



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Recommendations on the coordination of patient safety intelligence in Ireland

January 2016

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent Authority established to drive high quality and safe care for people using our health and social care and support services in Ireland. HIQA's role is to develop standards, inspect and review health and social care and support services, and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the quality and safety of 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, the Health Information and Quality Authority 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 and support services in Ireland.
- **Regulation** — Registering and inspecting designated centres.
- **Monitoring Children's Services** — Monitoring and inspecting children's social services.
- **Monitoring Healthcare Quality and Safety** — Monitoring the quality and safety 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 and support services.

Overview of HIQA's Health Information function

Health is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore very important that information is managed in the most effective way possible in order to ensure a high-quality safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has an important role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA or the Authority) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving its quality and filling in gaps where information is needed but is not currently available.

Information and communications technology has a critical role to play in ensuring that information to promote quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current information and communications technology infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevent the safe, effective, transfer of information. This results in people using services being asked to provide the same information on multiple occasions.

In Ireland, information can also be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, clear and trustworthy information on which to base our decisions.

HIQA has a broad statutory remit, including both regulatory functions and functions aimed at planning and supporting sustainable improvements. In line with the Health Act 2007 — sections 8(1) (j) and 8(2) (d) — one of the key functions of the Authority is to provide advice to the Minister for Health and the Health Service Executive (HSE) about deficiencies identified regarding health information. HIQA therefore aims to address the deficiencies outlined by the Chief Medical Officer (CMO) of the Department of Health through the development of recommendations for the Minister for Health on the coordination of patient safety intelligence in Ireland.

Acknowledgements

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Executive summary

The 2014 Chief Medical Officer's (CMO's) report to the Minister for Health on perinatal deaths in the Midland Regional Hospital, Portlaoise recommended the establishment of a National Patient Safety Surveillance System in Ireland. The report outlined that there was a gap in the coordination of national patient safety intelligence in Ireland, and a need to pool existing information across different agencies in order to create a better patient safety and risk profile of services. The CMO's report also outlined that there was no single agency with overall line of sight or responsibility for the coordination of patient safety intelligence in Ireland, and this represented a substantial deficiency in the health information infrastructure in the country.⁽¹⁾ This position remains unchanged.

In line with the Health Act 2007 — sections 8 (1)(j) and 8 (2)(d) — one of HIQA's key functions is to advise the Minister for Health and the Health Service Executive (HSE) about deficiencies in health information. HIQA therefore aims to address the deficiencies outlined by the CMO through the development of recommendations for the Minister for Health on the coordination of patient safety intelligence in Ireland. The process of developing these recommendations involved conducting an international review on patient safety surveillance systems and an 'As is' analysis of current patient safety intelligence systems and structures in Ireland. Following this, an Expert Advisory Group was convened by the Authority, to assist in developing the recommendations in this report.

In addition to the issues outlined in the CMO's report, a number of challenges have also been outlined previously, including by the Commission on Patient Safety and Quality Assurance in 2008, which made numerous recommendations in relation to the coordination of patient safety intelligence.⁽²⁾ Following the Commission's Report in 2008, an Implementation Steering Group was set up by the Department of Health to address the recommendations. While this group has made some progress on implementing recommendations, a number remain outstanding.

Furthermore, a number of the statutory healthcare investigations conducted by HIQA have also highlighted challenges in relation to patient safety intelligence and incident reporting which have not yet been addressed to date. Challenges with coordinating patient safety intelligence and incident reporting were described in particular in HIQA's *Report of the investigation into the safety, quality and standards of services provided by the HSE to patients in the Midland Regional Hospital Portlaoise* (HIQA Portlaoise Report 2015)⁽³⁾ and the Authority's *Report of the investigation into the safety, quality and standards of services provided by the HSE to patients, including those provided in the University Hospital Galway* (HIQA Galway Report 2013).⁽⁴⁾

In November 2015, the Minister for Health announced a number of patient safety reforms, which includes plans to establish a new National Patient Safety Office within the Department of Health. It was announced that the office will include a system for the coordination of patient safety surveillance. In addition, an independent National Advisory Council for Patient Safety is to be appointed in early 2016. This council will provide advice and guidance to inform the policy direction for the National Patient Safety Office.⁽⁵⁾

Also in November 2015, the Government published the Health Information and Patient Safety Bill (General Scheme).⁽⁶⁾ The Health Information and Patient Safety Bill makes a number of provisions for incident reporting including providing for mandatory reporting of certain patient safety incidents to the relevant reporting authority. The bill in relation to open disclosure⁽⁷⁾ was also published in November 2015 and provides for HIQA to set standards for both public and private providers on disclosing patient safety incidents to service users.

Based on the evidence documented in this report, HIQA is making recommendations in relation to both the coordination of patient safety intelligence and recommendations about national incident reporting — a key building block of a future patient safety surveillance system. Introducing these recommendations should improve patient safety and risk profiling of services. The following section sets out the Authority's recommendations to the Minister for Health. A number of elements support each high level recommendation to provide more detail.

Recommendations in relation to the coordination of patient safety intelligence (Recommendations 1-4)

Recommendation 1

An independent national organisation should be established with assigned responsibility for the governance, coordination and dissemination of national patient safety intelligence to ensure national oversight of patient safety, risk profiling and to inform policy development.

- a. This organisation should report directly to the Minister for Health and should enable the coordination and triangulation of patient safety intelligence from relevant agencies, including information from the National Incident Management System.
- b. Clear lines of accountability for this organisation should be set out detailing responsibilities for the coordination of intelligence.
- c. This organisation should develop and regularly review a 'national quality dashboard' comprised of an agreed suite of quality indicators that are aligned to national standards. These indicators will provide a shared view of risk and enable alignment of actions to mitigate risk.
- d. A mechanism for issuing patient safety alerts should be developed to allow for timely sharing of patient safety risk intelligence and there should be clear lines of accountability for acting on these alerts.
- e. An independent national quality council should also be established to provide advice and leadership to this organisation. This council should bring together senior representatives from national statutory organisations with responsibility for patient safety intelligence to provide a forum for multi-lateral collaboration in relation to quality and patient safety intelligence.

Recommendation 2

The Director General of the HSE should ensure that effective governance arrangements are in place for quality and patient safety groups within hospitals, hospital groups and across all community health organisations.

- a. These quality and patient safety groups should ensure timely and accurate collection and reporting of patient safety data and information to inform intelligence, and give focused consideration to any risks identified and concerns raised.
- b. The chair of each group should have clearly defined accountability to their chief executive and/or national director.
- c. Local governance structures that embed a 'just culture' should be in place to ensure timely review of patient safety intelligence for risk profiling and effective dissemination of learning.*
- d. A national review should be conducted to ensure that these groups are in place and includes monitoring of the efficacy of these groups.
- e. The HSE should also ensure that effective governance arrangements for quality and patient safety groups are in place in health and social services that are provided on behalf of the HSE.

Recommendation 3

An effective information governance framework should be put in place to support sharing of relevant intelligence between national agencies to enable the coordination of patient safety intelligence.

- a. To facilitate sharing of intelligence between agencies, formalised data sharing and or participation agreements should be developed in line with appropriate safeguarding structures.

* A 'just culture' seeks to balance the need to learn from mistakes and the need to take disciplinary action.⁽⁸⁾

Recommendation 4

The HSE's Knowledge and Information Strategy should be implemented in order to promote interoperability of information systems and to enable the coordination of patient safety intelligence.

- a. An effective information communications technology infrastructure, supported by standards for interoperability should be put in place to support the coordination of patient safety intelligence.
- b. Organisations with responsibilities in the area of patient safety intelligence should comply with legislative and regulatory requirements, including compliance with national and international health information standards and classifications.

Recommendations in relation to incident reporting (Recommendations 5-9)

Recommendation 5

A review of governance arrangements for the operational management of the National Incident Management System (NIMS) should be conducted in order to enhance the ownership and responsibility of the reporting system within the HSE and therefore facilitate learning and support a 'just culture'.

- a. Effective governance arrangements with clear lines of accountability and responsibility for the oversight, operational management and risk management of the National Incident Management System (NIMS) within the HSE should be ensured so that learning from patient safety incidents is shared locally, within hospital and community group structures and nationally across the wider health and social care sector.
- b. A memorandum of understanding between the HSE, the CEO of each hospital group and the State Claims Agency should be fully developed and implemented to ensure timely sharing of patient safety intelligence.*

* As previously outlined in Recommendation 8 of the *Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE) to patients in the Midland Regional Hospital, Portlaoise* (HIQA, May 2015).⁽³⁾

Recommendation 6

The upgraded National Incident Management System (NIMS) should be implemented in a standardised way across all hospital groups and community health organisations as a priority.

- a. A detailed implementation plan, with clear lines of responsibility and accountability for the rollout of NIMS should be published and should include details of a training and education programme for all healthcare professionals.
- b. Following implementation in a number of sites an evaluation of the implementation of NIMS should be conducted.
- c. A prioritisation exercise should be conducted to decide on the extension of the implementation of NIMS to other sites including private healthcare providers, in line with legislative requirements.
- d. NIMS should also be extended to facilitate reporting of incidents by patients and their families.

Recommendation 7

The Health Information and Patient Safety Bill and other relevant legislation should be introduced into law as a priority to allow the introduction of mandatory reporting of specified patient safety incidents in order to promote a culture of quality and patient safety.

- a. In particular, legislation on open disclosure should also be introduced into law in a timely manner to support the open disclosure to patients following patient safety incidents.

Recommendation 8

Effective information governance arrangements should be put in place to ensure that incident information reported to the National Incident Management System is quality assured.

- a. There should be one system for reporting and managing patient safety incidents in health and social care, to ensure standardisation and data quality.*
- b. National incident reporting forms aligned to the WHO standardised taxonomy as outlined in the International Classification of Patient Safety (ICPS) should be implemented nationally.
- c. A data quality framework should be developed and regular data quality audits conducted.
- d. Electronic point-of-occurrence reporting to the National Incident Management System should be fully implemented to ensure data quality and efficiency of reporting.
- e. An effective and integrated information and communications technology infrastructure, supported by standards for interoperability of systems, should be put in place to support national incident reporting.
- f. There should be compliance with national standards and guidance in relation to incident reporting.

Recommendation 9

The use of, and access to, patient safety information reported to the National Incident Management System should be optimised through the use of effective governance structures.

- a. Reports of data should be regularly published and learning widely shared with health and social care staff to support the development and monitoring of initiatives to improve patient safety and promote a 'just culture'.
- b. Aggregated validated data should be made available to the public in the form of annual reports.

* All HSE and section 38 agencies or groups have been directed to use the National Incident Management System (NIMS) for incident reporting. NIMS has been endorsed as the primary system for the reporting and management of incidents by the Department of Health⁽⁵⁾ and the HSE and is incorporated into HSE policy documents including the HSE's safety incident management policy.⁽⁸⁾

Recommendation in relation to review of previous recommendations concerning patient safety intelligence

Recommendation 10

The Department of Health should review and implement previous recommendations made in relation to incident reporting and patient safety intelligence.

- a. Previous recommendations made by both the Health Information and Quality Authority and the Commission on Patient Safety and Quality Assurance in relation to patient safety intelligence should be reviewed and implemented.

1. Introduction

1.1 Background

The 2014, the Chief Medical Officer's (CMO's) report⁽¹⁾ to the Minister for Health on perinatal deaths in Portlaoise Hospital Maternity Services recommended the establishment of a National Patient Safety Surveillance System. While such a system is not formally defined in the CMO's report, reference is made to the need for 'an overall process of pooling risk information and intelligence in order to create a composite risk profile for the healthcare system'. The report indicated that the full picture in relation to an ongoing problem with the outcomes of care experienced by service users and patients in Portlaoise was not available. It was further outlined that there was a requirement to pool intelligence that may exist across healthcare agencies to create better risk and safety profiling of services. The report also advocated a National Patient Safety Surveillance System for the benefit of the health and social care system and HIQA, as it could provide early warnings of potential safety issues and risks to the system. The CMO's report⁽¹⁾ also highlighted that there was no single body that had oversight at the national level of the risk management and patient safety issues that emerge for numerous single agencies. This position remains unchanged, and signifies that intelligence gathered within single agencies does not become part of an overall pooling of risk information.

In addition to the CMO's report, other recommendations concerning the coordination of patient safety intelligence and incident reporting have also been made previously. The recommendations made by the Authority in the investigation reports of its two most recent statutory investigations — namely the HIQA Portlaoise report 2015⁽³⁾ and the HIQA Galway report 2013⁽⁴⁾ — are still relevant in relation to coordinating patient safety intelligence and incident reporting. These recommendations can be found in Appendix 5.

The HIQA Portlaoise report 2015⁽³⁾ outlined that while there was knowledge within the system that there may be potential risks to patients, the sharing of intelligence between agencies within the system was not adequate and hence did not result in effective mitigation of the identified risks.⁽³⁾ These findings illustrate that different pieces of patient safety intelligence are held by different organisations and agencies in Ireland and there is a lack of coordination of this intelligence. There must be a stronger system of using and sharing information to improve quality and safety for patients. In addition, the HIQA Galway report 2013⁽⁴⁾ recommended that there must be strong governance structures and mechanisms in place to ensure that the findings and learning, in respect of implementing safety and quality issues emanating from serious adverse incidents and their investigations, are acted on.⁽⁴⁾ The HIQA Galway report 2013⁽⁴⁾ also recommended that arrangements should be in

place to collate and review information from national and international inquiries, reviews and investigations. It recommended that where relevant, learning and recommendations from such reviews should be acted on so that valuable lessons learned can be applied by each service provider in order to improve the outcome for patients in Ireland.

In 2008, the Report of the Commission on Patient Safety and Quality Assurance⁽²⁾ also made many relevant recommendations about the coordination of patient safety intelligence. A steering group was set up to promote the implementation of all the recommendations in the Commission's report. The group achieved progress on implementing a number of recommendations from the report. However, there are still a number of recommendations that have not been implemented to date.

1.2 Developments in relation to patient safety (November 2015)

In November 2015, the Minister for Health announced a number of patient safety reforms, which includes plans to establish a new National Patient Safety Office within the Department of Health. The role of the office will be to oversee patient safety measures and to build on the work of the National Clinical Effectiveness Committee. The office will report directly to the Minister, oversee the programme of patient safety measures and advise the HSE, HIQA and health professional regulatory bodies on patient safety issues. The office will also include a system for the coordination of patient safety surveillance. This system will produce patient safety profiles by bringing together data from various health information resources and the intelligence gathered will inform the setting of priorities for the HSE.

In addition, an independent National Advisory Council for Patient Safety is to be appointed in 2016. This council will have an independent chair and will have significant representation from healthcare leaders and from patients. This council will provide advice and guidance to inform the policy direction for the National Patient Safety Office. The council will also publish patient safety reports which through the interrogation of patient safety information will assist the health service and regulators to recognise the conditions that help to predict whether harm is likely to occur.⁽⁵⁾

In November 2015, the Government also published the Health Information and Patient Safety Bill (General Scheme).⁽⁶⁾ The Health Information and Patient Safety Bill provides that patient safety incidents must be reported to the relevant reporting authority. The bill in relation to open disclosure,⁽⁷⁾ also published by the Department of Health in November 2015, provides for HIQA to set standards on disclosing patient safety incidents to service users. These developments were considered when making the recommendations in this report.

1.3 Methodology

Under the Health Act 2007, sections 8(1)(j) and 8(2)(d), one of the Authority's key functions is to provide advice to the Minister for Health and the HSE about deficiencies identified regarding health information. HIQA therefore aims to address the deficiencies outlined by the CMO through the development of recommendations for the Minister for Health on the coordination of patient safety intelligence in Ireland. There were three stages involved in this project as follows:

1. International review of patient safety surveillance systems (full report available on the HIQA website, www.hiqa.ie).
2. 'As is' analysis of patient safety intelligence systems and structures in place in Ireland (full report available on the HIQA website, www.hiqa.ie).
3. Recommendations developed with input from an Expert Advisory Group (further details of its membership can be found in Appendix 3).

The international evidence, findings of the 'As is' analysis, and input from members of the Expert Advisory Group formed the basis for this set of recommendations to the Minister for Health on coordinating patient safety intelligence in Ireland.

1.4 Structure of this report

The recommendations made in this report are based on a number of key challenges that need to be addressed in relation to the coordination of patient safety intelligence in Ireland. These challenges include the need for national oversight and coordination of patient safety intelligence, a standardised approach and an information governance framework to support both incident reporting and the coordination of intelligence. As outlined in the CMO's report, a future National Patient Safety Surveillance System should pool and triangulate intelligence from many sources of patient safety information,⁽¹⁾ including incident information from the National Incident Management System (NIMS). To achieve this, the current sources of patient safety intelligence need to be strengthened and should include the full implementation and national roll-out of a national incident management system for patient safety incidents.

This report therefore sets out **10 key recommendations** in relation to:

- (a) a model for the coordination of patient safety intelligence in Ireland
- (b) implementation of a national incident management system.

The report also includes a final recommendation relating to the implementation of previous recommendations made in other reports concerning patient safety intelligence.

2. Recommendations on the coordination of patient safety intelligence

2.1 Introduction

The 2014 Chief Medical Officer's (CMO's) report to the Minister for Health on perinatal deaths in the Midland Regional Hospital, Portlaoise recommended the establishment of a National Patient Safety Surveillance System in Ireland. The report outlined that there was a gap in the coordination of national patient safety intelligence in Ireland, and a need to pool existing information and intelligence across different agencies in order to create a composite patient safety and risk profile for the healthcare system. The CMO's report also outlined that there was no single agency with overall line of sight or responsibility for the coordination of patient safety intelligence in Ireland, and this represented a substantial deficiency in the health information infrastructure in the country.

Many organisations, including the HSE, had partial information regarding the safety of services at Portlaoise that could have led to earlier intervention had it been collated. The CMO's report stated that patient safety issues that emerge from numerous single agencies do not form part of the overall process of pooling of risk intelligence which could create a risk profile of services. There is significant patient safety data and information gathering undertaken by single agencies (see Figure 1 overleaf for illustration of agencies). However, this intelligence is not part of an overall process of pooling intelligence to create a risk profile for the healthcare system. A proposed National Patient Safety Surveillance System should therefore provide a mechanism for bringing together a wide range of information sources for example serious reportable events data, rates of healthcare-associated infections, and concerns information from different organisations to form intelligence that would act as an early warning for patient safety risks in that service.

The following sections outline the international findings in relation to the coordination of patient safety intelligence and a summary of the findings from the 'As is' analysis of patient safety intelligence systems and structures in Ireland. The summary of these findings is followed by a number of recommendations in relation to the coordination of patient safety intelligence in Ireland.

Figure 1. Potential agencies and or bodies that hold patient safety intelligence in Ireland



2.2 Key international findings in relation to the coordination of patient safety intelligence

A review of national reporting systems for patient safety incidents in Europe was published in 2009.⁽⁹⁾ This review found that in European countries where a national patient safety reporting system has been implemented, the decision to implement the system has been accompanied by the appointment of a dedicated national-level coordinator point for patient safety intelligence. In addition, the international evidence highlights the need to combine learning from incident reporting with other important sources of patient safety intelligence.^(9;10) In order to coordinate intelligence from the incident reporting and learning system with other patient safety intelligence, the international locations reviewed have a number of arrangements in place. These arrangements include providing legislation for the sharing of information from the national reporting and learning system and through establishing participation and data-sharing agreements between the national reporting and learning system and other agencies that hold patient safety intelligence. Many health services have also begun to develop a model for

coordinating patient safety intelligence which brings together important organisations and their intelligence. A number of the structures in place internationally were reviewed in order to identify models for Ireland to consider.

The National Quality Board (NQB) in England brings together the leaders of statutory organisations across the health system, as it is recognised that there are a number of statutory organisations with distinct roles and responsibilities, but no one body that has a complete picture on the quality of care provided. Networks of regional quality surveillance groups have been developed across England to pool the patient safety information and intelligence from these key organisations to ensure that different parts of the service are working together and provide a shared view of risks to quality.

Quality surveillance groups review 'hard' and 'soft' intelligence from a range of sources including intelligence from a national quality dashboard and other sources, including data from the health and social care regulators, public health departments, staff feedback, complaints and incident data. When statutory organisations have concerns about a serious quality failure or concerns about the potential for a failure within a provider, they alert other quality surveillance group members to their concerns by triggering a risk summit to give specific focussed consideration to the concerns raised, facilitating rapid, collective judgments. This provides different parts of the system with an opportunity to align their actions so that they do not fail to act on concerns or duplicate actions.

Scotland has also addressed the coordination of patient safety intelligence through establishing a Sharing Intelligence for Health and Care Group (SIHCG) in 2014. This Group brings together the important audit, inspection and training bodies of the health and social care system in Scotland. The group provides a forum to share data and information to build a comprehensive picture about the quality of care in NHS boards in Scotland and to use this intelligence to determine how Healthcare Improvement Scotland (HIS) and its other partner organisations can work to support scrutiny and improvement. The aim of the group is to review combined intelligence on the quality and safety of health and care and to identify potential problems or concerns that may require further investigation. In the initial steps of establishing the group, focus has been on putting in place governance arrangements and establishing membership of the group, which includes Audit Scotland, Care Inspectorate, Healthcare Improvement Scotland, Mental Welfare Commission for Scotland, NHS Education Scotland and the Public Health and Information Services Division of NHS National Shared Services.

2.3 Summary of 'As is' analysis in relation to the coordination of patient safety intelligence

The 'As is' analysis of patient safety intelligence systems and structures in Ireland identified a number of sources of current patient safety intelligence that exists nationally. Currently, there is no formalised process of pooling and coordinating pre-existing patient safety intelligence between agencies in Ireland. Table 1 in this section provides a number of examples of the patient safety intelligence that is currently held by the HSE and Table 2 provides a number of examples of other agencies who hold patient safety intelligence in Ireland. The full report of the 'As is' analysis is available on the HIQA website, www.hiqa.ie.

Table 1. HSE sources of patient safety intelligence

Source	Key information collected
Quality and safety metrics	An accountability framework was introduced in 2015 following the restructuring* of the quality and patient safety function of the HSE. The framework sets out the means by which the HSE and its national divisions, hospital groups and community healthcare organisations are held to account for their performance. Key priorities are captured in a 'balanced scorecard' which are broken down into performance indicators to measure improvements in patient experience, effectiveness, health and wellbeing and assurance for quality and safety. ⁽¹¹⁾
Patient safety incident data	HSE funded services report all clinical and non-clinical incidents to the National Incident Management System (NIMS) and escalate high-risk serious clinical incidents, including serious reportable events, to the National Incident Management and Learning Team. The Incident Information Management System (IIMS) is used by the HSE's divisional leads for quality and patient safety and the National Incident Management and Learning Team to record investigation and management information on these incidents. The National Incident Management and Learning Team also accesses data from NIMS at a national level.
Complaints data	There is a statutory complaints system within the HSE. Complaints must be managed in line with the HSE's Complaints Policy. ⁽¹²⁾ Patients, services users and the public can make a complaint to the HSE through a number of avenues. The HSE's annual report for 2013 ⁽¹³⁾ reported that 6,823 complaints were recorded for HSE hospitals and 5,573 complaints by voluntary hospitals in 2013.
Health Protection Surveillance Centre (HPSC)	The HPSC is Ireland's specialist agency for the surveillance of communicable diseases. The HPSC provides timely information and independent advice, and carries out disease surveillance, epidemiological investigation and related research and training. The HPSC is authorised by law to collect information from doctors and laboratories about diagnoses of certain notifiable infectious diseases'.

* A quality and patient safety enablement programme was established in 2014 which required the restructuring of the HSE's former quality and safety functions. There are two new divisions within this programme, namely the Quality Improvement Division and the Quality Assurance and Verification Division.

Table 2. Other agencies who hold patient safety intelligence in Ireland

Source	Core remit
Health Information and Quality Authority (HIQA)	The Regulation Directorate within HIQA is responsible for the regulation of health and social care services and has a statutory responsibility to carry out inspections and investigations. As part of this process, HIQA collects information on health and social care services and concerns that people may have about these services. HIQA must be formally notified by the person or persons in charge of a nursing home or other designated centre when certain events or incidents take place.
State Claims Agency (SCA)	State authorities including the HSE are statutorily obliged to report 'adverse incidents' to the State Claims Agency, in line with the National Treasury Management Agency (Amendment) Act, 2000. ⁽¹⁴⁾ To enable State authorities to fulfil this requirement, the State Claims Agency hosts the National Incident Management System (NIMS). NIMS provides a single national platform on which all users can record incidents (including complaints and near misses), manage incident investigations, assist and tract tasks and recommendations and run reports and analysis.
National Office of Clinical Audit (NOCA)	NOCA carries out sustainable clinical audit programmes at national level. NOCA collaborates with clinical and executive leads in the HSE, hospital groups and local hospital quality and patient safety committees to ensure quality data collection and audit output is interpreted and used to direct quality improvement.
Health Products Regulatory Authority (HPRA)	By inspecting sites and investigating potential breaches of the law HPRA works to ensure that those who make and market health products do so in line with the legislation. The HPRA also gathers intelligence in relation to patient safety and quality from patients, carers, the public and healthcare professionals who report concerns, directly to it. ⁽¹⁵⁾ It is also mandatory by law for pharmaceutical companies to submit any reports of adverse reactions.
Mental Health Commission (MHC)	The MHC inspects mental healthcare services and promotes high standards in the delivery of mental healthcare services. There are certain incidents that are required to be reported to the Commission.
Professional regulatory bodies	The professional regulatory bodies in relation to health and social care in Ireland are also sources of patient safety intelligence and include the following organisations: The Medical Council, The Nursing and Midwifery Board of Ireland, The Pharmaceutical Society of Ireland, The Pre-Hospital Emergency Care Council and CORU is Ireland's multi-profession health regulator.

2.4 Current issues with the coordination of patient safety intelligence

This section outlines a number of the current issues in relation to the national coordination of patient safety intelligence in Ireland, including the need for governance of national patient safety intelligence.

2.4.1 Need for governance and coordination of national patient safety intelligence

A review of national reporting systems for patient safety incidents in Europe was published in 2009.⁽⁹⁾ This review found that in European countries where a national patient safety reporting system has been implemented, the decision to implement the system has been accompanied by the appointment of a dedicated national-level coordinator point for patient safety intelligence. The report also outlined that a reporting and learning system is just one of a number of resources that can be used for patient safety monitoring and that for a comprehensive overview of patient safety there is a need to triangulate existing and new sources of information. It was noted that many of the countries studied as part of the international review conducted for this project are now focusing on triangulating intelligence from the reporting and learning system with other sources of intelligence, such as from coroners' reports, public health data and concerns from the public, in order to identify patient safety concerns. This allows the pooling of patient safety intelligence from a range of sources to try to ensure a more accurate risk profile is identified. As mentioned in section 2.2 of this report, the NHS in England has developed a model for proactively sharing key information and intelligence, through establishing a network of quality surveillance groups to systematically bring together organisations and their intelligence. This enables organisations with patient safety intelligence — and who have statutory powers — to carry out their responsibilities in a more informed and collaborative way. Quality surveillance groups provide a forum through which different organisations who do have statutory powers and responsibilities can come together to carry out their responsibilities in a more informed and collaborative way. They are not statutory bodies nor do they interfere with the statutory roles of organisations.⁽¹⁶⁾ There is currently no such structure in place in Ireland.

The Report of the Commission on Patient Safety and Quality Assurance⁽²⁾ in 2008 outlines that it is essential that there is a national surveillance resource that receives reports of "serious adverse events" from across the system. This is required to ensure that the appropriate action has taken place, that trends were monitored and that learning took place to inform existing and future healthcare delivery and governance arrangements. However, currently in Ireland there is no single agency or body that has overall responsibility or specific accountability for creating such an oversight of the risk management and patient safety issues that emerge for numerous agencies. There is also no standardised process in place at present for the

coordination of patient safety intelligence from the numerous organisations who gather such information. The diffusion of this information is thereby a lost opportunity to provide early warnings to the HSE, HIQA and the Department of Health of potential patient safety issues and risks in the system. There is currently no formalised structure for bringing together representatives from the main agencies from different parts of the health and social care system to share information in relation to patient safety.

The following recommendations should be considered in light of the patient safety reforms that were announced by the Minister for Health in November 2015. These include plans to establish a new National Patient Safety Office within the Department of Health which will include a system for the coordination of patient safety surveillance. In addition, an independent National Advisory Council for Patient Safety is to be appointed in early 2016.

Recommendations in relation to the coordination of patient safety intelligence

Recommendation 1

An independent national organisation should be established with assigned responsibility for the governance, coordination and dissemination of national patient safety intelligence to ensure national oversight of patient safety, risk profiling and to inform policy development.

- a. This organisation should report directly to the Minister for Health and should enable the coordination and triangulation of patient safety intelligence from relevant agencies, including information from the National Incident Management System.
- b. Clear lines of accountability for this organisation should be set out detailing responsibilities for the coordination of intelligence.
- c. This organisation should develop and regularly review a 'national quality dashboard' comprised of an agreed suite of quality indicators that are aligned to national standards. These indicators will provide a shared view of risk and enable alignment of actions to mitigate risk.
- d. A mechanism for issuing patient safety alerts should be developed to allow for timely sharing of patient safety risk intelligence and there should be clear lines of accountability for acting on these alerts.
- e. An independent national quality council should also be established to provide advice and leadership to this organisation. This council should bring together senior representatives from national statutory organisations with responsibility for patient safety intelligence to provide a forum for multi-lateral collaboration in relation to quality and patient safety intelligence.

Recommendation 2

The Director General of the HSE should ensure that effective governance arrangements are in place for quality and patient safety groups within hospitals, hospital groups and across the nine community health organisations.

- a. These quality and patient safety groups should ensure timely and accurate collection and reporting of patient safety data and information to inform intelligence, and give focused consideration to any risks identified and concerns raised.
- b. The chair of each group should have clearly defined accountability to their chief executive and/or national director.
- c. Local governance structures that embed a 'just culture' should be in place to ensure timely review of patient safety intelligence for risk profiling and effective dissemination of learning.*
- d. A national review should be conducted to ensure that these groups are in place and includes monitoring of the efficacy of these groups.
- e. The HSE should also ensure that effective governance arrangements for quality and patient safety groups are in place in health and social services that are provided on behalf of the HSE.

2.4.2 Need for an effective information governance framework for sharing intelligence between agencies

In the international jurisdictions reviewed, a number of mechanisms for coordinating patient safety intelligence were identified, with some jurisdictions having voluntary participation agreements in place to share data between the reporting system and other relevant agencies that hold patient safety intelligence. Others had more formalised data sharing agreements in place. While there is no formalised process of pooling and coordinating pre-existing patient safety intelligence between all relevant agencies in Ireland, there are examples of data sharing currently in place between certain agencies.

For example, the Medical Council has an agreement with the Health Products Regulatory Authority (HPRA) to share any concerns relating to the improper behaviour, conduct, practice or professional competence of a doctor. Both organisations have an agreement to share information regarding the improper use, supply, administration or advertisement of medicinal or healthcare products that may breach legislation enforced by the HPRA or where patients' medical safety may

* A 'just culture' seeks to balance the need to learn from mistakes and the need to take disciplinary action.⁽⁸⁾

be at risk. The Medical Council also has an agreement with the Pharmaceutical Society of Ireland (PSI) to increase mutual cooperation to ensure maximum effectiveness regarding public safety and public health issues when they are carrying out their statutory functions.⁽¹⁷⁾

There are also memoranda of understanding (MOUs) in place between certain agencies in Ireland, for example, there is an MOU held between HIQA and the Mental Health Commission (MHC), which aims to promote collaboration in areas of joint strategic and operational interest, facilitate cooperation on the referral of concerns, and enhance formal communication and information sharing activities for the benefit of patients and other people using mental healthcare services. There is also an MOU in development between the SCA and the HSE to share clinical risk information that is reported to the National Incident Management System (NIMS), which is operated by the State Claims Agency.

In terms of sharing information from the National Incident Management System (NIMS) with other relevant agencies, NIMS has the functionality to notify or report on incidents to relevant agencies. NIMS has the capability to allow users to flag which incidents should be reported to which authorities. However, currently it is not configured to automatically share information with regulatory bodies. Existing functionality also allows for the development and provision of standard reports accessible to relevant users for reporting to regulatory bodies. For example, a standardised report has been developed for reporting to the Mental Health Commission. This model for sharing information to include the development of an effective information governance framework will be further explored and developed as part of Phase 2 rollout of NIMS where, with the agreement of regulatory bodies and the reporting authorities data could be standardised and automated. Despite these information sharing arrangements, significant gaps remain in sharing and coordinating national patient safety intelligence, which if coordinated would assist in identifying emerging patient safety risks.

Recommendation 3

An effective information governance framework should be put in place to support sharing of relevant intelligence between national agencies to enable the coordination of patient safety intelligence.

- a. To facilitate sharing of intelligence between agencies, formalised data sharing and or participation agreements should be developed in line with appropriate safeguarding structures.

2.4.3 Need for an integrated information infrastructure to support the coordination of patient safety intelligence

The current information communications technology (ICT) infrastructure in health and social care sector in Ireland is highly fragmented and siloed which inhibits the safe, effective, transfer of information. The Report by the European Commission (2014) recommends that ICT capacity should be sufficient to ensure continuous system improvements for reporting and learning systems.⁽¹⁸⁾ Another significant gap that has been identified in Ireland is the lack of an integrated and effective ICT infrastructure, supported by standards for interoperability of systems, which is required to support coordination of patient safety intelligence. The Knowledge and Information Strategy developed by the HSE in 2015 is seeking to address these deficits.⁽¹⁹⁾

Recommendation 4

The HSE's Knowledge and Information Strategy should be implemented in order to promote interoperability of information systems and to enable the coordination of patient safety intelligence.

- a. An effective information communications technology infrastructure, supported by standards for interoperability should be put in place to support the coordination of patient safety intelligence.
- b. Organisations with responsibilities in the area of patient safety intelligence should comply with legislative and regulatory requirements, including compliance with national and international health information standards and classifications.

3. Recommendations in relation to incident reporting

3.1 Introduction

A 2014 European Commission report of national reporting and learning systems for patient safety incidents in place in Member States in Europe⁽¹⁸⁾ outlines that an incident reporting system is one of a number of resources that can be used to monitor patient safety. Currently in Ireland, the National Incident Management System (NIMS) is the system to which all clinical and non-clinical incidents that happen in Delegated State Authorities* (including the HSE) must be reported. Under the National Treasury Management Agency (Amendment) Act, 2000,⁽¹⁴⁾ Delegated State Authorities are statutorily obliged to report 'adverse incidents' as soon as may be to the SCA. To assist the SCA in delivering on this function, the STARSweb system was introduced in 2004 to record adverse clinical incidents and 'near misses' reported by hospitals. The STARSweb system has recently been upgraded and has been replaced by the National Incident Management System (NIMS). This upgraded system was available across all the HSE and Section 38 bodies** by the end of June 2015. As a result, the information reported to the NIMS system provides a valuable source of patient safety intelligence.

An evaluation of the STARSweb system was undertaken jointly by the State Claims Agency, the HSE and HIQA and published in 2008 (*STARSweb: Evaluation Project*). The report highlighted a number of key issues and subsequent recommendations around the processes and practices of incident reporting within the healthcare organisations in Ireland.⁽²¹⁾ A number of the issues highlighted in the report are still relevant and have been reiterated in a publication by the State Claims Agency in October 2015, *Clinical incidents and Claims in maternity and gynaecology services – A five year review: 2010-2014*.⁽²²⁾

In addition, *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance*⁽²⁾ — also published in 2008 — outlined significant concerns in relation to adverse event reporting in Ireland. While it is recognised that some of the issues highlighted are now outdated or have been addressed by the Implementation Steering Group,⁽²³⁾ a number of the

* Delegated State Authorities are state agencies whose claims are delegated for management by the State Claims Agency.

** Section 38 of the Health Act, 2004 provides for the HSE to enter, into an arrangement with a person for the provision of a health or personal social service by that person on its behalf.⁽²⁰⁾ Therefore, Section 38 bodies refer to agencies or groups that are providing services on behalf of the HSE, for example voluntary hospitals.

recommendations made in this report are still relevant and are discussed in section 3.5.

As outlined in previous sections of this report, a number of issues with incident reporting have also been described in the 2014 CMO's report into perinatal deaths at Portlaoise Hospital.⁽¹⁾ That report outlined that there were inconsistencies in adverse event terminology, variability in the quality and completeness of incident report forms and no indications of regular trend reports being carried out from reported incidents.⁽¹⁾

A number of challenges and issues in relation to incident reporting have also been cited repeatedly in other reports, including the healthcare investigations undertaken by HIQA. The HIQA Portlaoise Report 2015 found there was no corporate collation, analysis, trending or use of incident information to proactively address risks, investigate incidents and share any resulting learning.⁽³⁾

Evidence from these previous reports along with the evidence gathered by the Authority to develop the recommendations set out in this report highlighted some of the current challenges in relation to incident reporting in Ireland. These challenges need to be addressed to ensure that information reported to the national incident management system is a valuable source of patient safety intelligence. To achieve national coordination the current sources of such intelligence need to be strengthened and the national roll-out of the national incident management system for all patient safety incidents should be fully implemented.

The following sections outline the international findings on incident reporting and learning systems, findings on incident reporting from the 'As is' analysis and the critically important issues that exist in this area in Ireland. The summary of these findings is followed by a number of recommendations in relation to national incident reporting for Ireland.

3.2 Key international findings in relation to patient safety reporting and learning systems

The 2009 Council of the European Union recommendation on patient safety (2009/C 151/01) regarding reporting and learning systems on incidents recommends that Member States of the EU:

- support the establishment or strengthen blame-free reporting and learning systems on adverse events that provide information on the extent, types and causes of errors, adverse events and near misses

- encourage healthcare workers to actively report through the establishment of a reporting environment which is open, fair and non-punitive
- differentiate these reporting systems from Members States' disciplinary systems and procedures for healthcare workers
- provide opportunities for patients, their relatives and other informal caregivers to report their experiences
- complement other safety reporting systems, such as those on pharmacovigilance and medical devices, while avoiding multiple reporting where possible.⁽¹⁰⁾

The main findings outlined in the international reviews of patient safety reporting and learning systems include the following objectives and lessons:

- The primary purpose of patient safety reporting systems is to learn from experience.
- The most important function of a reporting system is to use the results of data analysis and investigation to share recommendations for addressing patient safety risks.
- The system must encourage healthcare workers to actively report incidents through the establishment of a reporting environment which is open, fair and non-punitive.
- The reporting system should be separated from formal complaints, disciplinary action and litigation procedures. Healthcare professionals who report should be protected from disciplinary or legal action. Confidentiality of the reporter and appropriate anonymisation of the data should be ensured.
- The system should provide opportunities for patients, their relatives and other informal caregivers to report their experiences. Patient and family reports are a potentially rich resource for learning and patient safety improvement, and they should be encouraged.
- The system should complement other safety reporting systems, while avoiding multiple reporting where possible.

In terms of the governance arrangements in place for national reporting and learning systems, findings from the international review show that a number of locations host the system within the health service provider. In other regions, an independent agency under the ministry of health is responsible for the system. All jurisdictions reviewed emphasise that the main purpose of the incident reporting system is to improve patient safety by learning from past mistakes. Some of the

countries reviewed have legislation in place that requires the organisation which holds patient safety incident information to share learning nationally.

A 2014 report documenting reporting and learning systems for patient safety incidents across Europe⁽¹⁸⁾ outlines that incidents should be reported and analysed at the level of the healthcare provider in order to allow the organisation to react immediately at local level and then follow up the incident accordingly. Following local action, learning from incidents should be shared locally and to the wider system. To encourage reporting, all jurisdictions reviewed have tried to promote patient safety and the concept of a 'just culture'* at local level by having 'ground-up' structures in place, so most work is rooted locally where analysis and action can take place.

International evidence shows that incident reporting and learning systems that are separate from claims and complaints data help to promote a patient safety culture through emphasising that the purpose of the system is for learning, rather than for claims management. The 2014 European Commission report⁽¹⁸⁾ outlines that the reporting system should be separated from formal complaints, disciplinary action and litigation procedures.

The Council of Europe recommendation from 2009⁽¹⁰⁾ states that a reporting and learning system should provide opportunities for patients, their relatives and other informal caregivers to report their experiences. Overall, international evidence suggests that an incident reporting and learning system is an important resource for identifying patient safety risks and is beneficial in promoting incident reporting locally in order to create a positive patient safety culture.

Many of the countries and jurisdictions reviewed have expanded the benefit of incident reporting to allow the following areas to report into the system:

- private healthcare providers
- private care agencies
- pharmacies
- general practitioners (GPs)
- homecare
- community services
- patients and their families.

3.3 Summary of 'As is' analysis in relation to national incident reporting

At present, the National Incident Management System (NIMS — formerly STARSweb) within the State Claims Agency is the information system through which hospitals funded by the HSE (all enterprises covered by the Clinical Indemnity

* A 'just culture' seeks to balance the need to learn from mistakes and the need to take disciplinary action.⁽⁸⁾

Scheme) report clinical and non-clinical incidents. A number of hospitals are also using incident information systems which have either been procured or developed in house for recording and managing incidents locally. These systems are stand alone i.e. do not have any direct linkage or data sharing with NIMS, and as a result these sites may not be reporting all incidents to NIMS. There is also, an Incident Information Management System (IIMS), an internal HSE system, which is the information system used by hospital groups, community health offices, divisional offices for quality and patient safety and the National Incident Management and Learning Team within the Quality Assurance and Verification Division in the HSE to record and collate all relevant information regarding serious incidents that are escalated to the divisional quality and patient safety lead or to the National Incident Management and Learning Team. Further information on these systems is documented in the 'As is' analysis of patient safety intelligence systems and structures in Ireland, conducted by HIQA, which can be found on the HIQA website, www.hiqa.ie.

The upgrading of NIMS is being implemented in two phases. The objective of phase 1 of the roll-out of NIMS — which was to ensure that all existing user sites had access to NIMS and had been provided with training in using the NIMS data entry module by June 2015 — has been met. As a result, the old STARSweb system was turned off on 30th June 2015. A number of new user-sites that did not previously have access to NIMS now also have the system in place. Planning for Phase 2 of NIMS has commenced and aims to focus on implementing the new NIMS features such as 'point of occurrence' reporting and audit and recommendation tools.

The following recently developed policies are in place in the HSE to support incident reporting in health and social care services:

- Serious Reportable Events (SREs) Guidance (Jan 2015) ⁽²⁴⁾
- Criteria for the Communication or Escalation of Incidents to the National Incident Management and Learning Team (2015)⁽²⁵⁾
- Safety Incident Management Policy (May 2014) ⁽⁸⁾
- Guidelines for Systems Analysis Investigation of Incidents and Complaints (November 2012). ⁽²⁶⁾

In November 2015, the Government published the Health Information and Patient Safety Bill (General Scheme).⁽⁶⁾ The bill provides that patient safety incidents must be reported to the relevant reporting authority. The Provisions on Open Disclosure,⁽⁷⁾ (General Scheme) also published in November 2015, provides for HIQA to set standards for both public and private providers on disclosing patient safety incidents to service users. The standards will address how a disclosure should be made, what steps should be taken by the provider to prevent a recurrence of the incident and

how the incident information will be kept by the provider.⁽⁶⁾ In this way, the development of these standards will promote a patient safety and reporting culture.

Also during 2015, Section 38 service arrangements were revised to outline requirements for Section 38 bodies (including voluntary hospitals) to report incidents as follows: “providers shall comply with the requirements of the National Treasury Management Agency (Amendment Act) 2000 and any and all ancillary and related legislation in relation to incident reporting, risk management and claims management and use the National Incident Management System (NIMS) as the primary ICT system to report and manage incidents”.⁽²⁷⁾

In addition, the Authority is currently developing national standards for the conduct of reviews of adverse incidents, which is due to be completed during 2016. The development of these standards will contribute to a standardised process for reviewing adverse incidents and should also reduce the variability of incident reviews and implementation of recommendations within health and social care organisations.

3.4 Current issues in relation to national incident reporting and learning

This section outlines a number of the current issues in relation to national incident reporting in Ireland, including national implementation of NIMS and associated governance arrangements, under-reporting to NIMS, legislative issues and the coverage of the system.

3.4.1 Need for national roll-out of national incident management system

The State Claims Agency is the State body responsible for claims and associated risk management functions under the National Treasury Management Agency (Amendment) Act, 2000.⁽¹⁴⁾ The Clinical Indemnity Scheme is the main scheme under which the State Claims Agency manages clinical negligence claims taken against hospitals and healthcare professionals covered under this scheme. One of its objectives is to provide risk management advisory services to Delegated State Authorities, including the HSE, with the aim of reducing the frequency, severity and repetition of adverse events and in so doing, also reducing subsequent claims and the cost of claims.⁽³⁾

To oversee the implementation of the upgraded National Incident Management System (NIMS) in the HSE, a NIMS Implementation Steering Group was established in January 2015.

The NIMS Implementation Steering Group is chaired by the Quality Assurance and Verification Division (QAVD) of the HSE and consists of representatives from:

- HSE Service Divisions (Acute Hospitals, Mental Health, Primary Care, Social Care, and Health and Wellbeing)
- HSE Quality Assurance and Verification Division and National Incident Management and Learning Team
- State Claims Agency
- HSE ICT
- HSE Quality Improvement Division
- Voluntary hospitals.

The NIMS Implementation Steering Group is in place to oversee the implementation and rollout of the NIMS system. However, the lines of accountability around the operational management of NIMS within the HSE need to be clearly defined to ensure clear accountability for dealing with issues of quality of data reported, lack of consistency, under-reporting, and other issues as highlighted in the recent report by the State Claims Agency.⁽²²⁾

Under the National Treasury Management Agency (Amendment) Act, 2000,⁽¹⁴⁾ only Delegated State Authorities — which includes the HSE and organisations funded by the HSE — are required to report incidents to the State Claims Agency via NIMS. The Report of the Commission on Patient Safety and Quality Assurance⁽²⁾ recommended that the design of a reporting system must facilitate patient and family reporting of adverse events, while patients should also be advised accordingly. Currently in Ireland, NIMS does not facilitate patients and their families to report incidents to the system.

NIMS is currently implemented in all healthcare enterprises where STARSweb had been previously used and has also been implemented in a number of new sites where STARSweb had not been in place. In most cases, NIMS is in operation at data-entry module level, meaning that the additional functions of NIMS such as investigation, reporting, recommendations modules and audit tools are not currently in operation. This limits sites' ability to carry out incident analysis and action at local level using the NIMS system. Phase two roll-out of NIMS aims to fully implement these functions across all sites.

However, international evidence shows that incident reporting and learning systems that are separate from claims and complaints data help to promote a patient safety culture through emphasising that the purpose of the system is for learning, rather than for claims management. The 2014 European Commission report⁽¹⁸⁾ also outlines that the reporting system should be separated from formal complaints, disciplinary action and litigation procedures.

Recommendation 5

A review of governance arrangements for the operational management of the National Incident Management System (NIMS) should be conducted in order to enhance the ownership and responsibility of the reporting system within the HSE and therefore facilitate learning and support a 'just culture'.

- a. Effective governance arrangements with clear lines of accountability and responsibility for the oversight, operational management and risk management of the National Incident Management System (NIMS) within the HSE should be ensured so that learning from patient safety incidents is shared locally, within hospital and community group structures and nationally across the wider health and social care sector.
- b. A memorandum of understanding between the HSE, the CEO of each hospital group and the State Claims Agency should be fully developed and implemented to ensure timely sharing of patient safety intelligence.*

Recommendation 6

The upgraded National Incident Management System (NIMS) should be implemented in a standardised way across all hospital groups and community health organisations as a priority.

- a. A detailed implementation plan, with clear lines of responsibility and accountability for the rollout of NIMS should be published and should include details of a training and education programme for all healthcare professionals.
- b. Following implementation in a number of sites an evaluation of the implementation of NIMS should be conducted.
- c. A prioritisation exercise should be conducted to decide on the extension of the implementation of NIMS to other sites including private healthcare providers, in line with legislative requirements.
- d. NIMS should also be extended to facilitate reporting of incidents by patients and their families.

* As previously outlined in Recommendation 8 of the *Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE) to patients in the Midland Regional Hospital, Portlaoise* (HIQA, May 2015).⁽³⁾

3.4.2 Need for enactment of legislation to support incident reporting

The Report of the Commission on Patient Safety and Quality Assurance⁽²⁾ in 2008 recommended that a national mandatory reporting system should be introduced for the collection of standardised information on adverse events that result in death or serious harm. The report also recommended that the system must clearly delineate the events which must be reported, but should not be confined to those events and should include provision for the voluntary reporting of other non-serious adverse events and near misses.⁽²⁾

Under the National Treasury Management Agency (NTMA) Amendment Act, 2000,⁽¹⁴⁾ Delegated State Authorities, including the HSE and authorities funded by the HSE, are statutorily obliged to report 'adverse incidents' as soon as may be to the State Claims Agency. While there are specified requirements for Delegated State Authorities to report certain incidents, a report from the State Claims Agency, *Clinical Incidents and Claims Report in Maternity and Gynaecology Services — A Five Year Review: 2010-2014*, reports that 30% of hospitals do not refer to a list which identifies which incidents should be reported to NIMS. It reported that this may lead to confusion and inconsistencies in reporting incidents to the system.⁽²²⁾

Currently, there is also a subset of serious incidents described by the HSE as 'serious reportable events' (SREs). It is a mandatory requirement of the HSE that all SREs are reported on the National Incident Management System (NIMS).

The Health Information and Patient Safety Bill (General Scheme)⁽⁶⁾ provides that public health service providers must notify serious patient incidents (reportable incidents) occurring in their services to the State Claims Agency, HIQA and the Mental Health Commission as appropriate. The minister may prescribe such patient safety incidents as he or she considers appropriate to be reportable incidents which must be reported to the relevant reporting authority. The definition of a patient safety incident as provided in the bill can be found in Appendix 6.

In combination with the need for mandatory reporting of SREs, there is also a need for legal protection in Ireland for healthcare professionals who report patient safety incidents, because currently no such protection exists. In the absence of a 'just culture', healthcare professionals are therefore not encouraged to report incidents. Provisions on Open Disclosure (General Scheme)⁽⁷⁾ published in November 2015, provides for HIQA to set standards for both public and private providers on disclosing patient safety incidents to service users. The standards will address how a disclosure should be made, what steps should be taken by the provider to prevent a recurrence of the incident and how the incident information will be kept by the provider. ⁽⁶⁾ In this way, the development of these standards will promote a patient safety and reporting culture.

In light of the recommendations in the Report of the Commission on Patient Safety and Quality Assurance,⁽²⁾ the international evidence and the current situation in Ireland, HIQA believes that mandatory reporting of 'serious reportable events' — which is supported by legal protection for open disclosure — will drive timely reporting of incidents and a culture of reporting, which will ultimately improve patient safety.

Recommendation 7

The Health Information and Patient Safety Bill and other relevant legislation should be introduced into law as a priority to allow the introduction of mandatory reporting of specified patient safety incidents in order to promote a culture of quality and patient safety.

- a. In particular, legislation on open disclosure should also be introduced into law in a timely manner to support the open disclosure to patients following patient safety incidents.

3.4.3 Need to improve data quality and use of information from reported incidents

The report from the State Claims Agency, *Clinical Incidents and Claims Report in Maternity and Gynaecology Services — A Five Year Review: 2010-2014*,⁽²²⁾ highlights a number of the issues relating to the quality of data reported to NIMS. The report states that the quality of data is suboptimal as a result of some of the following issues, as outlined in its report.*

- Under-reporting of incidents exists nationally, for example, 59% of new patient claims received in the first six months of 2015 had no previous patient safety incident reported to the State Claims Agency (however, not all new patient claims will be known as a previous incident and so a proportion of under reporting is to be expected — this figure is currently not known).
- The State Claims Agency review reports that 12% of acute hospitals report to two reporting systems. It is likely that this figure is an underestimate of the true number of hospitals that are reporting to two systems.
- Variation exists nationally on the modes and patterns of incident reporting, including the percentage of incidents reported to the State Claims Agency, the backlog of incidents that exists, what incidents are reported and who makes the decisions to report these incidents.

* These findings highlight the issues at a time when not all acute hospitals were reporting to NIMS. Since this report has been published, all acute hospitals are now reporting to NIMS.

- A lack of uniformity exists across services in relation to severity of injury ratings, particularly in relation to incidents rated as extreme.
- There is mis-categorisation of incidents, where clinical incidents are rated as extreme but resulted in 'no harm' to the patient.*
- There is a lack of consistency regarding reporting of certain clinical incidents.
- Comparisons are inaccurate due to variation and lack of standardisation in incident reporting practices across healthcare enterprises.

The State Claims Agency report⁽²²⁾ found the process for reporting to NIMS varies between sites with no standardised process or best model for reporting in place. Electronic point-of-occurrence reporting to NIMS would help to standardise the process of incident reporting, however, this has not been implemented nationally to date. The report notes that point-of-occurrence reporting is in place in just 6% of hospitals at present.⁽²²⁾

There is also a need for consistency in the use of incident reporting forms. A National Incident Report Form aligned to the WHO International Classification of Patient Safety (ICPS),⁽²⁸⁾ has been distributed nationally. However, many sites are using old forms and inputting information from their own form to NIMS or their own local system, while some sites have multiple versions of reporting forms in use, depending on the type of incident that has occurred. Dual reporting exists in a number of sites, which can be inefficient and result in duplication of effort. There should be one single system for reporting patient safety incidents.

* Since the publication of the report by the State Claims Agency, *Clinical Incidents and Claims Report in Maternity and Gynaecology Services — A Five Year Review: 2010-2014*,⁽²²⁾ the incident severity rating is now automatically applied on NIMS.

Recommendation 8

Effective information governance arrangements should be put in place to ensure that incident information reported to the National Incident Management System is quality assured.

- a. There should be one system for reporting and managing patient safety incidents in health and social care, to ensure standardisation and data quality.*
- b. National incident reporting forms aligned to the WHO standardised taxonomy as outlined in the International Classification of Patient Safety (ICPS) should be implemented nationally.
- c. A data quality framework should be developed and regular data quality audits conducted.
- d. Electronic point-of-occurrence reporting to the National Incident Management System should be fully implemented to ensure data quality and efficiency of reporting.
- e. An effective and integrated information and communications technology infrastructure, supported by standards for interoperability of systems, should be put in place to support national incident reporting.
- f. There should be compliance with national standards and guidance in relation to incident reporting.

3.4.5 Need to improve access to and use of patient safety information for learning

In most sites, NIMS is in operation at data-entry module level, meaning that the additional functions of the upgraded NIMS such as investigation, reporting, recommendations modules and audit tools are not currently being used. This limits the ability of sites to carry out incident analysis and action at local level using the NIMS system. In addition to the new functions on NIMS, upgraded NIMS has the capability to notify incidents to different agencies, however, NIMS does not automatically share information to regulatory bodies. Currently, NIMS has the capability to allow users to manually flag which incidents should be reported to which authorities; however NIMS can provide automated reports to the individual notifying authorities directly. This model of sharing information between authorities is to be explored as part of the development of the upgraded NIMS system.⁽²⁹⁾

* All HSE and section 38 agencies and bodies have been directed to use the National Incident Management System (NIMS) for incident reporting. NIMS has been endorsed as the primary system for the reporting and management of incidents by the Department of Health⁽⁵⁾ and the HSE and is incorporated into HSE policy documents including the HSE's safety incident management policy.⁽⁸⁾

While NIMS has the capability to share information with agencies, there is currently no system or supporting management structure in place to manage issuing alerts to healthcare professionals or healthcare organisations from NIMS or other system, to enable the rapid notification of emerging patient safety risks.

Recommendation 9

The use of, and access to, patient safety information reported to the National Incident Management System should be optimised through the use of effective governance structures.

- a. Reports of data should be regularly published and learning widely shared with health and social care staff to support the development and monitoring of initiatives to improve patient safety and promote a 'just culture'.
- b. Aggregated validated data should be made available to the public in the form of annual reports.

3.5 Need for implementation of previous recommendations in relation to patient safety intelligence

The evidence gathered to inform this report highlights again issues and recommendations in relation to incident reporting and the coordination of patient safety intelligence that have been identified on a number of occasions previously. These include those issues highlighted in the more recent statutory investigations undertaken by HIQA;^(3;4) the Report of the Commission on Patient Safety and Quality Assurance;⁽²⁾ and the STARSweb evaluation report.⁽²¹⁾

A number of recommendations in relation to incident reporting and the coordination of patient safety intelligence have been made in the two most recent statutory investigations conducted by HIQA — namely the HIQA Portlaoise Report 2015⁽³⁾ and HIQA Galway Report 2013.⁽⁴⁾

The recommendations made by the Authority in these investigations that are still relevant in relation to the coordination of patient safety intelligence and incident reporting can be found in Appendix 6.

In relation to the recommendations made in the 2008 Report of the Commission on Patient Safety and Quality Assurance,⁽²⁾ an Implementation Steering Group was set up to address the implementation of these recommendations. To progress the recommendation of the Commission on making legal provision for (a) mandatory reporting of serious adverse incidents and (b) giving legal protections and

appropriate exemption from freedom of information (FOI) legislation for adverse incidents reports, open disclosure of adverse events to patients and clinical audit, the following progress was reported by the group in 2011:

- provision for the mandatory reporting of serious adverse events and or incidents in the Health Information Bill.
- provision for legal protections for adverse event and or incident reports, open disclosure of adverse events to patients and clinical audit and appropriate exemptions from FOI.⁽²³⁾

Since the publication of the Report of the Implementation Steering Group in 2011, the Health Information Bill has been renamed the Health Information and Patient Safety Bill. The Health Information and Patient Safety Bill (General Scheme) was published in November 2015 and includes the provisions outlined above.⁽⁶⁾

In relation to implementing recommendations, made by the Commission, on adverse event reporting and the development of a database to allow for the sharing of learning throughout the healthcare system, including the facilitation of rapid alerts, the Implementation Steering Group outlined the following achievements the 2011 report:

- preparatory work on a national policy in relation to the management of incidents
- development of a proposed list of mandatory reportable serious adverse events
- option appraisal process for the designation of a national agency with overall responsibility for the analysis of incidents
- guidance document on open disclosure policies
- a business requirements and functional specification for an information and communications technology system to support incident management.⁽²³⁾

While the Implementation Steering Group has achieved progress on the implementation of a number of recommendations made in the Commission's report, there are still a number of recommendations from that report that have not been implemented to date. A summary of the recommendations from the Commission's report in relation to the coordination of patient safety surveillance can be found in Appendix 4 of this HIQA report.

Recommendations from the Commission on Patient Safety that have not been implemented to date include:

- enactment of measures now included in the Health Information and Patient Safety Bill
- the development of standards for adverse event reporting
- a national mandatory reporting system for adverse events that:
 - facilitates patient and family reporting
 - is compatible with and captures data from all existing reporting systems
 - may replace local reporting systems
 - produces aggregated validated data made available to the public
- a national agency responsible for the collection and sharing of information from the mandatory reporting system
- effective governance arrangements to ensure that individuals responsible for safety and quality exchange learning and improvements resulting from adverse events and near misses at regional and national levels
- education and training supports in relation to reporting systems
- a managed approach to health surveillance including patient safety data to involve the collation, interpretation, learning and sharing of sources of information from across the system.⁽²⁾

It is essential that the current set of recommendations made in this report are implemented to ensure consistent incident reporting across the health and social care sector to improve incident information so that it provides a valuable source of patient safety intelligence. Information from the incident reporting system is an important source of patient safety intelligence and should be triangulated and coordinated with other sources of patient safety intelligence to identify emerging patient safety risks, learn from past mistakes and improve patient safety.

Recommendation 10

The Department of Health should review and implement previous recommendations made in relation to incident reporting and patient safety intelligence.

- a. Previous recommendations made by both the Health Information and Quality Authority and the Commission on Patient Safety and Quality Assurance in relation to patient safety intelligence should be reviewed and implemented.

4. Conclusion

HIQA recognises the many rich sources of patient safety information available and the potential for this information to reduce the risk of harm to patients. However, the lack of coordination of this information, along with the lack of a national incident reporting system, for system wide learning results in the system not reaching its full potential in terms of improving patient safety.

As outlined in the 2014 CMO's report⁽¹⁾ there is a need to pool information that exists across agencies to create better risk and safety profiling of services in order to improve outcomes of care for patients. The potential of the healthcare system to provide learning opportunities and to reduce risk to patients has not been realised due to a number of factors. In the first instance, a national system for reporting and learning from patient safety incidents needs to be fully implemented. This would include implementing:

- one national incident management system
- formalising governance structures for incident reporting at a local level,
- quality assuring incident data
- best use of information generated from the reporting system
- enacting legislation that provides for mandatory reporting of serious reportable events.

The CMO's report also highlights the need for a single agency or body that has overall responsibility at the national level of the risk management and patient safety issues that emerge for numerous agencies. For this to be realised, overall responsibility for coordination of patient safety intelligence must be assigned to one agency or body and arrangements should be place to collate and review information from all relevant sources. A mechanism will need to be developed to issue regular patient safety reports and alerts. It will be important to develop a legal framework to support the overall patient safety surveillance system.

The international review gave some insights into the workings of patient safety surveillance systems in Europe. While the scope, reporting, legislation and governance of reporting systems differed between regions and jurisdictions, it was possible to note the areas which needed to be addressed in Ireland. A key principle which arose from this review is that for a comprehensive picture on patient safety to emerge, there needs to be triangulation of existing and new data sources of patient safety intelligence. It is imperative that follow-up work through investigating incidents and subsequent sharing of findings is undertaken in order to learn lessons from incidents and prevent their future occurrence. The concept of creating a 'just culture' which seeks to balance the need to learn from mistakes with the need to

take disciplinary action also emerged from the international areas reviewed with some countries having legislation in place to promote an open and non punitive patient safety culture.⁽²⁸⁾

It is important to consider the scope of the proposed patient safety surveillance system. A National Patient Safety Surveillance System should involve the triangulation of many sources of patient safety information and intelligence, including learning from incidents. It is necessary that the current sources of patient safety intelligence should be strengthened, including the implementation and national roll-out of a reporting and learning system for patient safety incidents.

Conducting the 'As is' analysis allowed the HIQA review team to note the strengths and the weaknesses of the current system. While it is clear that there are many rich sources of patient safety intelligence, weakness is the lack of coordination of such intelligence. Moving forward, the creation of a single national incident management system should be a priority. This, along with other important national sources of data, will support the overall patient safety surveillance system which will be led by a single agency or body who will take responsibility for the overall oversight of patient safety intelligence.

The implementation of the recommendations proposed to the Minister for Health in this document should ensure a more coordinated approach to patient safety intelligence in Ireland. Pooling of information will allow for improved risk and safety profiling. A National Patient Safety Surveillance System should provide early warnings of potential safety issues and risks to the system thus allowing for action to be taken to mitigate the risk and reduce harm. The implementation of these recommendations will help address the recommendation made in the CMO's report⁽¹⁾ referencing the need for an overall process of pooling risk information and intelligence in order to create a composite risk profile for the healthcare system.

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6. Appendices

Appendix 1 — Glossary of abbreviations

Term	Explanation
ADR	Adverse drug reaction
CCG	Clinical Commissioning Group
CHO	Community health organisations
CIS	Clinical Indemnity Scheme
CMO	Chief Medical Officer
CQC	Care Quality Commission
CRA	Clinical risk advisor
DPSIMS	Development of the Patient Safety Incident Management System
FOI	Freedom of information
GP	General practitioner
HIQA	Health Information and Quality Authority
HPRA	Health Products Regulatory Authority
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
ICPS	International Classification for Patient Safety
IIMS	Incident Information Management System
MHC	Mental Health Commission
MOU	Memorandum of Understanding
NIMLT	National Incident Management and Learning Team
NIMS	National Incident Management System
NIRF	National Incident Report Form
NHS	National Health Service, UK

Term	Explanation
NHS TDA	NHS Trust Development Authority
NQB	National Quality Board
NRLS	National Reporting and Learning System
NTMA	National Treasury Management Agency
PI	Performance indicator
PSI	Pharmaceutical Society of Ireland
PSIMS	Patient Safety Incident Management System
QAVD	Quality Assurance and Verification Division
SIMP	Safety Incident Management Policy
SRE	Serious Reportable Event
WHO	World Health Organisation

Appendix 2 – Glossary of terms

Term	Explanation
Audit	The assessment of performance against any standards and criteria (clinical and non-clinical) in a health or social care service. ⁽³⁰⁾
Adverse event	An incident which results in harm to the patient. ⁽²⁸⁾
Benchmarking	A continuous process of measuring and comparing care and services with similar service providers. ⁽³⁰⁾
Business Intelligence (BI)	Business Intelligence includes the applications, infrastructure and best practices that enable analysis of information to improve and optimise decisions and performance. ⁽³¹⁾
Complaint	An expression of dissatisfaction on the part of the patient or carer that represents a particular perception of events. A complaint may or may not reveal that a mistake or error has occurred. ⁽²⁸⁾
Data	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed. ⁽³¹⁾
Healthcare	Services received by individuals or communities to promote, maintain, monitor and restore health. ⁽³¹⁾
Health information	Health Information is defined as information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present or future, physical or mental health or social care of an individual (also referred to as a cohort). Health information also includes information relating to the management of the health and social care system. ⁽³²⁾
Healthcare organisation	Entity that provides, co-ordinates, and/or insures health and medical services for people. ⁽²⁸⁾
Incident reporting	A system in many health care organisations for collecting and reporting adverse patient occurrences, such as medication errors and equipment failures. It is based on individual incident reports. For several reasons, including fear of punitive action, reluctance

Term	Explanation
	of non-physicians to report incidents involving physicians, lack of understanding of what a reportable incident is, and lack of time for paperwork, the effectiveness of the incident reporting is limited. ⁽²⁸⁾
Information and Communications Technology (ICT)	The tools and resources used to communicate, create, disseminate, store and manage information electronically. ⁽³³⁾
Just culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action. ⁽²⁸⁾
Key Performance Indicators (KPI)	Specific and measurable elements of practice that can be used to assess the quality and safety of care. ⁽³⁰⁾
National Health and Social Care Data Collections	National repositories of routinely collected health and social care data, including administrative sources, censuses, surveys and national patient registries in the Republic of Ireland. ⁽³³⁾
'Near miss'	A deviation from best practice in health care delivery that would have led to unwanted harm to the patient or to the mission of the organisation, but was prevented through planned or unplanned actions. ⁽²⁸⁾
Negligence	Failure to exercise the skill, care and learning expected of a reasonably prudent healthcare provider. ⁽²⁸⁾
Open Disclosure	An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event. ⁽⁸⁾
Patient safety	Actions undertaken by individuals and organisations to protect health care recipients from being harmed by the effects of health care services. ⁽²⁸⁾
Patient safety data	The broad heterogeneous information that includes, but is not limited to, the description of incidents with

Term	Explanation
	medical errors and near misses, their causes, their follow-up corrective actions, interventions that reduce future risk, and patient safety hazards. ⁽²⁸⁾
Patient Safety Incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to the patient. ⁽²⁸⁾
Patient Safety Surveillance	An overall process of pooling of risk information and intelligence in order to create a composite risk profile for the healthcare system. ⁽¹⁾
Performance Indicators (PI)	Specific and measurable elements of practice that can be used to assess the quality and safety of care. ⁽³⁰⁾
Risk Management	One of a number of organisational systems or processes aimed at improving the quality of health care, but one that is primarily concerned with creating and maintaining safe systems of care. ⁽²⁸⁾
Regulation	A sustained and focused control exercised by a public agency over activities that are valued by a community. ⁽³¹⁾
Risk	The likelihood of an adverse event or outcome. ⁽³¹⁾
Secondary Care	Specialist care provided by an ambulatory or inpatient basis usually following a referral from primary care. ⁽³⁴⁾
Surveillance	Routine collection and review of data to examine the extent of a disease, to follow trends, and to detect changes in disease occurrence. ⁽²⁸⁾
Serious Incident	An incident that results in serious harm or death. ⁽⁸⁾
Serious Reportable Events (SREs)	Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. ⁽¹¹⁾
Service User	Members of the public who use, or potentially use, health and social care services as patients, carers, parents and guardians. This also includes organisations and communities that represent the interests of people who use health and social care

Term	Explanation
	services. ⁽⁸⁾
Surveillance	Routine collection and review of data to examine the extent of a disease, to follow trends, and to detect changes in disease occurrence. ⁽²⁸⁾
Stakeholder	An individual who has an interest in the activities of an organisation and the ability to influence it. A hospital's stakeholders, for example, include its patients, employees, medical staff, government, insurers, industry, and the community. ⁽²⁸⁾

Appendix 3 – Members of the National Patient Safety Surveillance Advisory Group

Member	Representing	Stakeholder
Dr Almath Spooner	Health Products Regulatory Authority	Health Products Regulatory Authority
Bernard Gloster	Community Health Organisations	HSE
Bridie O Sullivan	South/South West Hospital Group	HSE
Brigid Doherty	Patient Advocate	Patient Focus
Dr Colm Henry	National Clinical Advisor and Group Lead for Acute Hospitals	HSE
Cornelia Stuart	Quality Assurance and Verification Division	HSE
Declan Carey	Council and Social Workers Registration	CORU
Eileen Ruddin	Acute Hospitals Division	HSE
Eileen Whelan	Dublin Midlands Hospital Group	HSE
Dr Philip Crowley/ Elaine Fallon	Quality Improvement Division	HSE
Prof Freddie Wood	Irish Medical Council	Medical Council
Dr Gary Courtney/ Eilis Croke	National Clinical Programme for Acute Medicine	HSE

Member	Representing	Stakeholder
John Sadlier	Fitness to Practice	An Bord Altranais
Dr Kieran Ryan	Irish College of General Practitioners	Irish College of General Practitioners
Pat Healy	Social Care Division	HSE
Pat Kirwan	State Claims Agency	State Claims Agency
Patrick Lynch	Quality Assurance and Verification Division	HSE
Richard Corbridge	Chief Information Officer	HSE

HIQA members

Rachel Flynn

Dr Barbara Foley

Helen Byrne

Catherine Duggan

Stakeholder

Health Information and Quality Authority

Appendix 4 — Summary of recommendations from the Commission on Patient Safety and Quality Assurance

Open communication with patients following an adverse event

R4.16 National standards for open disclosure of adverse events to patients should be developed and implemented.

R4.17 Legislation should be enacted to provide legal protection/privilege for open disclosure. Such legislation should ensure that open disclosure, which is undertaken in good faith in compliance with national standards developed in accordance with the recommendation above, cannot be used in litigation against the person making the disclosure.

R4.18 Open communication principles, policies and standards should be included in the education curricula of all healthcare professionals and embedded in codes of professional practice.

Education, training and research on patient safety

R5.18 All healthcare facilities must provide pre-employment mandatory induction training for all healthcare workers that specifically includes patient safety modules (including the reporting of adverse events). Refresher patient safety training should be provided on a regular basis.

Clinical Audit

R7.11 Legislation should be enacted to give exemption from Freedom of Information legislation and to grant legal protection from disclosure to data related to patient safety and quality improvement that are collected and analysed by healthcare organisations for internal use or shared with others solely for purposes of improving safety and quality.

Reporting, managing and learning from adverse events

R7.19 The WHO standardised taxonomy, which describes definitions of adverse events, should be adopted on a national basis.

- R7.20** Standards should be developed for adverse event reporting across both public and private healthcare providers.
- R7.21** A national mandatory reporting system should be introduced for the collection of standardised information on adverse events that result in death or serious harm. The system must clearly delineate the events which must be reported, such as those listed in the National Quality Forum's 28 Never Events, but should not be confined to those events. The system should include provision for the voluntary reporting of other non-serious adverse events and 'near-misses'.
- R7.22** In order to be effective, the collection and dissemination of this information must be the responsibility of a national agency that can provide national leadership on learning from errors. The agency should provide analysis and feedback in order to ensure that lessons are learned and models of best practice are implemented effectively.
- R7.23** Effective governance arrangements should be put in place to ensure that the Clinical Leaders responsible for safety and quality in healthcare facilities, and other relevant individuals, should exchange learning and improvements resulting from adverse events and near-misses at regional and national levels. Where these are employees of facilities within the Health Service Executive, these arrangements should connect seamlessly into the HSE's corporate governance arrangements.
- R7.24** A group should be established to collaborate and report on the detailed implementation of these recommendations and in particular the most appropriate repository for the maintenance of such a comprehensive database and the dissemination of learning throughout the system including the facilitation of rapid alerts as necessary.
- R7.25** The national reporting system should be compatible with and capture data from all existing incident reporting systems, or may replace local systems. The information collected in this database should inform all safety and quality initiatives, policies and clinical protocols.
- R7.26** Every healthcare facility must have a serious adverse event policy which is immediately triggered when a serious adverse event takes place. The Group needs to consider the reporting arrangements and timeframe for reporting such events into the proposed national system.
- R7.27** Every healthcare facility should ensure that, as part of its safety and quality governance arrangements, the reporting, investigating, monitoring, learning

and management of adverse events and near-misses is discharged effectively and reported to the Board of the facility.

R7.28 Professional regulatory bodies should include mandatory reporting as an ethical obligation within their Codes of Professional Practice.

R7.29 Professional regulatory bodies should collaborate to develop clear guidelines for health professionals in relation to reporting of adverse events and unsafe practices.

R7.30 The design of the reporting system must also facilitate patient and family reporting of adverse events, and patients should be advised accordingly.

R7.31 Aggregated validated data should be made available to the public in the form of annual reports.

R7.32 Information collected under the reporting system (both mandatory and voluntary) must be strictly confidential, protected from legal discovery and exempted from Freedom of Information legislation.

R7.33 Such legislation must require disclosure to appropriate professional regulatory bodies where there is evidence of significant deviation from agreed standards of care. If a criminal act has taken place, the appropriate legal authorities must be notified.

R7.34 There must be adequate administrative and IT resources in place to support the reporting system.

R7.35 Education and training supports in relation to reporting systems, including the development of appropriate skills for dealing with adverse events, must be provided at all levels of the health system, from undergraduate and postgraduate education to continuing professional development programmes.

Health information and health information technology (HIT)

R7.53 An effective information governance framework, and underpinning legislation, should be developed and implemented across the health system. This should include the requirement of providers to implement clear plans and the allocation of responsibility that forms the basis of business rules governing how health information is exchanged and utilised.

R7.46 The planning of health information and HIT developments should be an integral part of the planning of health service developments to ensure that the full potential of health information and HIT to improve patient safety is

realised. This should be driven by a patient-centred approach, with full clinical engagement learning systems design, in order to enable the delivery of health services to the patient in whatever setting.

R7.47 The underlying information communication technology (ICT) infrastructure, and applications within all aspects of healthcare, should be recognised as the foundation for all patient-centred systems. The infrastructure should therefore be seen as a key enabler of patient safety and quality and ICT infrastructure standards should be set at a national level to ensure good levels of reliability, performance, security and interoperability.

R7.55 A managed approach to health surveillance which includes patient safety data should be developed across Ireland. This should involve the coherent collation, interpretation, learning and dissemination of sources of information from across the system, including information from the national mandatory reporting system for adverse events.

Appendix 5 — Summary of recommendations in relation to patient safety surveillance from previous HIQA investigations

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.⁽³⁾

Recommendation 6 -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:

g. 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.

Recommendation 8 -The Health Service Executive (HSE), the chief executive officer of each hospital group and the State Claims Agency must immediately develop, agree and implement a memorandum of understanding between each party to ensure the timely sharing of actual and potential clinical risk information, analysis and trending data. This information must be used to inform national and hospital-group patient safety strategies.

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.⁽⁴⁾

N15 - The HSE should put in place arrangements to collate and review information from national and international inquiries, reviews, investigations and coroner's 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.

N19 - 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.

L14 - 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. The Group should ensure that the review, implementation and monitoring of actions, trend analysis and implementation of learning from such incidents are disseminated to staff and incorporated within the clinical governance arrangements in the Group.

N3 - 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

Appendix 6 — Health Information and Patient Safety Bill

Health Information and Patient Safety Bill – Definition of Patient Safety Incidents⁽⁶⁾

The Health Information and Patient Safety Bill defines a patient safety incident in relation to a relevant provider as:

- a) any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service
- b) an event that occurred when providing a health service to a service user that did not result in actual injury or harm but there are reasonable grounds to believe that the event concerned placed the service user at risk of unintended or unanticipated injury or harm (no harm incident)
- c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted if it had not been prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user (near misses).

Any private health service providers regulated by HIQA/the Chief Inspector of Social Services must notify the chief inspector of serious incidents. Private providers of mental health services will be required to notify the Mental Health Commission of serious incidents. Less serious incidents and near misses may be reported by public providers to the SCA. Requirements in the Bill supplement existing obligations by State Authorities (including the public health service) to report “adverse incidents” to the SCA under the National Treasury Management Agency (NTMA) Amendment Act 2000. HIQA and the Mental Health Commission will jointly set standards for the notifications and the intention is that notifications made in line with these standards will have the protections recommended by the Commission on Patient Safety and Quality Assurance.

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For further information please contact:

**Health Information and Quality Authority
Dublin Regional Office
George's Court
George's Lane
Smithfield
Dublin 7**

**Phone: +353 (0) 1 814 7400
URL: www.hiqa.ie**

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