the Symptomatic Breast Disease Service at University Hospital Galway (UHG), 2008[21]

This published report[21] outlines the findings of the investigation into the missed diagnosis of breast cancer on two separate occasions when a patient, referred to in this report as Ms A, presented with symptomatic breast disease in 2005 and again in 2007.

Following the discovery of these errors and a formal request from the Health Service Executive (HSE), the Health Information and Quality Authority (HIQA) made a decision to undertake an investigation in 2007. During the investigation, a number of documents were reviewed including relevant strategic plans, policies and procedures and evaluations at University Hospital Galway (UHG) and correspondence relevant to Ms A's experience. Site visits and interviews with clinical and non-clinical staff, Ms A, and other patients were conducted and the investigation team also carried out reviews of patient records, imaging material and pathological specimens.

The core purpose of the investigation was to consider the aspects of Ms A's care as they related to the pathology service at UHG. It also included a review of clinical and pathology services for the care and treatment of patients with symptomatic breast disease provided by UHG. The investigation team concluded that two errors were made in the interpretation and review of Ms A's pathology specimens, which led to a

diagnosis of a benign condition instead of breast cancer before she received a definitive diagnosis from another hospital.

Some of the key findings from the investigation were as follows:

- Wider lessons can be learned from the experiences of UHG in responding to this incident and used by the HSE for the purposes of reviewing its procedures and developing best practice guidelines for responding to adverse incidents. The response by UHG was as follows:
    - When it was identified that errors had occurred UHG senior managers were informed.
    - An adverse incident group was established by UHG, which led to the request for an external independent review of symptomatic breast disease and related pathology services.
    - UHG set up and managed a helpline for women who may have been concerned about their care.
- Changing practice as a result of learning from mistakes should be encouraged as part of the organisation's culture. Staff should feel confident in routinely reporting concerns, near misses and incidents as an integrated part of their daily work and the proactive management of risk should be encouraged.

3.1.3 Investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital (MWRH) Ennis, 2009[22]

In September 2008, the Health Information and Quality Authority (HIQA), at the request of the Minister for Health and Children, undertook an investigation of the arrangements for providing services at Mid-Western Regional Hospital (MWRH) Ennis. In the period running up to and during the investigation, serious concerns were raised by family members of patients in relation to care received across a variety of different services provided at MWRH Ennis. These concerns highlighted a number of potential risks to the health and welfare of patients at MWRH Ennis.

The scope of the investigation was to ascertain the quality and safety of the services provided at MWRH Ennis. It did not set out to undertake a forensic investigation of each of these patients' care. However, the experiences of all the families who came forward informed the investigation and helped to shape the review of the quality and safety of services provided in MWRH Ennis. The investigation consisted of a review of clinical practices, systems and processes within the services, including a documentation review, at both local and national level, site visits to MWRH Ennis,

data analysis, as well as conducting interviews with patients and their relatives as well as clinical and non-clinical health services staff.

International evidence shows that patients with specific conditions obtain safer and better outcomes when treated by clinicians who routinely care for high numbers of patients with such conditions. Conversely, patients receive poorer outcomes when they are cared for by clinicians working in systems where they only occasionally care for patients with specific conditions. In this context, the investigation team concluded that the MWRH Ennis has an important part to play in providing high-quality and safe services for its community. However, the hospital will need to change the range and types of services it provides for its patients in the future.[22]

Some of the key findings from the investigation were as follows:

- There was a lack of clarity around local accountability and the authority to make decisions at MWRH Ennis, with no single person at hospital level fully accountable for the quality and safety of services.
- Risk management processes were not proactive. Adverse events, complaints and claims processes were not formally integrated within MWRH Ennis and therefore the outcomes from these processes are not patient focused.
- There were limited systems in place for effective clinical governance in order to provide the necessary assurance for patients.
- Communication difficulties were identified between the staff in the MWRH Ennis and patients and relatives; especially in relation to the communication of clinical information required to ensure the safe and effective continuing care of the patient.
- Patient expectations were not met by the complaints process, in particular around the management of their complaints, the lack of an acknowledgement that something went wrong and an apology.
- Staff reported difficulty in attending education sessions, indicating that there was a need for more structured, focused training and education for all staff members.
- There was no systematic approach for the dissemination of lessons learned from complaints or actions taken to avoid reoccurrence.

3.1.4 Report of the investigation into the quality and safety of services and supporting arrangements provided by the HSE at Mallow General Hospital, 2011[23]

This report[23] presents the findings from the Health Information and Quality Authority (HIQA) investigation into the quality and safety of services and supporting

arrangements provided by the Health Service Executive (HSE) at Mallow General Hospital (MGH), a site of the Cork University Hospital Group (CUH Group).

HIQA received confidential information, which was not a formal complaint, in relation to the treatment of a patient with complex clinical needs in MGH. This information indicated that the type of care provided to patients receiving some services in the hospital was not in line with the national recommendations made in a previous HIQA investigation report of services provided by the HSE at the MWRH Ennis.[22] That report highlighted a number of risks arising from low numbers of patients being treated for certain conditions, and the clinical staffing cover possible in such hospitals.

As a result of receiving the information, HIQA sought assurances from the HSE about how patient care was provided in MGH, a hospital similar in size to MWRH Ennis. The HIQA Board took the decision to instigate an investigation when it did not receive sufficient assurances from the HSE that the necessary arrangements were in place at the CUH Group site at MGH for the provision of a safe, high-quality service for acutely ill patients with complex needs.

During this investigation, HIQA reviewed the system of care for acutely ill patients in place at MGH, rather than individual incidents or the practice of any specific practitioners. It went on to explore the governance arrangements for the provision of this service within the wider context of the CUH Group. The investigation also ascertained how managers and clinicians at national level in the HSE, and the associated governance arrangements, had addressed the implementation of previous recommendations made by HIQA in relation the provision of safe and sustainable systems of care for acutely ill patients. In this context, HIQA concluded that a number of changes were required to minimise clinical risk for patients at MGH and that the type and scope of services that can be safely provided in a small stand-alone hospital such as MGH should be reviewed.

Some of the key findings from the investigation were as follows:

- There was a lack of robust and effective governance arrangements and risk management within the CUH Group's governance structures to include MGH.
- The complaint management arrangements at MGH lacked sufficient engagement with, and support from, the complaints management governance structures of the CUH Group. MGH did not have a formal forum to review patient complaints, monitor trends or follow through the resultant actions, apart from the recently formed Quality, Risk and Safety Committee that was identified as assuming responsibility for this.

- The HSE's corporate and clinical governance systems failed to effectively disseminate learning from an adverse finding in one part of its organisation[22] for the benefit of patients across the healthcare system.

3.1.5 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, 2012[24]

HIQA published an investigation report [24] into the quality, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (the Hospital) for patients who require acute admission in 2012.

Since 2009, HIQA has had extensive engagement with the hospital due to concerns raised in relation to risks to the health and welfare of patients associated with a number of aspects of the systems of care provided at the hospital and, in particular, the clinical risks to patients who required acute admission being accommodated on the corridor adjacent to the Emergency Department while awaiting transfer to an inpatient bed at the hospital.

In June 2011, HIQA received a report of the hospital's internal review into the unexpected death of a patient in March 2011. HIQA was concerned that the report of this review did not indicate that the hospital was effectively identifying and managing the clinical, health and welfare risks to patients requiring acute admission to the hospital despite the history of engagement with HIQA highlighting these risks.[24]

On 24 June 2011, the HIQA Board considered these risks, and the degree of assurances that had been provided by the hospital, and took the decision to commence an investigation into the quality, safety and governance of the care provided to patients who required acute admission to the hospital.

In carrying out the investigation, HIQA looked in detail at the quality, safety and governance of the system of care in place for patients requiring both unscheduled (unplanned, emergency care) and scheduled (elective and planned) care in the hospital and, in particular, those patients admitted through the Emergency Department. HIQA also investigated the effectiveness of the Board of the hospital and the corporate and clinical governance arrangements that it had in place to assure itself that risks to patients were being appropriately managed by the hospital – particularly the risks to patients receiving care in the Emergency Department and

requiring acute admission. In addition, HIQA investigated the effectiveness of the planning, accountability and oversight arrangements that were in place between the Health Service Executive (HSE) and the hospital, as a service provider in receipt of State funds, with a focus on how the HSE held the hospital to account for the quality and safety of the services that it was providing. In addition to this, HIQA also considered the national context for patients receiving similar services across the country in order to compare the performance of the Emergency Department service in the hospital with other hospitals in the same period and to inform national learning for the purposes of improving the quality and safety of care for these patients. [24]

HIQA was also contacted directly by individual members of the public who had received care themselves or had accompanied family members who had received care at the hospital. While the majority reported that staff were caring, these accounts highlighted the reality of long waiting times to be seen by a doctor, lack of communication and the indignity of being accommodated for long periods of time on a public access corridor.[24]

As a result of this investigation, a number of recommendations were made in the published report[24] that focused on improvements required in the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital, those required in similar hospitals, the changes necessary to improve the provider or 'commissioner' oversight and accountability relationship and, finally, the improvements necessary for effective governance of the health and social care system by the State.

Some of the key findings from the investigation were as follows:

- It was not made clear who had overall executive accountability for the quality and safety of the services delivered at the hospital.
- There was a lack of integration across the corporate and clinical governance arrangements in place at the hospital.

3.1.6 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, including those provided in University Hospital Galway (UHG), and as reflected in the care and treatment provided to Savita Halappanavar, 2013 [25]

In October 2013, HIQA published the report of its investigation into the safety, quality and standards of services provided by the HSE to patients, including pregnant women, at risk of clinical deterioration, including those provided in

University Hospital Galway (UHG), and as reflected in, among other things, the care and treatment provided to Savita Halappanavar.[25] This included a review of Savita Halappanavar's pathway of care as documented in her healthcare records and the governance arrangements and structures that had evolved in the months following her death. In addition to this, the investigation also considered the effectiveness of the HSE's role in planning and delivering maternity services nationally in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public.

In summary, the investigation found that there was a general lack of provision of basic, fundamental care in the case of Savita Halappanavar, a failure to recognise that she was at risk of clinical deterioration and a failure to act or escalate concerns to an appropriately qualified clinician when there were signs of clinical deterioration. HIQA was also significantly concerned about the absence of a national overview and structured assurance arrangements to monitor the safety and quality of maternity services in Ireland, and the ambiguity regarding overall ownership of and responsibility for implementing learning from previous investigations and inquiries.

As a result of the findings of the investigation, HIQA made a series of local and national recommendations that focus on the improvements required in UHG and across all other maternity hospitals in Ireland.

Some of the key findings from the investigation were as follows:

- There is wide variation in the local clinical and corporate governance arrangements in place across the 19 public maternity hospitals or maternity units nationally; making it impossible to properly assess the performance and quality of the maternity service nationally.
- The clinical governance arrangements in place within the hospital failed to recognise that vital hospital policies were not in use nor were there arrangements in place to ensure the provision of basic patient care.
- At the time of the investigation, there was no agreed national dataset of quality and safety measures for maternity services in Ireland and no centralised and consistent approach to reporting clinical outcomes.
- A number of deficits were identified in how learning had been adopted and implemented following previous investigations and inquiries. These included an inability to apply system-wide learning from adverse findings in one part of the system to minimise clinical risk for all patients.

3.1.7 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, 2015[26]

This report presents the findings of the investigation carried out by HIQA in 2015 into the governance and assurance arrangements that the HSE had in place to ensure the safety, quality and standard of services provided to patients in Midland Regional Hospital, Portlaoise (Portlaoise Hospital).

In 2014, the RTE Investigations Unit broadcast a *Prime Time* programme about the tragic deaths of newborn babies in Portlaoise Hospital and the subsequent management of patients and their families by the hospital and the HSE. Following this broadcast, the then Minister for Health asked the Chief Medical Officer of the Department of Health to conduct a preliminary assessment of perinatal deaths and related matters from 2006 up to that point in 2014 in the maternity services in Portlaoise Hospital. Following publication of the Chief Medical Officer's report, HIQA's Board considered and agreed to a request from the then Minister for Health to conduct an independent investigation into the services provided by the HSE at Portlaoise Hospital.[26]

As part of this investigation, HIQA considered the effectiveness of the HSE's role in overseeing a hospital where concerns about the quality and safety of services had been raised previously on a number of occasions. HIQA also reviewed the progress that had been made in ensuring that the findings from previous investigations and reviews conducted by HIQA, the HSE, the Chief Medical Officer and others had been implemented. Essentially, this included an assessment against the hospital's service model to assure the delivery of high-quality, safe and reliable care.[26]

In addition to this, HIQA also investigated the experience of a number of patients and families whose experience of care fell well below the standard expected in a modern acute hospital. The assessment of these patients and families' experience reflects their experience of care and its aftermath when they raised concerns at local and national levels of the HSE. The investigation examined the quality and safety of clinical services, and the governance arrangements in place for the maternity and the general healthcare services at Portlaoise Hospital and how these were governed by the HSE's relevant national directorate.

Six previous investigations into hospital care in Ireland had been carried out by HIQA between 2007 and 2013. These made a number of important findings and recommendations which were intended to be used by all healthcare services to

inform and improve practice. Had the relevance of these investigations been reviewed in the context of Portlaoise Hospital and the aligned recommendations been subsequently implemented, HIQA was of the opinion that the identified risks in the services being provided to patients could have been vastly reduced.

Seven national investigations undertaken by HIQA had a number of recommendations for the relevant hospitals and the HSE nationally which should have been used by all healthcare services as a learning tool to inform, improve practice and drive service quality and safety. Had the relevance of investigation findings been reviewed in the context of Portlaoise Hospital, and the aligned recommendations been subsequently implemented, HIQA concluded this could have vastly reduced the number of adverse findings identified throughout the Portlaoise investigation. In addition, the report also showed that risks in general hospital services and maternity services at Portlaoise Hospital were already identified and known about at all levels of health service management.[26]

As a result of the findings of the investigation, HIQA made a series of significant system-wide recommendations in this report[26] to improve the safety, quality and standards of services provided by the HSE.

Some of the key findings from this report included:

- This investigation found that the governance, leadership and management arrangements in the HSE at national, regional and local levels were not sufficiently focused to ensure effective risk management arrangements in Portlaoise hospital.
- Portlaoise hospital had major deficiencies in corporate and clinical governance arrangements in addition to ineffective performance management processes and clinical audit arrangements.
- There was a lack of effective risk management structures to include dealing with adverse patient events or complaints. These included ineffective monitoring, reporting, review and analysis of adverse events, delayed patient complaint management, protracted incident investigation and poor general oversight of patient safety and quality standards.
- The investigation team also found that Portlaoise hospital lacked formal systems to ensure close clinical cooperation, communication and integrated systems of clinical governance between it and a larger training hospital.

3.2 MHC Investigation Reports

3.2.1 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[27]

This report presents the findings, recommendations and subsequent implementation of the recommendations by the Health Service Executive (HSE) in relation to a Targeted Intervention Quality Improvement initiative undertaken by the Mental Health Commission through the Office of the Inspector of Mental Health Service in Carlow/Kilkenny and South Tipperary Mental Health Services.

In March 2014, the Office of Inspector of Mental Health Services was requested by the Mental Health Commission to carry out a Targeted Intervention into service user safety and governance in the Carlow/Kilkenny/South Tipperary Mental Health Services in response to being made aware of difficulties in the clinical governance process and an alleged cluster of unexpected deaths by a group of consultant psychiatrists working in the service. During the process, documentation including correspondence, policies, procedures, clinical files and minutes of meetings were reviewed. Site visits and interviews with clinical and service user representatives were also conducted.

The scope of the review was to consider service user safety culture; clinical and corporate governance; sudden unexpected deaths and serious untoward incidents; communication between the service and service users, families and carers in Carlow/Kilkenny/South Tipperary Mental Health Service.

Some of the key findings from the review included

- There were some differences in the manner in which the reviews of incidents were conducted in Carlow/Kilkenny compared to South Tipperary.
- There were variances in the manner in which incidents were reviewed based on their geographic location. This, in turn, led to inconsistencies in how information was shared and lessons learned following serious untoward incidents and sudden unexpected deaths.
- There were inconsistencies in the level and quality of communication between service users, families, carers and the service.
- The various clinical governance groups did not appear to meet the needs of the various stakeholders and were thus not an effective forum.

3.3 Other National Review/ Investigation Reports into patient safety incidents in Ireland

This chapter will provide an overview of the key findings of other national investigations and reviews into patient safety incidents in Ireland.

3.3.1 National Miscarriage Misdiagnosis Review, 2011[28]

In early June 2010, reports of two initial cases of misdiagnosis of miscarriage appeared in the Irish news media, leading to widespread concern and public discussion about diagnosis of early pregnancy loss. A diagnosis of miscarriage had been made in error, and medical or surgical intervention was recommended to women, but subsequently it was found that the pregnancy was viable and the women went on to continue their pregnancies. Over the following weeks, several other women raised similar concerns with their hospitals.

The HSE responded to the issue as a 'serious incident' and set up a National Miscarriage Misdiagnosis Review to manage the incident and examine any similar cases that had occurred over the previous five years where drug or surgical treatment was recommended following a diagnosis of miscarriage, and where subsequent information demonstrated that the pregnancy was viable. The National Miscarriage Misdiagnosis Review was tasked with providing an analysis of all of the cases involved in this incident.[28]

The core purpose of the published report[28] was to aggregate the outcomes of the reported cases, in order to identify trends about the causes of the misdiagnoses. The analysis allowed national recommendations for improvements to be developed. The findings from each hospital's individual systems analysis investigation, together with the findings from the national review of cases, were used to develop a series of recommendations for overall improvement in services. Recommendations were made in the areas of guidance, facilities and equipment, clinical management, education, training and accreditation, and support for women.

Some of the key findings from this report included:

- In relation to the clinical governance arrangements, some of the reports called for an audit of compliance with revised guidelines and for systems analysis of errors identified to become routine. Others noted the need for a review of governance arrangements in place and for consistent adherence to risk management processes, for example, incident reporting.

- There was no consistency to the types of supports offered to women, when their ongoing pregnancy was confirmed. None of the hospitals offered external support options following each incident.

3.3.2 HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006 – 2014), 2014[3]

A preliminary report was undertaken by the Chief Medical Officer (CMO), at the request of the Minister for Health. It was in relation to the issues that arose following a *Prime Time Investigates* programme relating to maternity services in Midlands Regional Hospital, Portlaoise on 30 January 2014. The report provides a preliminary assessment of Portlaoise hospital focusing on perinatal deaths from 2006 to 2014 and related matters.[3] Through a series of recommendations, this report sets out the need for further examination or actions where the findings of the preliminary assessment suggest such a need. It also makes clear who should be responsible for these further examinations or actions.

The critical initial question which the report sought to address was whether the maternity services provided by Portlaoise hospital can be said to be safe from the time of the review and into the future, given the events that were reported in public and Portlaoise hospital's response to these events. In order to inform the preparation of the report, meetings were held with some of the families involved, patient advocacy group Patient Focus, the senior management team at Midland Regiopnal Hospital, Portlaoise, the National Clinical lead for the Obstetrics and Gynaecology programme, the HSE Quality and Patient Safety Directorate, the HSE Directorate, the State Claims Agency, HIQA and other relevant regulatory bodies.

Clinical activity and outcome data, investigation reports, incident reports and desktop reviews, all relating to the period 2006 to the time of the review, were examined. The analysis was further informed by a detailed examination of National Perinatal Surveillance Data from the various systems in existence that collects and reports such data. In addition, relevant HSE and Portlaoise Hospital policies and guidelines were reviewed.

Some of the key findings from this report included:

- At the time of the investigation, it was identified that there were ineffective governance arrangements in place. These lacked many of the important criteria required to deliver, on a stand-alone basis, a safe and sustainable maternity service at Portlaoise hospital.

- Families and patients were not engaged with appropriately and, at times, with limited respect, kindness, courtesy and consideration. In addition to this, it was found that information had been withheld from families without justifiable cause.
- It was highlighted that Portlaoise hospital maternity services had identified and were aware of a number of poor outcomes that could have been prevented. However, these were not adequately and satisfactorily acted upon.
- The investigation team found that many organisations, including Portlaoise hospital, had partial information regarding the safety of maternity services at the hospital which could have led to earlier intervention had it been brought together.
- The report also concluded that the external support and oversight from the HSE should have been stronger and more proactive, given the issues identified in Portlaoise hospital in 2007.

3.3.3 A Review of 28 Maternity Case Notes, 2015[29]

In June 2015, the HSE published a report by Dr Peter Boylan and his Clinical Review Team of 6 Obstetricians: "A Review of 28 Maternity Case Notes".[29] This report is a clinical review of 28 case notes from three maternity units, Midland Regional Hospital Portlaoise (23 cases), University Maternity Hospital Limerick (three cases) and Midland Regional Hospital Mullingar (two cases) by a team of obstetricians referred to as the Clinical Review Team.

The review was requested by the HSE as a consequence of patients contacting either a helpline, or the hospitals directly, following an RTE *Prime Time* programme broadcast in January 2014 related to maternity services at Portlaoise. Patients who made contact were then written to, requesting consent, if they wished their own healthcare records to be reviewed. By midsummer 2014, 28 patients had consented. No time limit was set by the HSE regarding patients' care and the clinical review team only reviewed case notes provided to them by the HSE, relying on the HSE for the provision of all relevant records. The clinical review team did not meet with any patient, family or staff during the course of the review. Subsequent to the implementation of Dr Boylan's Clinical Review, the HSE received consent from a further 103 patients for a clinical records review. In light of the volume of cases, the process was adapted to request that the hospital involved conduct a clinical records review of their own cases.

For reasons of patients' privacy and confidentially, only individual patients received their own report. These were not published and as such the findings from the review were not made available. However, a number of recommendations from the report[28]

have been included in Chapter 4 of this document to demonstrate where they link to the themes in the National Standards for the Conduct of Reviews of Patient Safety Incidents.

3.3.4 Keyes Report, 2015[30]

This report [30] documents the findings of an independent review in relation to the care of Shauna Keyes and her baby Joshua at the Midlands Regional Hospital, Portlaoise. The review was initially commissioned by the HSE Dublin Mid-Leinster in response to a request by Shauna and her partner Joseph Cornally for a review of Shauna's care. This request was made following a *Prime Time Investigates* programme into issues relating to infant deaths in Portlaoise hospital. In accordance with changes to the establishment of Hospital Groups, the role of the commissioner transferred to the Dublin Midlands Hospital Group, the Hospital Group to which Midland Regional Hospital Portlaoise is now aligned.

In October 2009, Shauna Keyes, a first time mother, was admitted to Midlands Regional Hospital, Portlaoise after she was found to be in early labour. After being given a Syntocinon drip to augment her labour, and an epidural at her request, a series of issues occurred in Shauna's care. The outcome, which resulted in the death of her baby Joshua, highlighted four key areas of concern in Shauna's care. Key areas of concern related to the interpretation of the CTG[12], the absence of fetal blood sampling, the delay in delivering Joshua, the absence of a formal bereavement service and a lack of support for relatives in relation to the coronial process.

In relation to the support given to Shauna and her family in the immediate period following the death of Joshua, it was noted that the hospital failed to have a consistent, individualised approach to support. Based on the lack of appropriate support given in the immediate period following the loss of Joshua, a number of recommendations were made. Following on from a number of meetings held with both Shauna and her partner after her discharge from hospital, a number of additional recommendations were made in relation to issues Shauna raised about a lack of bereavement support and a lack of respect from staff when those meetings took place.

Some of the key findings from this report included:

12 Cardiotocography (CTG) is a technical means of recording (*-graphy*) the baby's heartbeat (*cardio-*) and the contractions of the uterus (*-toco-*) during pregnancy

- The review found that the hospital failed to have a consistent, individualised approach to the support given to Shauna and her family, in the immediate period following the death of Joshua.
- Following her discharge from hospital, Shauna and her partner had a number of meetings with members of staff who had been involved in her care. She raised concerns that their need for personal support was not addressed and that she did not feel assured in relation to actions to be taken on foot of her experience.

3.4 Summary

The above reviews and investigations into patient safety incidents highlight serious failings with regard to the care provided to patients, and challenges with governance and management arrangements, methods and time frames for the review of incidents and staff training. They also highlight poor engagement with patients and their families and provision of support following a patient safety incident. The National Standards will promote improvements in the conduct of reviews of patient safety incidents through the provision of a person-centred, systematic approach to the review of patient incidents in services that are well governed, accountable and focused on sharing the learning from reviews to improve patient outcomes and service quality.

Chapter 4: Linking learning from national reviews and investigations into patient safety incidents in Ireland to the five themes in the Draft National Standards

4.0 Overview

The national reviews and investigations into patient safety incidents summarised in this document have highlighted that many improvements to patient safety do not involve additional financial resources but effective planning, management, recruitment and training to ensure safe practices. All staff can improve patient safety by engaging with patients and their families, learning from errors, and sharing the learning for improvement across the service.

This document relates the recommendations made in twelve national reviews and investigations into patient safety incidents to the five themes in the Draft National Standards for the Conduct of Reviews of Patient Safety Incidents. As the Draft National Standards cover reviews of patient safety incidents, which fit into a service's overall incident management process, a number of recommendations relating to the overall incident management process were also included; this covers reporting, open disclosure and notification to external bodies.

When things go wrong or desired outcomes are not achieved, there needs to be systems in place to collect, analyse, investigate and learn so that care is improved and mistakes are not repeated. Any learning and recommendations following the review of patient safety incidents are shared within and across services to drive improvements in quality and safety for all patients.

4.1 Linking learning from recommendations in national reviews and investigations into patient safety incidents to the themes in the Draft National Standards for the Conduct of Reviews of Patient Safety Incidents

Theme 1: Governance and Accountability

Review	Recommendations
Investigation Report into the Pathology Service and the Symptomatic Breast Disease Service at University Hospital Galway, 2008[21]	Arrangements must be in place to ensure effective governance, management and review where the care of patients is shared across more than one facility or institution. Regular multidisciplinary team meetings must be held (at least weekly) and in particular, clear leadership of care planning must be maintained.
Investigation Report into the care received by Rebecca O'Malley, Symptomatic Breast Disease Services at the Mid Western Regional Hospital Limerick and the Pathology Services at Cork University Hospital, 2008[20]	Governance arrangements need to be strengthened to ensure: ▪ clarity of delegated levels of authority, reporting relationships and accountability at local, regional and national levels ▪ transparent decision making processes ▪ effective engagement and involvement of clinicians in the executive management process.
	The HSE should urgently review the formal communications processes, policies and procedures which its hospitals use to respond to patients when there is a serious incident, including communications within and between its hospitals.
	A robust clinical governance framework should be adopted at local, regional and national level.

Review	Recommendations
	It should include as a minimum: ▪ At National and Hospital level, a named individual at senior management level should be responsible and accountable for clinical governance. ▪ A quality and safety framework that includes a schedule of internal and external audits.
	Risk management arrangements at all hospitals involved in the shared care of patients, should be reviewed to ensure they demonstrate clarity of purpose, transparency in decision-making and accountability in order to safeguard high standards of treatment and care. This should include a review of their arrangements for managing risk. Specifically they should: ▪ ensure that structures, roles and lines of accountability are clearly defined and reviewed on a regular basis to ensure consistency and clarity of purpose ▪ identify areas where there may be gaps in controls and or assurances, and put in place corrective action as required ▪ ensure monitoring and reporting systems are timely and effective ▪ review arrangements for communicating risk management policies to all staff ▪ ensure that risks associated with working with other organisations or partners are explicitly assessed and managed.
The Ennis Report, 2009[22]	A code of governance should be established that sets out the management board's roles and responsibilities, including an oversight role in respect of safety and quality of health services provided. This must include clear lines of accountability and devolved decision-making.
	A proactive patient-centred approach to risk management should be taken and implemented throughout hospitals according to national policies. This should include improving integration

Review	Recommendations
	between its risk management, complaints, and Freedom of Information systems to facilitate timely, patient-focused responses and to enable shared learning.
	A regular audit of the views of complainants should be carried out to ensure that the approach taken to complaints and concerns is improved and the necessary changes identified in such audits are implemented.
	The HSE should ensure that the regional risk management structures have clearly defined lines of responsibility and levels of accountability. The processes must be transparent, patient-focused and have clear learning pathways. At a regional level, the risk management process should be regularly monitored and audited with the outcomes reported through the national risk management structure to the Chief Executive Officer of the HSE.
Report of the investigation into the quality and safety of services and supporting arrangements provided by the HSE at Mallow General Hospital, 2011[23]	The HSE and all healthcare service providers should ensure that all hospitals and hospital groups have integrated corporate and clinical governance structures with clear accountability arrangements in place. Organisational codes of governance, which clearly identifies safety and quality as core objectives should be implemented, monitored and evaluated.
	Hospitals should ensure that effective arrangements are in place for the timely and accurate collection, monitoring and reporting of all activity data at each site. Activity data should be reported and managed through the hospital and or hospital group's governance structure.

Review	Recommendations
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, 2012[24]	A clear scheme of delegation of accountability from the board to chief executive and executive directors should be in place. This should include unambiguous delegated executive accountability and responsibility for the quality and safety of patient care.
	National data pertaining to the quality, safety and timeliness for patients in all hospitals providing emergency department services should be monitored and published at local, regional and national level.
A Review of 28 Maternity Case Notes, 2015[29]	Each hospital should have in place a formal system of review of adverse outcomes. The results of these reviews should be shared with the patients in a timely fashion. It was recommended that within two months of the incident. This timeline is subject to any relevant legal issues, external investigations or inquiries external to the hospital which might arise.
HIQA's Portlaoise Report, 2015 [26]	The HSE along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by: ▪ regular evaluation and audit of the quality and safety of services provided ▪ a system to proactively evaluate the culture of patient safety in each hospital as a tool to drive improvement.
Chief Medical Officer's Portlaoise Report, 2014[3]	Every maternity service (and later every health service provider) is required to complete a Patient Safety Statement which is published and updated monthly.

Review	Recommendations
	The HSE should ensure consistency of adverse event terminology across its documentation and guidance.
	The HSE should issue a directive to all providers to require them to notify the director of quality and patient safety, and HIQA of all 'never events'.
	The Health Service Executive (HSE), in conjunction with the Chief Executive Officer of the Dublin Midlands Hospital Group, should: ▪ immediately address the local clinical and corporate governance deficiencies in the maternity and general acute services in Portlaoise Hospital.

Review	Recommendations
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, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar, 2013 [25]	The Chief Executive must be assured and provide assurance to the Hospital Group Board and the HSE about the quality, safety, timeliness and standards of care provided by the Hospital. These assurances should be provided by regular reviews of key performance indicators (KPIs), patient outcome measures and self assessment against National Standards. KPIs that measure the outcomes and experiences of women using the maternity services should be developed as a priority.
Report of the Targeted Intervention into the Carlow/Kilkenny/South Tipperary Mental Health Services, 2015 [27]	Policies on clinical and operational procedures should be standardised across the whole Carlow/Kilkenny/South Tipperary area.

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

Review	Recommendations
Investigation Report into the Pathology Service and the Symptomatic Breast Disease Service at University Hospital Galway, 2008[21]	The role of independent advocacy services should be developed in all hospitals. These advocacy services should facilitate patients coming forward to raise concerns and have them addressed. Hospitals should encourage such services as part of a helpline and or as part of patients' hospital attendance.
Investigation Report into the care received by Rebecca O'Malley, Symptomatic Breast Disease Services at the Mid Western Regional Hospital Limerick and the Pathology Services at Cork University Hospital, 2008[20]	Senior management, together with clinicians, should introduce new arrangements for the effective delivery of patient-centred services. This should be measured, monitored and published in an annual report.
	The hospitals should establish an effective, patient-focused communication strategy that addresses the needs of internal and external audiences. This should include: ▪ ensuring that the views and perspectives of patients, service users and front-line staff are taken into account ▪ supplementing the formal communication process with regular visits to the wards and face-to-face dialogue. The effectiveness of this strategy should be reviewed on a regular basis.

Review	Recommendations
	A robust clinical governance framework should be adopted at local, regional and national level. It should include as a minimum: A patient liaison programme, which involves access to an independent advocate and a hospital appointed dedicated patient liaison person, as part of a complaints structure. This patient liaison person, who should be at a senior level, will be the principal point of contact with the patient and or family. They must be kept informed of all developments in the case and have the responsibility to brief the patient and or family in a timely fashion of these developments. Protocols should be established to implement such arrangements
The Ennis Report, 2009[22]	To support and facilitate patients coming forward to raise concerns and have them addressed, an effective independent advocacy service should be in place for patients.
	Risk management and complaints processes in the Health Service Executive (HSE) and health services generally must include a stage in the process to establish, understand and document the outcomes desired by affected patients and or relatives before any investigation or review is undertaken.
	The HSE should identify a suitable independent person or organisation, agreed with individuals/persons that request it, to offer mediation with a view to discussing in detail and resolving any residual concerns in the way with which their complaint was dealt.

Review	Recommendations
Report of the investigation into the quality and safety of services and supporting arrangements provided by the HSE at Mallow General Hospital, 2011[23]	The HSE and all healthcare service providers must put arrangements in place to ensure that honest, open and timely information is communicated to patients once adverse events affecting them have occurred or become known.
A Review of 28 Maternity Case Notes, 2015[29]	The commissioner of this review, or a person nominated by the commissioner, should meet with each of the patients to relay the conclusions and or recommendations in their individual case.
HIQA's Portlaoise Report, 2015 [26]	The Health Service Executive (HSE) along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by: ▪ systems in place to ensure patient feedback is welcomed and used to improve services and that patient partnership and person-centred care is promoted, as per the *National Standards.*
	The HSE National Open Disclosure Policy should be implemented in full.
	The HSE should develop a national policy on disclosure where no harm arises.

Review	Recommendations
National Miscarriage Misdiagnosis Review, 2011[28]	<u>Communication after a clinical error:</u> The Medical Council in their 2009 guidance document; 'Guide to Professional Conduct and Ethics for Medical Practitioners' state that 'Service users and their families are entitled to honest, open and prompt communication with them about adverse events that may have caused them harm'. The Guidance goes on to state that in relation to communicating with a service user following an adverse event that the medical practitioner should: ▪ acknowledge that the event happened ▪ explain how it happened ▪ apologise, if appropriate, and ▪ give assurance as to how lessons have been learned to minimise the chance of this ever happening again in the future.
	<u>Management of Complaints:</u> Access to independent advocacy and a hospital appointed dedicated service-user liaison person should be provided as part of a complaints structure. The service-user liaison person should be at a senior level and should be the principal point of contact with the woman. The woman should be made aware of the progress of her complaint or concern.

Review	Recommendations
Report of the Targeted Intervention into the Carlow/Kilkenny/South Tipperary Mental Health Services, 2015[27]	Family members should, with the service user's consent, have appropriate and timely communication with members of the treating team.

Theme 3: Workforce

Review	Recommendation
Investigation Report into the care received by Rebecca O'Malley, Symptomatic Breast Disease Services at the Mid Western Regional Hospital Limerick and the Pathology Services at Cork University Hospital, 2008[20]	Ensure that all staff involved in the risk management process are appropriately qualified, trained and supported with adequate resources available to them to fulfil their role effectively.

Review	Recommendation
The Ennis Report, 2009[22]	The HSE should ensure the planned implementation of their new Quality and Risk Framework takes account of the lessons from investigations, and that an appropriate training programme on risk management and feedback is delivered that emphasises the importance of communication and outcomes as well as process.
Keyes Report, 2015[30]	That health service staff attending a coroner's inquest should be aware of how their demeanour and conduct may be interpreted by relatives and families. Staff should demonstrate empathy and sensitivity towards relatives and families for whom the experience can be stressful and involve them re-living the circumstances of the death of their loved one.
HIQA's Portlaoise Report, 2015 [26]	The Health Service Executive (HSE) along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by: ▪ systems to support a competent and appropriately resourced workforce.
Chief Medical Officer's Portlaoise Report, 2014[3]	Support should be provided to the Portlaoise Hospital senior management team. This should lead to a wider programme of support for front-line leaders, particularly in smaller hospitals, to ensure that they can and do provide safe and effective care.
	Training should be provided by the HSE for senior clinical staff in dealing appropriately with patients in the context of serious adverse events.

Review	Recommendation
	All staff should be obliged to participate openly and honestly in all investigation processes
	There should be an appropriately resourced special support team that is deployed from the HSE's Quality and Patient Safety Directorate to guide a consistent response to major adverse events.
	The HSE should ensure that systems are in place in order that a senior consultant and a senior nurse or midwife take responsibility for dealing with serious adverse events when they occur.
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, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar, 2013[25]	The Hospital Group must ensure that arrangements are put in place to support and train all staff responsible for managing risk, adverse incidents, near misses, claims and complaints.
Report of the Targeted Intervention into the	Training in assessment and management of risk should take place to build a culture of patient safety.

Review	Recommendation
Carlow/Kilkenny/South Tipperary Mental Health Services, 2015[27]	

Theme 4: Reviews of Patient Safety Incidents

Review	Recommendation
Investigation Report into the Pathology Service and the Symptomatic Breast Disease Service at University Hospital Galway, 2008[21]	It was recommended that the hospital's response to this incident, including the process adopted for patient management, should be captured and used to inform the development and implementation of national guidelines for handling adverse incidents. When the error was detected UHG senior managers were informed. An adverse incident group was established by UHG, which led to the request for an external independent review of symptomatic breast disease and related pathology services. UHG set up and managed a helpline for women who may have been concerned about their care.
	Hospital staff engaged in reviewing policies and procedures for services where adverse incidents or near misses have occurred should be trained in carrying out root cause analysis and ways of achieving immediate changes in service redesign as a result of their analysis.
Investigation Report into the care received by Rebecca	A delayed diagnosis should trigger a formal incident response, including an internal root cause analysis, and the relevant senior management should be notified. The patient should be

Review	Recommendation
O'Malley, Symptomatic Breast Disease Services at the Mid Western Regional Hospital Limerick and the Pathology Services at Cork University Hospital, 2008[20]	informed of the findings and outcome as a priority.
Report of the investigation into the quality and safety of services and supporting arrangements provided by the HSE at Mallow General Hospital, 2011[23]	The HSE and all healthcare service providers should ensure that there are arrangements in place to promptly act upon the recommendations of national reports of reviews and investigations or enquiries in relation to the quality and safety of services provided by, or on behalf of, the HSE. The HSE should ensure the system-wide application and dissemination of learning from these national reviews for the benefit of all service users.
HIQA's Portlaoise Report, 2015 [26]	The Health Service Executive (HSE) along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by: ▪ effective arrangements to ensure the timely completion of investigations and reviews of patient safety incidents and associated dissemination of learning. These arrangements must ensure that patients and service users are regularly updated and informed of findings and resultant actions.
	The Health Service Executive (HSE), in conjunction with the Chief Executive Officer of the Dublin

Review	Recommendation
	Midlands Hospital Group should: ▪ publish an action plan outlining the measures and timelines to address the safety concerns and risks at Portlaoise Hospital, to include both general and maternity services. This action plan should include a named person or persons with responsibility and accountability for implementation of recommendations and actions in internal and external reviews and investigation reports, and be continuously reviewed and updated in order to drive improvement and mitigate risk.
Chief Medical Officer's Portlaoise Report, 2014[3]	HIQA should develop national standards for the conduct of reviews of adverse incidents.
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, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar, 2013[25]	The Hospital Group must ensure that the recommendations of this investigation, and the HSE incident investigation, are implemented in full through the development of an implementation plan with clear timelines and identified individuals with responsibility for each recommendation.

Review	Recommendation
National Miscarriage Misdiagnosis Review, 2011[28]	Systems Analysis Investigations It is the policy of the HSE that all incidents causing harm shall be identified, reported, communicated and investigated. Hospitals should have enhanced capacity to conduct systems analysis investigations such as misdiagnosis of miscarriage
Report of the Targeted Intervention into the Carlow/Kilkenny/South Tipperary Mental Health Services, 2015[27]	Where an external review of serious untoward incidents and sudden unexpected deaths is indicated, this should be completed in a timely manner.
	All sudden unexpected deaths and serious untoward incidents should be followed by a review by the multidisciplinary team with responsibility for the care of the service user. This does not preclude a systems review by the HSE where indicated.

Theme 5: Sharing the Learning for Improvement

Review	Recommendations
The Ennis Report, 2009[22]	The Health Service Executive (HSE) should ensure the planned implementation of its new Quality and Risk Framework takes account of the lessons from this investigation and that an appropriate training programme on risk management and feedback is delivered that emphasises the importance of communication and outcomes as well as process.

Review	Recommendations
Report of the investigation into the quality and safety of services and supporting arrangements provided by the HSE at Mallow General Hospital, 2011[23]	The HSE should ensure the system-wide application and dissemination of learning from these national reviews for the benefit of all service users.
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, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar, 2013 [25]	The HSE must demonstrate that it has the governance structures and mechanisms in place to ensure that the findings, learning and performance management of relevant healthcare organisations, in respect of implementing safety and quality issues emanating from serious adverse incidents, near misses and their investigations, are implemented.
	The HSE should put in place arrangements to collate and review information from national and international inquiries, reviews, investigations and coroners' inquests and, where relevant, act on learning and recommendations so that valuable lessons learned can be applied by each service provider in order to improve the outcomes for patients in Ireland.
	The HSE, in line with the Department of Health's strategy, *Future Health,* should develop a more formal communication with the Clinical Indemnity Scheme in order to share information and learning on safety incidents within healthcare services and enable the effective prioritisation and development of tailored quality and safety programmes across services nationally. This learning should actively inform the respective Clinical Care Programmes and relevant guidelines and guidance.
	The Hospital Group should ensure that the review, implementation and monitoring of action,

Review	Recommendations
	trend analysis and implementation of learning from such incidents are disseminated to staff and incorporated within the clinical governance arrangements in the Group.
Report of the Targeted Intervention into the Carlow/Kilkenny/South Tipperary Mental Health Services, 2015[27]	The Executive Management Team should disseminate reports of internal and external reviews of serious untoward incidents (SUIs) and sudden unexpected deaths (SUDs) through an appropriate clinical governance forum.

5.0 Conclusion

This report documents the desktop research that was undertaken to inform the development of the *National Standards for the Conduct of Reviews of Patient Safety Incidents*. The research was conducted as follows:

- a review of policies, procedures and guidelines for the conduct of reviews of patient safety incidents internationally
- an overview of the Irish context, including existing policies, procedures and guidelines, and reviews and investigations of patient safety incidents in Ireland.

This desktop research informed an initial draft of the standards that was refined at different stages throughout the standards development process including:

- detailed discussions at meetings of the Standards Advisory Group,
- individual meetings with relevant stakeholders,
- focus groups with service users and front-line staff and management working in health and social care settings,
- a six-week national public consultation, resulting in 47 submissions that were analysed and reviewed.

Each of these steps, in conjunction with the desktop research documented in this report, formed the evidence base for the development of the *National Standards for the Conduct of Reviews of Patient Safety Incidents*.

Appendices

Appendix 1: Overview of the Conduct of Reviews of Patient safety incidents in 7 Countries, as at 16 November 2015

Country	Time frame for Notification	Level of Review	Methods	Time frames for completion	Procedure for Unique Anonymisation	Sharing the Learning
Ireland	Within 24 hours.	Depends on level of harm, risk assessment and incident type.	- Aggregate analysis - Systems analysis - Look-back review	Investigation report within 120 days.	None identified but reference in policy to reports being anonymised.	Anonymised reports shared with patients and families, staff and third parties.
Northern Ireland	Within 24 hours.	Risk matrix used to determine level of impact and level of review.	- Level 1: Significant Event Audit -Level 2: Root Cause Analysis - Level 3: Independent Investigation	- Level 1: within four to six weeks - Level 2: within 12 weeks - Level 3: to be agreed	None indentified but reference in procedure to reports being anonymised.	Recommendations monitored and learning shared within HSCB/PHA structures.
England	Within two working days.	Risk matrix used to determine level of impact and level of review.	Using Root Cause Analysis - initial review -concise internal investigation - comprehensive internal investigation -independent investigation.	- Initial review: within 72 hours - concise or comprehensive internal investigation: within 60 days - independent investigation: within six months.	None indentified but reference in framework to reports being anonymised. NHS Caldicott Guardian has responsibility to protect confidentiality of service user information and appropriate sharing of information.	Review reports shared with patients and families. All organisations have responsibility for disseminating learning and share findings with the NRLS.

Country	Time frame for Notification	Level of Review	Methods	Time frames for completion	Procedure for Unique Anonymisation	Sharing the Learning
Scotland	As soon as possible after even occurs in line with local policy.	Risk matrix used to determine level of impact and level of review. Category I, II and III events.	Using RCA methods -Category I: comprehensive analysis - Category II: local management review with multidisciplinary input - Category III: local management review.	- Category I: Commenced within 2 weeks of incident being reported and completed within 3 months. - Category II: Commenced within 2 weeks of incident being reported and completed within 6 weeks. Category III: Commenced and completed within 2 weeks of incident being reported.	None indentified but reference in procedure to reports being anonymised and identifiable information being redacted.	Learning from adverse events is disseminated across all services. Category I and II adverse event reviews must develop and improvement plan and these are shared with those who reported and are updated regularly.
British Columbia, Canada	As soon as possible after even occurs in line with local policy.	Risk matrix used to determine if critical patient safety event review (CPSER) is necessary.	Using RCA methods to determine contributory factors.	Four months or sooner. CPSER toolkit suggests 60 days for report and by day 120 recommendations are implemented.	Policy does not make reference to anonymisation procedures or anonymisation of data.	All reviews must have a Patient Safety Learning summary leaflet completed and disseminated within the organisation.

Country	Time frame for Notification	Level of Review	Methods	Time frames for completion	Procedure for Unique Anonymisation	Sharing the Learning
Denmark	Within seven days.	Safety Assessment Code (SAC) matrix used to determine level of impact and level of review.	RCA Methods - SAC Score of 3 undergo an RCA - SAC score of 2 undergo and aggregated RCA - SAC Score of 1 undergo a local review.	The case handling and analysis must be completed within 90 days after the incident.	No reference to procedures for anonymisation but reference to all personal identifiable information being redacted to protect confidentiality.	National Agency for Patients' Rights and Complaints disseminates learning from reviews of patient safety incidents nationally.
New Zealand	Within 15 days.	Severity Assessment Code (SAC) matrix used to determine level of impact and level of review.	Root Cause Analysis for all SAC 1 incidents.	SAC Score of 1 or 2 reported within 70 days. SAC Score of 3 or 4 reported within 28 days.	No reference to procedures for anonymisation but states that investigators take appropriate action to maintain confidentiality and security of data.	Local procedures for tracking implementation of recommendations from review report. All services are encouraged to notify all SAC 3 or 4 incidents for national learning.

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Published by the Mental Health Commission and the Health Information and Quality Authority.

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