



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

'As is' analysis of patient safety intelligence systems and structures 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.

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1. Introduction

1.1 Background

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. 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 of risk information and intelligence in order to create a composite risk profile for the healthcare system'.⁽¹⁾

The report indicates that had the data obtained in the course of the CMO's review, been collated and examined, it could have shown that there was good reason to suspect that there may have been an ongoing problem with the outcomes of care experienced by service users and or patients in Portlaoise Hospital. The report⁽¹⁾ outlined that there is a need to pool information that may exist across agencies in order to create better risk and safety profiling of services. It also stated that a National Patient Safety Surveillance System would be of benefit to the health and social care system and to HIQA, as it could provide early warnings of potential safety issues and risks to the system.

The CMO's report also highlights that there is no single agency or body that has national oversight of the risk management and patient safety issues that emerge for numerous single agencies. This signifies that intelligence gathered within single agencies does not become part of an overall pooling of risk information. HIQA's patient safety investigation at the Midlands Regional Hospital, Portlaoise reported that while there was knowledge within the system that there may be potential risks to patients, the interaction between relevant agencies in relation to the sharing and use of the available information did not result in effective mitigation of the identified risks.⁽²⁾ These findings illustrate that different pieces of patient safety intelligence are held by different agencies in Ireland, an identified weakness of Ireland's patient safety system (Figure 1 illustrates some of the current agencies that are sources of patient safety intelligence in Ireland). There must be a stronger system of using and sharing information to improve quality and safety for patients.

In 2008, the Report of the Commission on Patient Safety and Quality Assurance⁽³⁾ also made a number of recommendations about the coordination of patient safety intelligence. It outlined that it is essential that there is a national surveillance resource that receives reports of 'serious adverse events' from across the system in order to ensure that appropriate action has taken place, that trends are monitored

and that learning takes places to inform future healthcare delivery and governance arrangements.⁽³⁾

Figure 1. Potential agencies and or bodies with patient safety intelligence in Ireland⁽¹⁾



1.1.1 Definition of a national patient safety surveillance system

A formal definition of 'national patient safety surveillance system' is not provided in the CMO's report, however, reference is made to the need for 'an overall process of pooling of risk information and intelligence in order to create a composite risk profile for the healthcare system'.⁽¹⁾

The 2009 Council of the European Union recommendation on patient safety (2009/C 151/01)⁽⁴⁾ 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; these reporting systems should be differentiated 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.⁽⁵⁾

In light of the CMO's report,⁽¹⁾ this 'As is' analysis aims to document the systems that are currently in place for reporting, analysing and implementing learning from patient safety incidents and adverse events at a national level, through identifying current sources of national patient safety information in Ireland.

1.2 Purpose of this 'As is' analysis and the overall project

Under the Health Act 2007,⁽⁶⁾ sections 8(1)(j) and 8(2)(d), one of HIQA's functions is to provide advice to the Minister for Health and the HSE about deficiencies identified regarding health information.

There are four stages involved in this project to develop recommendations for the Minister for Health on coordinating patient safety intelligence in Ireland. The first stage of the project, which was completed in May 2015, involved conducting an international review of patient safety surveillance systems in four jurisdictions. This 'As is' analysis of patient safety intelligence systems and structures in Ireland forms the second stage of the project and documents existing sources of patient safety intelligence in Ireland.

The third stage of the project involves convening an advisory group to access expertise in this area and to engage with people on whom the final outputs of the project will have an impact. The international evidence, findings of the 'As is' analysis and advisory group input will form the basis for a set of recommendations to the Minister for Health on coordinating patient safety intelligence in Ireland.

Stage 1: International review of patient safety surveillance systems.

Stage 2: 'As is' analysis documenting existing sources of patient safety intelligence in Ireland.

Stage 3: Convening of an expert advisory group.

Stage 4: Developing recommendations for coordinating patient safety intelligence in Ireland.

1.3 International review of patient safety reporting and learning systems

As part of this project, HIQA conducted a review of the existing international evidence in relation to patient safety reporting and learning systems. A number of relevant international and European reviews of patient safety reporting and learning systems have been published in the past decade and these include the following:

- Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe (2014).⁽⁷⁾
- Council of the European Union Recommendations on patient safety (Council Recommendation 2009/C 151/01).⁽⁵⁾
- World Health Organization (WHO) draft guidelines for adverse event reporting and learning systems (2005).⁽⁸⁾

The main findings in relation to patient safety reporting systems outlined in the reviews listed above include the following:

- 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 make recommendations for addressing patient safety risks.
- The system must encourage healthcare workers to actively report 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.

HIQA also carried out an in-depth analysis of the structures in place in four international regions and jurisdictions. This international review is available at www.hiqa.ie. Detailed discussions were held with representatives from four locations, namely British Columbia (Canada), Denmark, England and Scotland. The importance of coordinating and sharing patient safety intelligence was evident in all of the regions reviewed, with various mechanisms in place for sharing intelligence such as national alerting systems and data sharing agreements.

1.4 Methodology for this 'As is' analysis of patient safety systems and structures in place in Ireland

Following completion of the international review of patient safety surveillance systems, this 'As is' analysis forms the second stage of the overall project to develop recommendations to the Minister for Health on coordinating patient safety intelligence in Ireland. This 'As is' analysis involved both desktop research and meetings with relevant stakeholders in relation to patient safety intelligence in Ireland. Desktop research was initially conducted to determine the main sources of patient safety intelligence in Ireland and to document the current structures in place for reporting, analysing and learning from patient safety incidents. This was followed up by meetings with relevant stakeholders to clarify the information obtained and to further discuss relevant themes. The themes explored during the discussions related to the current systems in place for:

- patient safety structures
- policies surrounding patient safety
- reporting processes and systems
- coordination and sharing of data
- ongoing developments.

1.5 Summary of current systems for national incident reporting in Ireland

There is currently no overarching agency or body at national level with oversight or specific responsibility for monitoring risk management and patient safety issues

emerging from single agencies, such as hospitals, community care, and other health and social services.

There is currently one national system for health and social care incident reporting in Ireland. The **National Incident Management System** (NIMS — formerly STARSweb) within the State Claims Agency is the information system through which hospitals funded by the Health Service Executive (HSE) report clinical and non-clinical incidents. All these services are covered by the State's Clinical Indemnity Scheme.

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.

There are also a number of additional sources of patient safety intelligence in Ireland, held by other agencies including:

- Health Information and Quality Authority (HIQA)
- Health Products Regulatory Authority (HPRA)
- National Haemovigilance Office (NHO)
- Health Protection Surveillance Centre (HPSC)
- Coroners service
- Mental Health Commission (MHC)
- National Office of Clinical Audit (NOCA)
- Medical Exposure Radiation Unit (MERU)
- Environmental Protection Agency (EPA)
- Health and Safety Authority (HSA)
- Other agencies who hold patient safety intelligence.

The following sections of this 'As is' analysis will detail the current situation in relation to:

- quality and patient safety structures and policies in place within the HSE
- the National Incident Management System managed by the State Claims Agency
- additional sources of patient safety intelligence in Ireland.

2. Quality and patient safety structures and policies within the HSE

2.1 Introduction

At the time of this analysis, the HSE had recently re-structured its national quality and patient safety functions to give it an enhanced role in relation to both quality improvement and quality assurance. The following section discusses the new quality and patient safety structures within the HSE that were introduced in 2015.

2.1.1 Quality and patient safety enablement programme

A quality and patient safety enablement programme was set up in October 2014 and required a re-structuring of the HSE's former quality and safety functions to support a quality and safety agenda at corporate, divisional and service-provider levels. There are two new divisions within its quality and patient safety enablement programme, namely the Quality Improvement Division and the Quality Assurance and Verification Division. To deliver on the quality and patient safety enablement programme, two national directors had been assigned organisational leadership roles with responsibility for the Quality Improvement Division and the Quality Assurance and Verification Division. At the time of this report, there are also six divisional leads for quality and patient safety within the HSE (covering the areas of primary care, acute hospitals, mental health, health and wellbeing, social care, and ambulance services).

2.1.2 Quality Improvement Division

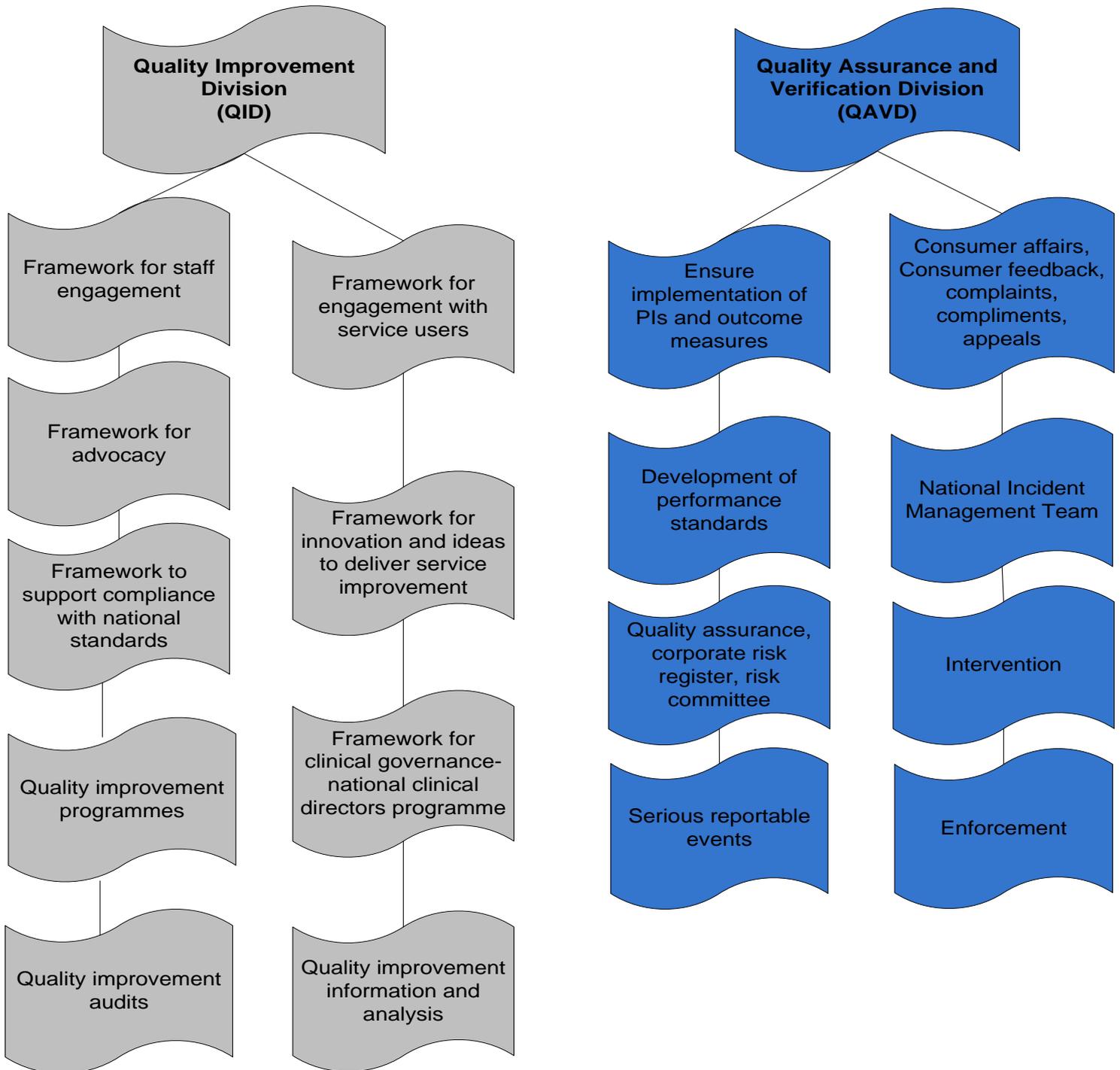
The Quality Improvement Division of the HSE is responsible for the oversight of all areas of quality improvement including quality improvement programmes and quality improvement information and analysis. Examples of quality improvement programmes include measures to reduce pressure ulcers, and its nourishment, nutrition and hydration programme. The Quality Improvement Division is directly supporting a number of other quality improvement initiatives including the National Office of Clinical Audit (NOCA). The Quality Improvement Division is also tasked with developing a number of quality improvement frameworks including ones for staff engagement, service users and a framework for advocacy (see Figure 2 for a breakdown of Quality Improvement Division functions).

2.1.3 Quality Assurance and Verification Division

The Quality Assurance and Verification Division has important functions in terms of assuring performance within the HSE, risk management for all hospitals, hospital groups and community health organisations (CHOs) and implementing recommendations that are made across the health and social care sector.

The National Performance Oversight Group (NPOG) has been established under the remit of the Quality Assurance and Verification Division. The National Incident Management and Learning Team, Consumer Affairs and Quality Assurance and Verification are now incorporated into the Quality Assurance and Verification function (see Figure 2 for a breakdown of Quality Assurance and Verification functions).

Figure 2. Areas of responsibility of Quality Improvement Division and Quality Assurance and Verification Division⁺



⁺ HSE's National Service Plan 2015.⁽⁹⁾

2.1.4 HSE Accountability Framework 2015

Following the HSE's re-structuring of its quality and patient safety functions in 2015, a new accountability framework has also been introduced as outlined in the HSE's National Service Plan 2015.⁽⁹⁾ The accountability framework for 2015 sets out the means by which the HSE and its national divisions, hospital groups and community healthcare organisations (CHOs) are held to account for their performance.

An important feature of the new accountability framework is the introduction of formalised performance agreements, which explicitly links accountability for the delivery of the HSE's National Service Plan to managers at each level of the organisation, supporting the new structures within the health service. The performance agreements focus on a number of priorities (access, quality and safety, financial resources and workforce) that are outlined in the HSE's service plan and are captured in a 'balanced scorecard'.[‡]

These metrics are further broken down into a series of key performance indicators (specific and measurable elements of practice that can be used to assess quality and safety of care, also known as KPIs). For example, compliance with the reporting of serious reportable events is now a KPI for measuring quality. Another important feature of the new accountability framework has been the establishment of a National Performance Oversight Group which is now the principal planning and performance assurance group within the HSE, replacing the National Planning, Performance and Assurance Group. The standing membership of the National Performance Oversight Group includes the Deputy Director General, Chief Financial Officer, National Director of the Quality Assurance and Verification Division and the National Director of Human Resources. It is the responsibility of the National Performance Oversight Group to account for performance against the HSE's service plan through individual meetings with each of the six national directors for services on a monthly basis, in order to review the performance of their division against the HSE's service plan. It is stated with the HSE service plan 2015 that where there are issues of persistent under-performance, the HSE will implement a formal performance escalation, support and intervention process to address any issues with underperformance.⁽⁹⁾

[‡] Note: An example of a balanced scorecard for acute services can be found in Appendix 3.

2.1.5 HSE's key performance indicators introduced in 2015

A number of new key performance indicators in relation to quality and patient safety have been introduced in 2015 by the HSE and are outlined in its service plan for 2015⁽⁹⁾ (see table 1 below).

Table 1. Key performance indicators for quality performance for 2015

Key performance indicator	Expected activity or target 2015
Serious reportable events Percentage of serious reportable events being notified within 24 hours to designated officer	99%
Percentage of mandatory investigations commenced within 48 hours of event occurrence	90%
Percentage of mandatory investigations completed within four months of notification of event occurrence	90%
Reportable events Percentage of events being reported within 30 days of occurrence to designated officer	95%
Adverse events Percentage of claims received by the State Claims Agency that should have been reported previously	New performance indicators 2015

2.2 HSE policies in relation to incident reporting and patient safety

The HSE's Safety Incident Management Policy (2014)⁽¹⁰⁾ outlines its policy for managing safety incidents. In this policy it is outlined that the HSE recognises the importance of learning from safety incidents and therefore promotes an environment within which healthcare professionals are encouraged to report, investigate, share and implement learning from safety incidents promptly. It is stated within the policy that safety incident management happens within the framework of the principles of open disclosure, integrated risk management, 'just culture' and fair procedures. The following policies and guidelines are in place in the HSE in relation to incident management:

- Safety Incident Management Policy (May 2014)
- Serious Reportable Events (SREs) Guidance (Jan 2015)
- Guidelines for Systems Analysis Investigation of Incidents and Complaints (Nov 2012)
- Criteria for the Communication or Escalation of Incidents to the National Incident Management and Learning Team (2015)
- HSE and State Claims Agency Open Disclosure: National Policy (Oct 2013)
- The HSE and State Claims Agency National Guidelines: Open Disclosure: Communicating with service users and their families following adverse events in healthcare (2013).

An outline of these HSE policies is provided in more detail in the following sections.

2.2.1 HSE Safety Incident Management Policy

The Safety Incident Management Policy defines an incident as 'an event or circumstance which could have, or did lead to unintended and or unnecessary harm'. Incidents include:

- adverse events which result in harm
- near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention
- events reported by staff, or service-user complaints, which are associated with harm.⁽¹⁰⁾

Incidents can be clinical or non-clinical and include incidents associated with harm to patients, service users, visitors and staff. Incidents can also be related to information communications technology (ICT) systems, data security (for example, data protection breaches) and environment-related, such as slips and trips. A 'serious incident' is defined as an incident that results in death or serious harm.

It is the policy of the HSE that all safety incidents are identified, reported, investigated and disclosed as outlined below. The six steps in managing and investigating a safety incident that has occurred are outlined in the Safety Incident Management Policy (2014)⁽¹⁰⁾ as follows:

- Step 1: Identification of a safety incident
- Step 2: Reporting of a safety incident
- Step 3: Assessment of a safety incident
- Step 4: Convening a safety incident management team
- Step 5: Investigation of a safety incident
- Step 6: Safety improvement.

Step 1: Identification of a safety incident

Incidents can be identified by an employee, patient, service user, carer, visitor or through surveillance, audit or the patient-transfer process. All healthcare employees must ensure that they manage all immediate safety concerns following identification of a patient safety incident and follow national guidance on open disclosure as outlined in the HSE/State Claims Agency 'Open Disclosure: National Guidelines' and Policy (2013).⁽¹¹⁾ Further information on open disclosure is outlined in section 2.2.4.

Step 2: Reporting of a safety incident

The person who identifies the incident must complete a safety incident report form and report the incident to their line manager. All incidents (including serious reportable events) must be reported to the National Incident Management System. Further information on reporting to this incident management system is outlined in Chapter 3.

Following a reported incident, it is the responsibility of the manager to manage minor incidents locally. All 'serious incidents' must be reported to the senior accountable officer[‡] within 24 hours of happening so that it can be communicated and or escalated (see definitions below) to the divisional level of management.

Communication- by the local manager to the next level of management refers to providing information about the incident so that the higher level of management is aware of it. There is no transfer of responsibility for the management of the incident to the next or any higher level of management.

[‡] The senior accountable officer is the person who has ultimate accountability and responsibility for the services under his or her governance, for example, in the case of a hospital, it is the hospital's chief executive officer and in the case of a community area it is the community health officer.

Escalation- refers to the process whereby the local manager reports the safety incident to the management level above them and onward to the hospital group and or primary care area and or administrative area and national-director level as required. An incident is escalated when the local manager determines that additional support is required for managing and investigating the incident (a copy of a blank communication and or escalation form can be found in Appendix 4).

The HSE's Safety Incident Management Policy⁽¹⁰⁾ and the National Incident Management and Learning Team⁽¹²⁾ outline criteria for incidents which must be escalated and or communicated through the line management structure to the national director level or the National Incident Management and Learning Team level for further management and investigation. An overview of the HSE's escalation process for serious incidents is provided in Figure 3.

Following an incident report, the HSE is also required to report certain incidents to other internal or external agencies in line with HSE reporting requirements. For example, radiation incidents (such as a patient receiving the wrong dose of radiation) are required to be reported to the HSE's Medical Exposure Radiation Unit (MERU). Appendix 14 outlines in detail the agencies to whom the HSE reports.

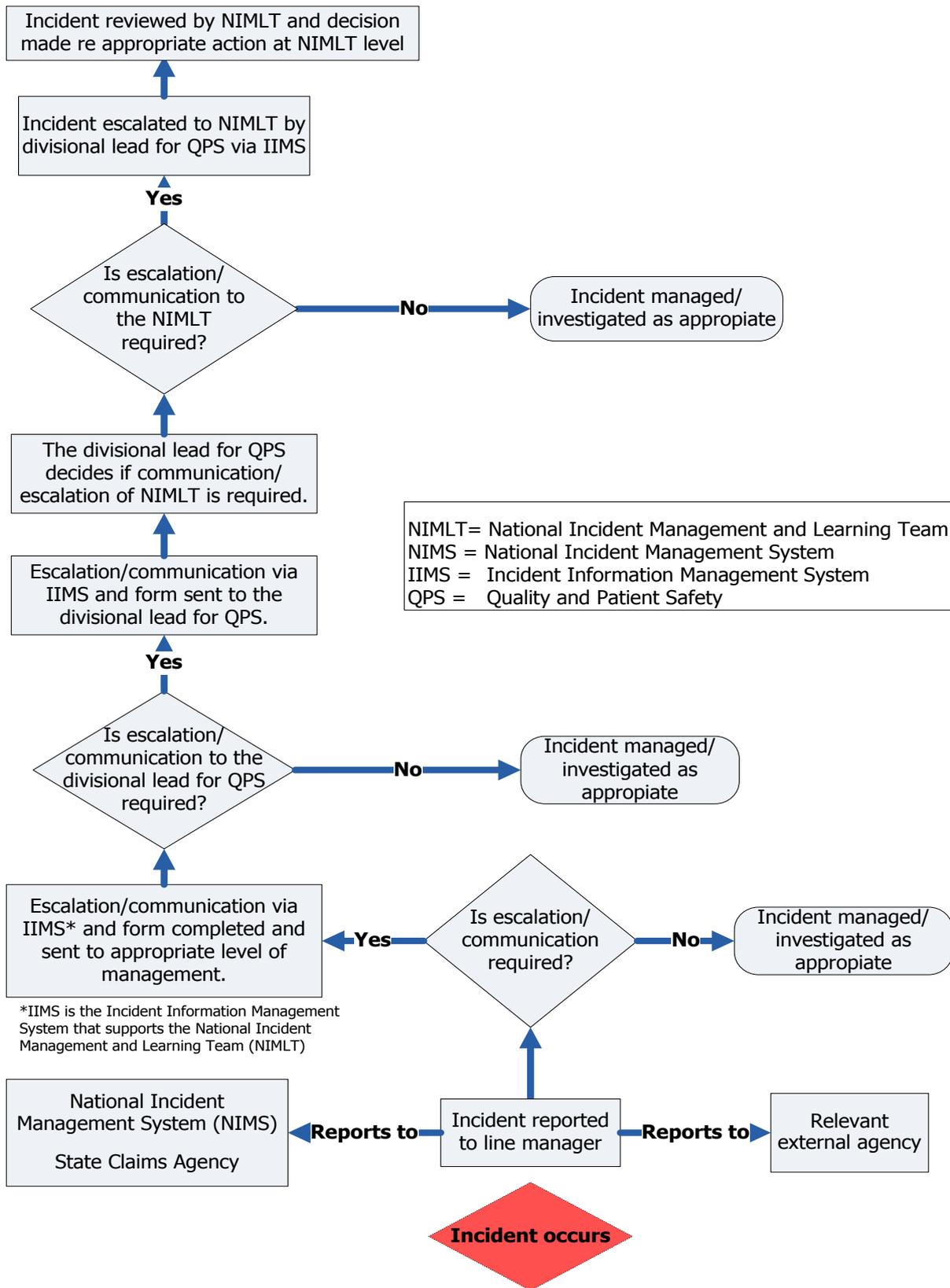
Step 3: Assessment of a safety incident

Following the management of immediate safety concerns, line managers must assess the safety incident to determine the level of investigation required. For 'serious incidents' the assessment must happen within 24 hours after the incident has occurred. Assessment of an incident involves establishing the context of the incident, its impact, and deciding on the appropriate type of investigation required. It also covers reporting requirements, ongoing management plan and whether onward escalation and or communication to the next level of management is required. The local manager may decide that no further investigation is required.

Step 4: Convening a safety incident management team

All safety incidents that require investigation are managed by a safety incident management team, convened by the senior accountable officer within 24 hours of the incident being notified. (This is a new key performance indicator for 2015.) The safety incident management team must be convened for incidents resulting in death or serious harm and rated as causing major or extreme harm according to an impact table.⁽¹⁰⁾ The full impact table can be found in Appendix 6.

Figure 3. Overview of the HSE's escalation/communication procedure for incidents⁽¹²⁾



Step 5: Investigation of a safety incident

As stated in the Safety Incident Management Policy of the HSE the purpose of safety investigations is to collect and analyse data to identify the system-causes of harm so that recommendations can be made to improve the safety of health services. In all safety investigations there must be communication and management of safety concerns before the investigation is complete and furnished to the investigation commissioner, who is normally the senior accountable officer in a service and or division. This person must ensure that associated recommendations are urgently communicated within the service and to other relevant parts of the HSE for both learning and quality and safety improvement purposes.

All incidents that result in death or serious harm — classed as serious incidents — must be assessed by appropriate local senior managers within one day of the reported incident to determine whether the incident was preventable and or avoidable. If the incident is assessed as being unpreventable or unavoidable, based on strong immediately available evidence, then a decision not to undertake a further investigation is made. This must be communicated to all relevant individuals including the senior accountable officer, the service user and or family where appropriate and staff. The decision must also be considered at the next meeting of the senior-accountable-officer level quality and patient safety committee.

If there is no immediate evidence that the incident was unpreventable or unavoidable, then an investigation must be started in line with the HSE's guidance as set out in its Guidelines for Systems Analysis Investigation of Incidents and Complaints⁽¹³⁾ (see section 2.2.3 of this report). The senior accountable officer must commission the investigation team within two working days of a reported incident (another new key performance indicator for 2015). The need for external and or expert input will become apparent as the investigation progresses. The lead investigator should attend meetings of the safety incident management team to give updates on the progress of investigations and communicate any immediate safety concerns that the incident management team needs to address.

Step 6: Safety improvement

Following an investigation of a patient safety incident, recommendations to improve the quality and safety of services must be acted on. Recommendations should be assigned to a person or persons who are accountable and responsible for their implementation, with a designated time frame for completion. The investigation team and the safety incident management team should be separate teams with different members.

The investigation commissioner (normally the senior accountable officer) is responsible for ensuring the assessment, circulation, monitoring and implementation of the recommendations and sharing of the learning both locally and nationally, as appropriate, once they have received a report from the investigators. All final investigation reports should be anonymised in terms of location and identifiable persons. The investigation report should be provided to the patient or their family member or advocate. Responsibility for implementing recommendations depends on the governance level to which the recommendation is addressed, for instance, local management is responsible for implementing local recommendations, and national directors are responsible for implementing national recommendations. It is the responsibility of local managers to communicate nationally applicable recommendations to the appropriate national director in the HSE.

The safety incident management process outlined above generally refers to individual incidents, but some elements apply to multiple incidents where aggregate analyses and look-back reviews are covered. It is the policy of the HSE that safety incident investigations should always proceed where possible. An overview of the incident management process in the HSE can be found in Appendix 7.

2.2.2 Guidance in relation to serious reportable events

One subset of all serious incidents is described by the HSE as serious reportable events. These are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.⁽¹⁴⁾ Since January 2015, the number of serious reportable events reported has been published on the HSE website⁽¹⁵⁾ as part of its monthly performance report. In addition, a special report⁽¹⁶⁾ on serious reportable events published by the HSE in November 2015 stated that in the 19 months between March 2014 and September 2015, 233 serious reportable events were reported with 74% of these occurring in the acute hospitals division, following implementation of mandatory reporting for serious reportable events.

Formal reporting of serious reportable events started in March 2014 and it is a mandatory requirement of the HSE that all such events are reported to the National Incident Management System and are managed through the Safety Incident Management Policy⁽¹⁰⁾ and the National Incident Management and Learning Team communication and or escalation process.⁽¹²⁾ There are also specified timelines for reporting. For example, serious reportable events must be reported to the relevant line manager within 24 hours.

Investigations must start within 48 hours of the organisation becoming aware of the incident and these investigations must be completed within four months of

commencing (a new key performance indicator for 2015). All serious reportable events must also be communicated to the National Incident Management and Learning Team. Serious reportable events that have national implications or are cross-divisional in nature must be escalated to the National Incident Management and Learning Team from divisional level via the communication and or escalation form and through the Incident Information Management System.

There are 35 events included in the HSE's list of serious reportable events classified into the following categories:

- surgical events (for example, wrong-site surgery)
- product or device events (such as a patient's death or serious disability associated with the use of contaminated drugs)
- patient protection events (for instance, a child or dependent person discharged to the wrong person by a healthcare provider)
- care management events (e.g. the wrong route administration of chemotherapy by a healthcare provider)
- environmental events (for example, a patient's death or serious disability associated with a fall while being cared for in a healthcare facility)
- criminal events (such as a patient's death or serious disability associated with physical assault while being cared for in a healthcare facility).⁽¹⁴⁾

If there are no serious reportable events for a particular period, a 'no event declaration' must be signed by the responsible national director. A full list of serious reportable events in place from January 2015 can be found in Appendix 8.

2.2.3 Guidelines for systems analysis investigation of incidents and complaints

The purpose of the Guidelines for Systems Analysis Investigation of Incidents* and Complaints is to provide a standardised methodology for systems analysis investigations that are undertaken by the HSE. In particular, incidents that result in death or serious harm (serious incidents) should be investigated using a systems analysis method. The guidelines are designed to guide investigators in conducting investigations using the systems analysis method and good investigation practice.⁽¹³⁾

2.2.4 Open disclosure — national policy and guidelines

The HSE's National Policy on Open Disclosure⁽¹⁷⁾ aims to ensure that communication with service users and their families following an adverse event is undertaken in an empathetic, informed and timely manner. Open disclosure forms part of the incident

* This policy is currently under review and a new version of the policy is due to be published in the coming months.

management process in line with the HSE's Safety Incident Management Policy 2014⁽¹⁰⁾ and must be recognised as a necessary component in the management and review of incidents. To support the implementation of the HSE's Policy on Open Disclosure,⁽¹⁷⁾ the HSE and the State Claims Agency have jointly developed open disclosure guidelines.⁽¹¹⁾ These guidelines aim to establish a standardised approach by healthcare professionals when communicating with service users following an adverse event and ensure that communication with service users and staff members involved happens in a supportive and timely manner.⁽¹¹⁾

While there are policies and guidelines in place to support open disclosure, Ireland currently has no protective legislation in place to promote a 'just culture' or to assist and protect healthcare staff when reporting or disclosing incidents.

2.2.5 HSE complaints policy

The Health Act 2004 made provision for the introduction of a statutory complaints system within the HSE. Complaints must be managed in line with the 'Your service your say' complaints policy,⁽¹⁸⁾ which outlines the complaints management process within the HSE. Patients, services users and the public can make a complaint through a number of avenues including the following:

- HSE — in person through contact with HSE staff; a service manager or complaints officer or via telephone, email or online (feedback form).
- advocacy services — through contact with a number of advocacy services including the National Advocacy Unit (HSE), Citizens Information and the advocacy group, Patient Focus.

The complaints policy outlines a three-stage process which can ultimately be escalated to warrant an internal review within the HSE. The HSE's annual report for 2013⁽¹⁹⁾ reported that 6,823 complaints were recorded for HSE hospitals and 5,573 complaints by voluntary hospitals in 2013. Of these, 200 complaints resulted in escalation to stage three of the complaints process. Staff or service-user complaints which are associated with harm can be deemed as incidents and must be managed and reported in line with the HSE's Safety Incident Management Policy (2014).⁽¹⁰⁾ Complaints that have resulted in death or serious harm should be investigated in line with the HSE's guidelines for systems analysis and investigation of complaints.⁽¹³⁾ The State Claims Agency is working on an enhanced complaints module which is designed in line with the HSE's 'Your service your say' complaints policy.⁽¹⁸⁾ This module will allow HSE complaints officers to log complaints and associated issues on the National Incident Management System in line with the HSE structures, and then manage these complaints through to closure.

The above section outlines the policies in place within the HSE for managing incidents. The following section aims to discuss the National Incident Management and Learning Team and its role in the oversight of the incident management and investigation process in line with HSE policies for safety incidents.

2.3 HSE's National Incident Management and Learning Team (NIMLT)

The role of the National Incident Management and Learning Team is to promote and support improvements in the management and investigation of incidents, including ensuring a standardised approach, with supporting policies, procedures, guidelines and training. The National Incident Management and Learning Team was formerly comprised of alternating team members who convened on a part-time basis. Since 2014, it now operates as a full-time function within the Quality Assurance and Verification Division structure of the HSE and includes a team lead, a number of case managers and support staff. The National Incident Management and Learning Team also seeks input from external experts for some incidents.

An Incident Information Management System (further details on this system are outlined in section 2.4 of this report) within the HSE was developed to support its divisions to manage incidents in line with its Safety Incident Management Policy (2014).⁽¹⁰⁾ However, Phase 2 implementation of the National Incident Management System within the State Claims Agency will involve extending this system's function to address the incident information management needs currently being recorded on the HSE's system. Once in place, the HSE system will be discontinued and the State Claims Agency's system will be the single system that is used throughout the HSE for incident reporting.

2.3.1 Functions of the HSE's National Incident Management and Learning Team

1. Development of policies, procedures, protocols and guidelines

The National Incident Management and Learning Team develops incident management policies, procedures, protocols and guidelines. These are continuously enhanced and updated based on learning from HSE incident and complaint management experiences, including learning from analysis and the National Incident Management System. This includes ensuring that all incident management documentation, policies and guidance are up to date.

2. Capacity building

The National Incident Management and Learning Team (NIMLT) continuously builds on the capacity of the organisation to better manage, investigate and learn from incidents so that there is evidence of continuous improvement in this area. This

includes deploying members of the NIMLT to support local serious incident management in agreed situations and in collaboration with the HSE's divisional leaders in the areas of quality and patient safety.

3. Training and development

The National Incident Management and Learning Team (NIMLT) develops a pool of trained and experienced investigators to be rapidly deployed to conduct investigations in agreed situations and who would train, support and mentor local investigators. The NIMLT delivers training on safety incident management and systems analysis investigation within the HSE as part of its role within the HSE's Quality Assurance and Verification Division.

4. Supports certain serious incidents

The National Incident Management and Learning Team currently supports divisions to manage certain serious incidents.

5. Analysis

The National Incident Management and Learning Team (NIMLT) analyses the quality and reliability of investigations following their completion. The NIMLT also conducts aggregate analysis of data from incident reporting, complaints and investigations to identify the factors that cause most harm most often in order to inform national interventions that will have the greatest safety impact.

6. Information communications technology (ICT)

The National Incident Management and Learning Team (NIMLT) has a role in contributing to developing and implementing an incident information management system that is as fit for purpose as possible for the HSE. In collaboration with the divisional leads for quality and patient safety, the NIMLT has developed an Incident Information Management System for use by the HSE divisions and the NIMLT for cases that are communicated and or escalated to the divisions and or itself. The NIMLT also leading on implementing phase one of the National Incident Management System, which achieved its target of implementation by June 2015. Phase 2 of the implementation project for the National Incident Management System will focus on ensuring that it becomes the only incident information management system used throughout the HSE, replacing the HSE's own system currently in use. An illustration of the NIMLT functions can be found in Appendix 9.

2.3.2 Role of the HSE's National Incident Management and Learning Team (NIMLT) in the oversight of incident management in the HSE

The role of the National Incident Management and Learning Team (NIMLT) is to support and build the capability of local areas and divisions to manage and investigate incidents satisfactorily. Most incidents do not require communication and or escalation to the NIMLT level and are managed and investigated satisfactorily at local or divisional level in line with the HSE's Safety Incident Management Policy and through the processes that are audited by the divisions or by the Healthcare Audit Function of the HSE's Quality Assurance and Verification Division. In most circumstances, the NIMLT supports divisional management and investigation of incidents to enable divisions to continuously improve their incident management and investigation skills. While supporting divisional management of cases, the NIMLT provides expert advice in areas covered in the HSE's Safety Incident Management Policy.⁽¹⁰⁾

2.3.3 Role of the HSE's National Incident Management and Learning Team in incident management

At the time of writing, the National Incident Management and Learning Team directly manages and investigates a small number of patient safety incidents, following escalation of the incident to the NIMLT via the escalation and or communication form process and through the HSE's Incident Information Management System. The NIMLT becomes involved in the management of an incident when the issue is very substantial, or crosses multiple geographic or specialty boundaries, or is national in scope. Some examples of incidents that it previously investigated included the miscarriage misdiagnosis incident and the DePuy hip replacement systems recall. In line with its criteria for communication and or escalation of incidents to it,⁽¹²⁾ the following types of incidents must be escalated to the NIMLT, where:

- trained and experienced HSE investigators deem that external expert input into an investigation is required
- there is adverse media attention associated with the incident
- there is a known significant risk to public confidence in services
- a serious incident and or serious reportable event is national in nature or where the incident has national implications
- a serious incident and or serious reportable event is cross-divisional in nature
- the risk assessment following a look-back review indicates the need to continue to audit or recall stage.

It is anticipated by the HSE that the NIMLT will play a lesser role in this in the future and shift its focus to building the capacity of the divisional leads for quality and patient safety to manage their own incidents.

While most learning from a patient safety incident occurs at the local level following the incident management process, the NIMLT aims to achieve wider system learning through the following mechanisms:

- Building a culture of patient safety which promotes and supports incident reporting, investigation and management.
- Enhancing investigation methods to find actual problem causes and solutions.
- Building a population of risk registers with outputs of incident management process.
- Publishing reports of incident investigations.
- Publishing reports of the aggregate analysis of completed investigation reports.
- Supporting divisions with learning events through information sessions where learning from incident investigations and incident management is shared.

2.4 The HSE's Incident Information Management System

The Incident Information Management System is an internal HSE system. It is used by hospital groups, community health offices, divisional offices for quality and patient safety and the HSE's National Incident Management and Learning Team to record and collate all relevant information regarding a serious incidents that has been communicated and or escalated to the HSE's divisional quality and patient safety leadership or to the NIMLT. Effective use of the Incident Information Management System helps secure efficient monitoring of information related to the management of incidents entered onto the system. Case-managers in the National Incident Management and Learning Team and the divisional leads for quality and patient safety are responsible for ensuring that information on incidents included on the HSE system at divisional level and NIMLT level is collated in line with HSE procedure.⁽¹²⁾ The HSE's procedure for the collation of information on IIMS states that information recorded elsewhere should not be entered on the HSE's IIMS system as it represents unnecessary duplication. For example, incident report forms should not be entered on the IIMS system as these are communicated to the State Claims Agency via the National Incident Management System.⁽²⁰⁾

The HSE's procedure for the collation of information on IIMS outlines that the following information must be entered for all cases entered on the HSE's Incident Information Management System:

- description of the incident that will give an understanding of what happened

- details of the division, community health organisation and service or hospital group and hospital as appropriate
- date of incident occurrence
- copy of the safety incident communication escalation form
- category and sub-category of serious reportable event
- all relevant communication regarding the incident, such as copies of emails
- copy of terms of reference for the investigation
- copy of request form for external input into investigation
- clear and concise 'updates' in the relevant fields related to significant activity or decisions related to the case and routine updates
- decision or decisions to de-escalate a case and the rationale for this
- copy of the final investigation report
- National Incident Management System (formally STARSweb) reference number and date reported to it
- any other information deemed relevant.⁽²⁰⁾

2.4.1 Access to the HSE's Incident Information Management System

Only those that have been assigned access rights in compliance with the HSE's access control policies can have access to its Incident Information Management System. This includes users that have been nominated at hospital group and community health organisation level and the users that have been assigned at divisional level. National Incident Management and Learning Team users only have access to incident information that has been communicated and or escalated to it. NIMLT do not have access to information on incidents that are communicated and or escalated to divisional level and subsequently do not meet the criteria to be escalated and or communicated to NIMLT. The information regarding such an incident remains with the divisional leadership of the HSE's quality and patient safety function.

As previously outlined, the HSE plans to phase out its Incident Information Management System and replace it with the National Incident Management System (formally STARSweb) to ensure that there is only one system in place for reporting patient safety incidents within the HSE.

Summary of findings

- There is no national oversight for the coordination of patient safety intelligence across the health and social care system at present.
- As outlined in the CMO report, a number of issues with incident reporting exist, including problems with consistent 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⁾
- There is currently some duplication in reporting between reporting to the National Incident Management System (NIMS) hosted by State Claims Agency and the HSE's Incident Information Management System.
- Phase 2 implementation of NIMS is focusing on integrating the functionality of the HSE Incident Information Management System (IIMS) into NIMS. The HSE plans to eventually discontinue the IIMS so that there is only one system for reporting safety incidents in the HSE.
- 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.
- While there are policies and guidelines in place to support open disclosure, at the time of writing, there is no legal protection in Ireland to protect the disclosure of information received as part of safety incident investigations for learning purposes, creating the absence of a 'just culture'.

3. National Incident Management System (NIMS)

3.1 Introduction

The State Claims Agency is responsible for hosting and maintaining the National Incident Management System (formerly STARSweb). It is a national web-based system that is used by HSE-funded hospitals in Ireland to report all incidents (including adverse clinical incidents and near misses) to the State Claims Agency. A number of hospitals are also using local risk management information systems for recording and managing incidents locally.

During 2015, an upgraded version of the National Incident Management System was rolled out by the HSE in conjunction with the State Claims Agency. The project is being implemented in two phases which will be outlined in more detail in the following sections. The Quality Assurance and Verification Division of the HSE is responsible for the national implementation of the new system.

The following section documents the role of the State Claims Agency in relation to risk management, the background to the development of the National Incident Management System, and details the plans for the implementation of the upgraded incident management system across the health and social care sector.

3.2 State Claims Agency — role and functions

Under the National Treasury Management Agency (Amendment) Act, 2000,⁽²¹⁾ the management of personal injury and third-party property damage claims against Delegated State Authorities and the underlying risks was delegated to the National Treasury Management Agency (NTMA). When performing these claims and risk management functions, the NTMA is known as the State Claims Agency. The general indemnity scheme operated by the State Claims Agency is similar to the cover provided by employers liability and public liability insurance provided by the commercial insurance sector.

The State Claims Agency's remit further expanded with the establishment of the Clinical Indemnity Scheme (CIS) in July 2002 to manage clinical negligence claims and associated risks. Healthcare enterprises are delegated to the Clinical Indemnity Scheme and in some cases to the general indemnity scheme as well. The HSE and voluntary hospitals are covered by both schemes operated by the State Claims Agency. The State Claims Agency has a mandate to:

- advise and assist Delegated State Authorities on measures to be taken to prevent the occurrence, or to reduce the incidence, of claims
- ensure the Delegated State Authorities are fully aware of the measures necessary to address any risks highlighted by their claims' records and by risk evaluations and or audits and or inspections and or reviews.⁽²²⁾

3.2.1 Legislative remit

Under the National Treasury Management Agency (Amendment) Act, 2000,⁽²¹⁾ State authorities including the HSE are statutorily obliged to report 'adverse incidents' as soon as may be to the State Claims Agency[◇] and to facilitate any subsequent investigation.⁽²³⁾ This allows the State Claims Agency, in conjunction with Delegated State Authorities, to identify and analyse developing trends and patterns and to work with the Delegated State Authorities concerned to develop and implement risk mitigation strategies. It is also important in the investigation of any subsequent claim. All Delegated State Authorities (including the HSE) also have a statutory duty to:

- furnish relevant information when requested to do so
- preserve relevant evidence
- permit and facilitate investigations by or on behalf of the State Claims Agency to include furnishing complete and properly ordered healthcare records when, requested to do so by the State Claims Agency.⁽²⁴⁾

The exact wording from the National Treasury Management Agency (Amendment) Act, 2000 can be found in Appendix 10.

3.2.2 Risk management function of the State Claims Agency

One of the objectives and statutory duty of the State Claims Agency is to provide risk management advisory services to State authorities, including the HSE, with the aim of reducing the frequency, severity and repetition of incidents and in so doing, also reducing subsequent claims and the cost of claims. The State Claims Agency's risk management programme focuses on collaboration with risk managers and other relevant personnel in healthcare enterprises to support risk management and patient safety and to help minimise the occurrence of clinical claims.

Claims made under the scheme are managed by a team of clinical claims managers within the State Claims Agency. The clinical risk management programme focuses on

[◇] Previously, there had been a list of 'serious adverse clinical events' that required rapid notification to the State Claims Agency. This process has now been superseded.

providing advice and support in relation to professional medical services. Figure 4 illustrates the structure and functions of the State Claims Agency.

Figure 4: Organisational structure of the State Claims Agency's functions



Specifically, the State Claims Agency provides a range of practical risk management services and advice to include:

- hosting of the National Incident Management System, a web-based database which facilitates direct reporting of incidents by Delegated State Authorities and healthcare enterprises
- analysing incidents and claims data and providing this analysis to Delegated State Authorities in order to identify risk clusters
- publishing risk management guidance and providing practical risk management tools
- providing information and training by means of seminars and publications, including website information and newsletters
- providing risk management solutions directly to Delegated State Authorities about specific macro-risk issues
- carrying out risk management reviews and assisting with developing and implementing delegated risk management policies and procedures in State authorities

- supporting the implementation of the State Claims Agency's recommendations issued to Delegated State Authorities
- providing insurance, indemnity and liability advices to Delegated State Authorities.

3.2.3 Risk management work programmes

Each year, the State Claims Agency carries out risk management work programmes in association with client State authorities and healthcare enterprises. It was involved in a number of risk management projects during 2015, including:

- obstetrics — a programme of site visits to maternity units
- under- and postgraduate training — a pilot course on clinical risk management
- open disclosure — training sessions to acute hospitals on open disclosure
- National Falls Prevention and Bone Health Implementation Project.

Further information on these work programmes undertaken by the State Claims Agency in the area of patient safety can be found in Appendix 11.

3.3 Development of the National Incident Management System

3.3.1 Background

A collaborative evaluation of the original STARSweb system was previously undertaken by the Clinical Indemnity Scheme, the HSE and HIQA, with the final report being published in 2008.⁽²⁵⁾ A number of the important recommendations made in this evaluation have been addressed in the planned development of the upgraded National Incident Management System.

The rebranding of STARSweb as the National Incident Management System (NIMS) took place in January 2015.⁽²⁶⁾ The rebranding was warranted due to an expansion in the scope of the system to cater for no-harm incidents, near misses, dangerous occurrences and complaints in line with the World Health Organization's definition of an incident and to align with the HSE's Safety Incident Management Policy.⁽²⁶⁾

Over one million incidents have been reported to date on the National Incident Management System, with over 100,000 incidents reported annually (this includes clinical incidents, employee and public accidents and motor accidents). Over a five-year period between January 2010 and December 2014, the average number of service user and or patient-related incidents reported to the system was 96,000 with 43% of these relating to clinical care while 57% were related to general service user and or patient incidents.

3.3.2 Features of the National Incident Management System

The upgraded National Incident Management System within the State Claims Agency is an end-to-end risk management tool that, when fully implemented, will allow Delegated State Authorities to manage incidents throughout the incident lifecycle in Ireland. The upgraded National Incident Management System includes:

- reporting of incidents (including serious reportable events)
- management of investigations
- recording of investigation conclusions
- recording of recommendations
- tracking recommendations to closure
- analysis of incident, investigation and recommendations data and other functionality.

The types of incidents that are reported to the National Incident Management System are as follows:

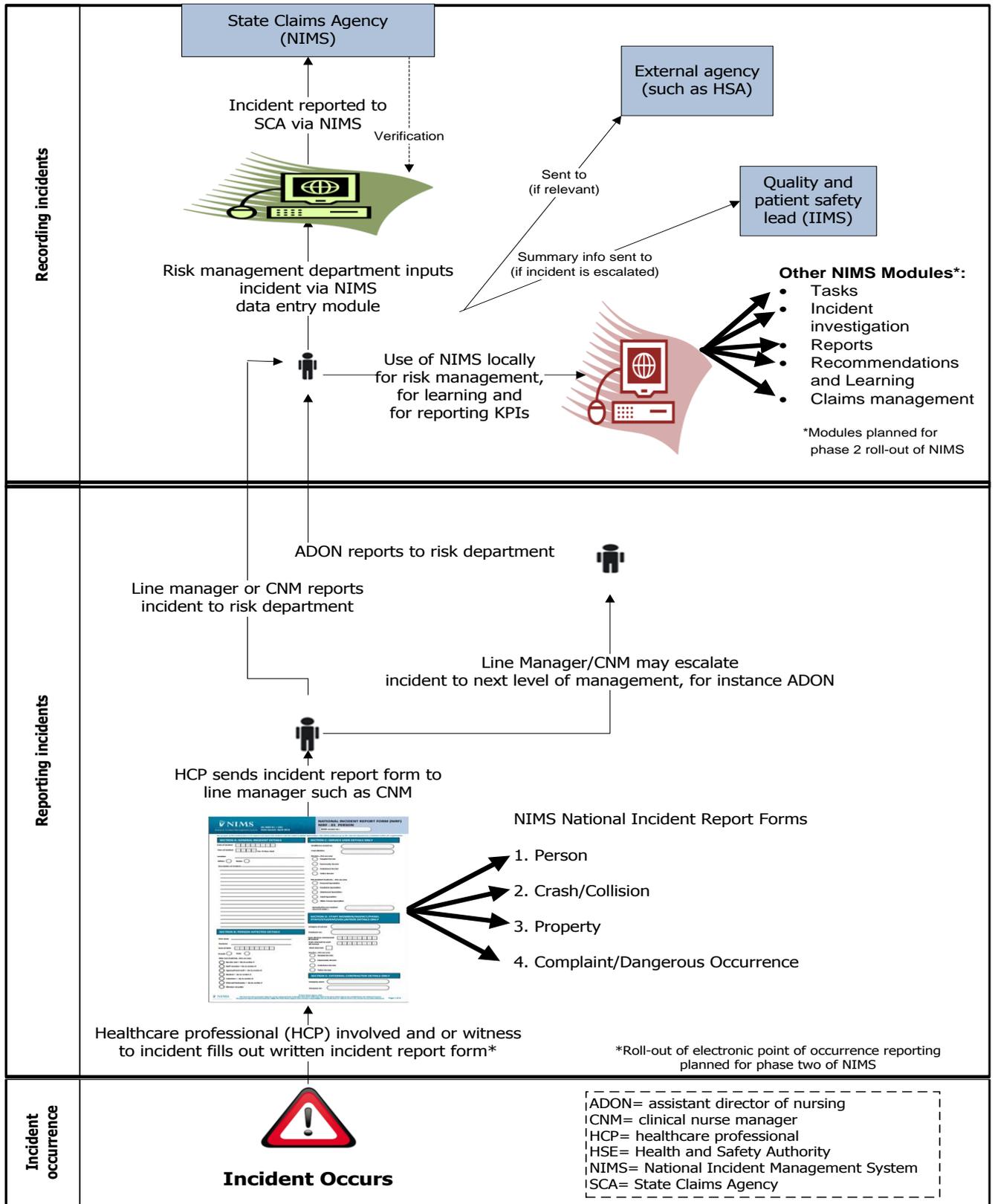
- a harmful incident (adverse event) is an incident that results in harm and or damage
- a 'no harm' incident is an incident where no harm has occurred
- a 'near miss' is an incident which nearly occurred
- a 'dangerous occurrence' (reportable circumstance) as described by the Health and Safety Authority (HSA) or any other reportable circumstance as prescribed and or deemed appropriate by the Delegated State Authority
- a 'complaint' made about any action and or inaction of Delegated State Authority.

Incidents are also sub-divided down into the following categories:

1. Person.
2. Property.
3. Crash or collision.
4. Dangerous occurrence (reportable circumstance).
5. Complaint.

Figure 5 provides an example of the current information flows in relation to how an incident is reported to the National Incident Management System in an acute hospital setting. This reporting model will change following the eventual rollout of electronic point of occurrence reporting during Phase 2 implementation of the system.

Figure 5: Example of information flows to the National Incident Management System after an incident happens



3.3.3 Data quality and use of information from the National Incident Management System

A report from the State Claims Agency, *Clinical Incidents and Claims Report in Maternity and Gynaecology Services - A Five Year Review: 2010-2014*⁽²⁷⁾ highlights some of the current issues relating to the quality of incident data reported to the National Incident Management System. The report states that the quality of data is suboptimal in some cases as a result of some of the following issues.

- Variation exists nationally about 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.
- There is a lack of uniformity across services about severity of injury ratings, particularly in relation to incidents rated as extreme.
- There is miscategorisation of incidents, where clinical incidents are rated as extreme but resulted in 'no harm' to the patient.
- There is a lack of consistency about reporting of certain clinical incidents.
- Comparisons are inaccurate due to variation and lack of standardisation in incident reporting.
- There is under-reporting of incidents nationally; 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.
- The State Claims Agency's review reports that 12% of acute hospitals reported to two reporting systems, as well as reporting to its own National Incident Management System. It is likely that this figure is an underestimate of the true number of hospitals that are reporting to two systems. Dual reporting can be inefficient and results in duplication of effort.

3.4 Progress on rollout of the National Incident Management System

The section looks at progress on the roll-out of the National Incident Management System as of September 2015.

The planned roll-out of the system to Delegated State Authorities (DSAs) included a communication, information and training process, which started in early 2013. The project aim is that all Delegated State Authorities, public healthcare enterprises and the large number of agencies under the remit of the State Claims Agency will be using this singular, cost-effective risk management system on completion of the project. The project objectives are overseen by a National Incident Management

System implementation steering group and the project has been divided into two major phases as outlined in the following sections.

3.4.1 National Incident Management System Implementation Steering Group

In January 2015, a National Incident Management System implementation steering group was established to oversee the implementation of the system in the HSE. The steering group consists of representatives from the internal and external informed and interested parties and includes representatives from:

- HSE service divisions (acute hospital, mental health, primary care, social care and health and wellbeing)
- HSE Quality Assurance and Verification Division (QAVD) and National Incident Management and Learning Team
- State Claims Agency
- HSE information communications technology (ICT)
- HSE Quality Improvement Division (QID).

3.4.2 National incident report form

As part of the upgrading of the National Incident Management System, the State Claims Agency recognised the need for a national incident report form across all the Delegated State Authorities who report into the incident system. To this end, a National Incident Report Form was developed by the State Claims Agency in conjunction with all the relevant interested and informed parties, including the HSE and voluntary hospitals. At the time of writing, these forms were going through a national procurement process and in the interim, forms have been issued to all Delegated State Authorities for local printing. At the time of writing the majority of hospitals are using paper based forms which are then manually inputted into the system.

The form includes selecting routes based on previous question, auto-population of severity rating, the ability to group incidents together and report as an occurrence, and the ability to copy information from previous entries. There are four types of National Incident Report Form as follows:

1. Person.
2. Property.
3. Crash or collision.
4. Complaints and or dangerous occurrences (reportable circumstances).⁽²⁶⁾

3.4.3 Phase 1 rollout of the National Incident Management System —completed June 2015

- There were three 'early adopter' sites in phase 1 roll-out of National Incident Management System namely, the Rotunda Hospital, Midland Regional Hospital, Portlaoise and the Mater Hospital Risk Department.
- The objective of phase 1 rollout of the National Incident Management System was that all existing user-sites and a number of new sites have access to the national system and were provided with training for the purpose of using its data entry module by June 2015. The objective of phase 1 was met.
- At the time of writing, training on the National Incident Management System data entry module is still ongoing and will be delivered via the online National Incident Management System eLearning tool which will be hosted on the 'HSELand' website (www.hseland.ie).
- Following phase one implementation of the new national system, the STARSweb system was subsequently shut down at the end of June 2015.

A summary of the current situation (as of September 2015) following roll-out of phase 1 is as follows:

- All existing user-sites (that had previously been using STARSweb) and a number of new user-sites now have access to the National Incident Management System and have been provided with training on using its data entry module.
- Staff in a number of sites, such as the 'early adopter' sites, have been trained in and are using additional functionality on the National Incident Management System, such as its incident investigation module and its reports module.
- No sites were using electronic-point-of-occurrence reporting and it was planned this would be rolled out during phase 2.
- The new National Incident Report Form has been issued to all HSE and voluntary hospitals. In advance of national procurement, this can be printed locally. Many sites are currently still using their own version of an incident reporting form and inputting this information from these forms onto the National Incident Management System.
- The State Claims Agency's report, *Clinical Incidents and Claims Report in Maternity and Gynaecology Services - A Five Year Review: 2010-2014*⁽²⁷⁾ outlined that under-reporting of incidents exists nationally, with 59% of new patient claims that were received in the first six months of 2015 having had no previous patient safety incident reported to the State Claims Agency. The State Claims Agency's report⁽²⁷⁾ also outlines that 12% of acute hospitals report to two reporting systems, as well as reporting to the National Incident

Management System. Dual reporting can be inefficient and results in duplication of effort.

- A number of sites continue to use their own local systems. These sites are not reporting to the State Claims Agency, in breach of their statutory requirement to do so.

3.4.4 Phase 2 rollout of National Incident Management System — started July 2015

Planning for Phase 2 of the rollout of the National Incident Management System is now underway and aims to focus on implementing the new system's features and modules such as 'point-of-occurrence' reporting, audit and recommendation tools as outlined below.

- Phase 2 rollout of National Incident Management System will also shift the focus to training in the use of the new system for risk management. This will include report generation, incident investigations and identifying serious reportable events.
- The State Claims Agency is also working on an enhanced complaints module, which is designed in accordance with the HSE 'Your Service Your Say' Complaints Policy⁽¹⁸⁾ and due for release during phase 2. This module will allow complaints officers to log complaints and associated issues on the National Incident Management System in line with the HSE structures and manage these complaints through to closure.
- Phase 2 of the implementation of the National Incident Management System is focusing on integrating the functionality of the HSE's [Incident Information Management System](#) into the National Incident Management System, with a view to eventually discontinuing the HSE system so that there is only one system for reporting patient safety incidents in the HSE. NIMS has been endorsed as the primary system for the reporting and management of incidents by the Department of Health⁽²⁸⁾ and by the HSE and is incorporated into HSE policy documents including the HSE's Safety Incident Management Policy.⁽¹⁰⁾

3.4.5 Benefits of the fully upgraded National Incident Management System

The State Claims Agency has outlined that the upgraded National Incident Management System will deliver on the following:⁽²⁹⁾

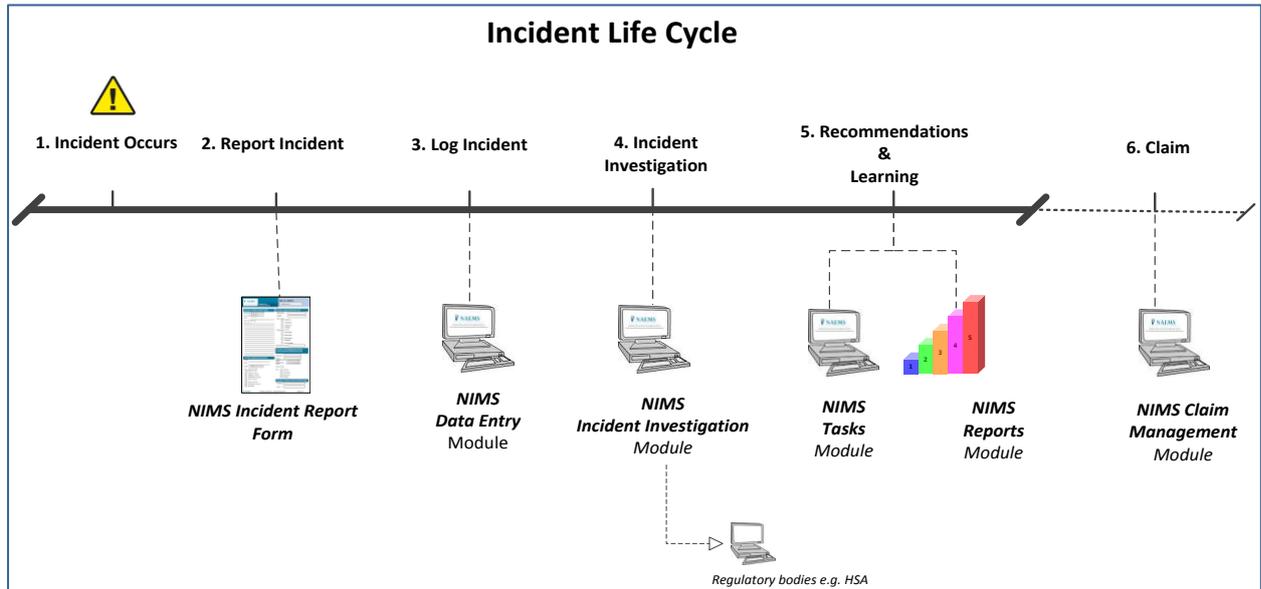
- [Improved incident entry screens](#) — from a data entry perspective it will mean simple user-friendly interview entry-screens in plain English, as opposed to

using risk, clinical, legal terminology or claims language. The form will be clear and will allow a user to select pre-determined routes based on previous questions.

- A “pick list” — closely aligned to the World Health Organization’s (2009) International Classification for Patient Safety (ICPS) will be used in the upgraded version of the National Incident Management System.⁽³⁰⁾ The purpose of this classification system is to enable categorisation of patient safety information using standardised sets of concepts with agreed definitions, preferred terms and agreed relationships between the terms (such as patient safety).⁽³¹⁾
- **Enhanced reporting capabilities** — reporting will be improved with the addition of dashboards to allow users to customise screen views. Risk management information will be readily available. Customised reporting capability will be available to meet the specific requirements of individuals and or enterprises, for example, CEOs, general managers, risk managers, HSE senior management and the State Claims Agency. Additionally, for a limited number of high-level users there will be a report that will provide more comprehensive data.
- **Point-of-occurrence reporting** — this will be implemented incrementally to all State authorities and or health and social care enterprises and will allow reporting at the point of occurrence of incidents to the National Incident Management System electronically.
- **End-to-end management of incidents** — this will allow information, following investigation, to be captured on the system about incidents so that they may be flagged to relevant persons and or sections in an organisation, remedial actions identified, assigned and tracked to close.
- **Audit tool** — this will be available to those State authorities and or health and social care enterprises that would like to avail of this tool. National, regional or local level audit tools can be built on to the system to facilitate auditing and performance scoring.
- **Recommendations module** — this will record and track recommendations and associated actions at both a national and local level.
- **Performance benchmarking** — the system will allow important values, such as service-user bed hours, employee numbers, appointment volume, number of employee sick days, number of clinical procedures performed and so on to be recorded. This combined with the number of ‘adverse incidents’ reported, will facilitate performance benchmarking between enterprises. Over time, when these processes have improved, the system could play an important part in risk pooling and licensing.

A summary of the life cycle of an incident being reported to the National Incident Management System is illustrated in Figure 6.

Figure 6. Incident life cycle, National Incident Management System^{*(32)}



*Note: This illustration was provided by the State Claims Agency.

3.4.6 Access to the National Incident Management System

Users of the National Incident Management System in Delegated State Authorities have varying degrees of access to the system. Local users can only view incident data in their own facility. There are also access limitations within facilities, for example, in a hospital some users may have access to clinical incidents while others may have access to incidents involving staff. The CEO of each hospital group can view data on all incidents reported to the National Incident Management System within their hospital group.

Access to the system has also been granted to the HSE's National Incident Management and Learning Team and the divisional leads for quality and patient safety. The claims section of the State Claims Agency has access to the data on National Incident Management System at an appropriate level. The State Claims Agency continues to work on providing corporate-level access to all appropriate sections.

3.4.7 National Incident Management System information governance

A number of stakeholders have established a National Incident Management System Information Governance Group, chaired by the Chief Medical Officer (CMO) in the Department of Health. Its role is to develop a framework to support the implementation, maintenance, upgrade, use and review of the system when the upgrade is launched. The group is not responsible for implementing the roll-out of the National Incident Management System, however, it is tasked with enabling effective functionality of all aspects of the system.

The terms of reference of this group are as follows:

- To ensure the system has the capacity to meet the requirements for effective adverse event management.
- To oversee the implementation, maintenance, upgrade, use and review of the National Incident Management System.
- To oversee governance of data on the system, in respect of data protection, freedom of information, ownership of and or access to data, data sharing.
- To enable the development of assurance in respect of the quality, timeliness and comprehensiveness of data.
- To oversee the provision of training to support effective use of the system.
- To oversee the provision of a communication strategy to ensure stakeholder understanding and engagement.

3.5 Sharing of information via the National Incident Management System

Under the National Treasury Management Agency (Amendment) Act, 2000,⁽²¹⁾ State authorities including the HSE are statutorily obliged to report 'adverse incidents' as soon as may be to the State Claims. The State Claims Agency is responsible for hosting and maintaining the National Incident Management System. In this respect its primary objective as a data processor under the relevant law is to ensure the data is secure from unauthorised access, disclosure, destruction or accidental loss. The State Claims Agency does not provide any personal detail in respect of an enterprise's data to a third party other than where the enterprise has given express permission to do so.

The National Incident Management System has the capability to allow users to manually flag which incidents should be reported to which authorities including:

- The Medical Council
- The Health Products Regulatory Authority (HPRA)
- The Health Service Executive (HSE)

- The Health and Safety Authority (HSA)
- The Mental Health Commission
- The Environmental Protection Agency (EPA)
- The Health Protection Surveillance Centre (HPSC)
- Health Information and Quality Authority (HIQA)
- Garda Ombudsman
- Coroner Service

It should be noted that the system does not automatically share information to regulatory bodies, however the system can forward reports to the individual notifying authorities directly. This model will be explored as part of the Phase 2 implementation of the National Incident Management System.

Summary of findings

Under reporting to the National Incident Management System (NIMS)

- The State Claims Agency is aware of under-reporting in certain areas across the delegated State authorities, even though there is a statutory requirement to report 'adverse incidents' to the State Claims Agency.
- A report by the State Claims Agency reported that 59% of new patient claims received in the first six months of 2015 had no previous patient safety incident reported to the National Incident Management System.⁽²⁷⁾ It is likely that the figures for under-reporting are even higher as this only gives an indication of those incidents that subsequently led to claims.
- The State Claims Agency review reported that 12% of acute hospitals report to two reporting systems, as well as reporting to the National Incident Management System.⁽²⁷⁾ It is assumed that this figure is underestimated. Dual reporting can be inefficient and results in duplication of effort.
- In addition, a number of sites are using local risk management systems to report incidents instead of reporting to the National Incident Management System. It is expected that non-reporting and under-reporting of incidents to the National Incident Management System will improve with its roll-out and the implementation of electronic reporting at the point of occurrence. Phase 2 implementation aims to target non- and under-reporting sites.

Data quality in the National Incident Management System

- The process for reporting to the National Incident Management System varies between sites with no 'standardised process or best model' for reporting, although the State Claims Agency advocate point-of-occurrence reporting.⁽²⁷⁾
- Point of occurrence reporting for the National Incident Management System depends on local processes and practices. Some sites have data clerical officers who enter incidents onto the system on behalf of risk manager, while other sites allow healthcare staff to enter incidents onto the system directly.
- There is 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), has been rolled out nationally, however, many sites are using old forms and some sites have multiple versions of reporting forms in use, depending on the type of incident that has occurred.

Need for full implementation of the National Incident Management System

- The National Incident Management System is currently implemented in all healthcare enterprises where STARSweb had been previously in operation. In most cases, the system is in operation at data-entry module level. The additional functions of the National Incident Management System, such as investigation, reporting, recommendations modules and audit tools, are — at the time of writing — not currently in operation in most sites. The option to use these functions should be made available to user-sites during phase two roll-out of the system.
- The Department of Health and the HSE have recently endorsed the National Incident Management System as the national system which should be implemented in a standardised way across all hospital groups and community health organisations.

4. Other sources of patient safety intelligence in Ireland

One of the overall conclusions of the Chief Medical Officer's (CMO's) Report⁽¹⁾ published in 2014 was that many organisations, including the maternity services in Portlaoise Hospital, had partial information regarding the safety of its maternity services that could have led to earlier intervention had it been collated. The report stated that at the time of its publication, there was no single agency or body with responsibility for the oversight of risk management. It also stated that patient safety issues that emerge from numerous single agencies do not form part of the overall process of pooling of risk information intelligence which could create a composite risk profile for the healthcare system.

The diffusion of this information was thereby a lost opportunity to provide early warning signals to HIQA, the Department of Health and the HSE of potential patient safety issues and risks to the system. The CMO's report outlines a list of potential agencies or bodies as sources of patient safety intelligence in Ireland. The list includes HIQA, the Health Products Regulatory Authority (formerly the Irish Medicines Board), coroners' reports, other regulatory bodies, the HSE corporate and the State Claims Agency. A number of other sources of patient safety intelligence have been identified during the course of this 'As is' analysis and these are explored in detail below.

4.1 Health Information and Quality Authority

The Health Information and Quality Authority (HIQA or the Authority) was established in May 2007 and is an independent authority whose role is to encourage continuous improvement in Ireland's health and social care services. Reporting directly to the Minister for Health and the Minister for Children and Youth Affairs, HIQA's role is to promote quality and safety in the provision of health and social services for the benefit of the health and welfare of the public. HIQA derives its mandate from and undertakes its functions in line with the Health Act 2007 and other relevant legislation (the Child Care Act, 1991 and the Children Act, 2001).

In relation to patient safety, HIQA must be formally notified by the person or persons in charge of a designated centre (such as a nursing home) when certain events or incidents take place. These are known as 'notifiable events'. Depending on the nature of the incident, event or change, HIQA must be notified within three working days, at the end of each quarter, on a six-monthly basis and in response to proposed changes within the designated centre. For example, 'any serious injury to a resident which requires immediate medical or hospital treatment' must be notified to HIQA within three working days of the incident. It is the responsibility of those in

charge of a centre to be familiar with the relevant timescales and ensure notifications are submitted within the prescribed period. Failure to do so may be treated by HIQA as evidence of lack of fitness of the designated centre. This could have implications for registration or renewal of registration as well as possibly constituting an offence under the Health Act 2007. A full list of events notifiable to HIQA and the time frame they must be reported within is included in Appendix 12.⁽³³⁾

4.2 Health Products Regulatory Authority

The Health Products Regulatory Authority's (HPRA), formerly known as the Irish Medicines Board (IMB), is a state agency that serves to protect and enhance public and animal health by regulating medicines, medical devices and other health products. The HPRA has a role in regulating human and veterinary medicines, clinical trials, medical devices, controlled drugs, blood and blood components, tissues and cells, cosmetic products, protection of animals used for scientific purposes and human organs intended for transplantation.

The HPRA's primary goal is to protect the health of those who use and benefit from the products they regulate. It assesses information about a product, including relevant research, to evaluate the benefit-risk profile. The HPRA's scientific, clinical and legal expertise forms the basis of its independent regulatory actions and decisions. The regulation of all health products under the remit of the HPRA is based primarily on European law which is implemented into Irish legislation. The HPRA's role is to ensure that the health products sector complies with those laws and regulations.

For the majority of products under its remit, HPRA is responsible for monitoring their safety and quality once in use and on the market. For other products, primarily medicines, HPRA is also involved in their assessment before they are placed on the market. In addition, it carries out compliance inspections of manufacturers, distributors and certain other health product facilities. HPRA seeks to ensure that those who make and market health products do so in accordance with the legislation. It inspects sites and investigates potential breaches of the law. Where necessary and in the interest of public health, HPRA takes appropriate corrective actions including legal proceedings.

In relation to patient safety and quality, concerns can be reported directly to the HPRA by patients, carers, other members of the public and healthcare professionals using its online reporting service.⁽³⁴⁾ Online report forms and print forms are available at www.hpra.ie and include 'Human Medicine Adverse Reaction', 'Serious

Adverse Event (Clinical Trial Investigator)' and 'Medical Device Adverse Incident' forms.

4.3 National Haemovigilance Office

The National Haemovigilance Office was set up by the Irish Blood Transfusion Service (IBTS) and launched by the Minister for Health and Children in 1999. The purpose of a haemovigilance programme is to identify unexpected or undesirable effects of transfusion of blood components by ensuring that they are reported in a timely and reliable manner. The remit of the National Haemovigilance Office is to:

- receive, collate and follow up reports from hospitals and general practitioners (GPs) of adverse reactions or events connected with transfusion of blood components or products and provide feedback information to those making the report as appropriate
- advise on the follow-up action necessary, particularly with regard to suspected hazards
- report adverse reactions to the HPRA according to an agreed procedure
- provide ongoing support to hospital-based haemovigilance officers and to medical, nursing and technical staff as appropriate
- provide medical, scientific and nursing analysis of adverse reaction reports
- advise on improvements on the safety of transfusion practice based on the data made available by hospitals
- support development of clinical guidelines for hospitals in relation to the use of blood components or products
- support, as appropriate, the training of medical, nursing and technical staff in haemovigilance
- support the audit function of hospitals in relation to transfusion practice
- report to the National Blood Users Group on a periodic basis with a view to developing national best transfusion practice
- educate, train and support in relation to best transfusion practice at hospital level.⁽³⁵⁾

Since 1999, the National Haemovigilance Office has collated data relating to serious adverse reactions and events associated with blood and blood components and SD plasma (solvent detergent plasma), as well as serious adverse events associated with some blood-derived medicinal products. While this remit is broader than that mandated by EU and national legislation, the National Haemovigilance Office will continue to capture these adverse reactions and events. It is mandatory to report serious adverse reactions which may be attributed to the quality and safety of blood

components and serious adverse events relating to the collection, testing, processing, storage and distribution of blood and blood components.

Serious adverse reactions to be reported to the National Haemovigilance Office include:

- suspected bacterial infection
- viral, parasitic or other post-transfusion infection
- transfusion related acute lung injury (TRALI)
- failure in blood processing or equipment in blood establishments, for instance failure of irradiation.

It is also crucial that any infectious complication (bacterial or viral) suspected to be due to the recent transfusion of a blood component is rapidly reported directly to the Irish Blood Transfusion Services (IBTS) so that other implicated components can be withdrawn.⁽³⁶⁾

4.4 HSE Health Protection Surveillance Centre

The Health Protection Surveillance Centre (HPSC) is Ireland's specialist agency for the surveillance of communicable diseases. HPSC is part of the HSE and it reports that it works in partnership with health service providers and public health departments in Ireland and with similar organisations around the world. It collates, interprets and shares data and information on communicable diseases. HPSC aims to protect and improve the health of the Irish population by providing timely information and independent advice, and by carrying out disease surveillance, epidemiological investigation and related research and training. HPSC has six main areas of responsibility as follows:

- surveillance of some of the major communicable diseases, which involves collecting, collating, analysis and communication of information to those who need to know
- operational support — providing expert advice to, and responding to requests for support from, departments of public health or hospitals
- training for professionals working in communicable disease control
- research — identifying and developing best practice in communicable diseases
- policy advice — providing advice to government departments and appropriate agencies in relation to the development of standards, guidelines and practices, and promoting the adoption of best practice by different agencies
- public information — providing information on infectious diseases to the public and the media.⁽³⁷⁾

Under the Infectious Diseases Regulations 1981, and subsequent amendments, the HPSC is authorised by law to collect information from doctors and laboratories about diagnoses of certain infectious diseases in Ireland. These diseases are referred to as notifiable diseases. The law exists to monitor and control the occurrence of infectious diseases, and to help prevent further illness. The most recent amendment to the regulations is the Infectious Diseases (Amendment) Regulations 2011 which contains an up-to-date list of notifiable diseases. Examples of notifiable diseases include measles, rotavirus infection and tuberculosis (TB).

To be effective, the collection of surveillance data must be standardised on a national basis and be made available at local, regional and national level. All medical practitioners, including clinical directors of diagnostic laboratories, are required to notify their relevant public health doctor about notifiable diseases. These public health doctors — called medical officers of health (MoHs) — are located in the eight departments of public health throughout the country. Laboratory notifications are made electronically through the Computerised Infectious Disease Reporting System (CIDR).

Notifications from clinicians are entered into CIDR in the Department of Public Health. The MoHs provide information on a weekly basis to the HPSC on the infectious diseases notified to them. Access to the information in CIDR is controlled so that personally identifiable information is visible only to those with a need to manage the individual case. All CIDR information is protected by appropriate security and confidentiality mechanisms and complies with data protection legislation. Information collected by HPSC is used to:

- evaluate the effectiveness of control and preventive health measures
- detect outbreaks
- monitor changes in infectious diseases
- educate health professionals
- support health planning and the allocation of appropriate resources within the healthcare system
- identify high-risk populations or areas to target interventions, such as vaccinations
- provide a valuable archive of disease activity for future.⁽³⁸⁾

4.5 Coroner Service

The Coroner Service is a network of coroners located throughout the country. A coroner's core function is to investigate sudden and unexplained deaths so that a death certificate can be issued. In the majority of cases, a report to the coroner is made by the registered medical practitioner in whose care the patient is, but reports can also be made by other clinical staff. The work of the coroner is governed by the Coroners Act 1962. The coroner is an official charged with the legal responsibility for investigating sudden, unexplained and unnatural deaths in their district. The coroner acts in the public interest on the State's behalf.

The purpose of making a report to the coroner is to allow for the determination of the medical cause of death, to allay rumours or suspicions, to draw attention to the existence of circumstances which, if unresolved, might lead to further deaths, to advance medical knowledge and to preserve the legal interests of the deceased persons' family, heirs or other interested parties. There are 32 types of deaths reportable to the coroner by law. One such example is in the case of 'death occurring during a surgical operation or anaesthesia'. A full list of death reportable to the coroner is provided in Appendix 13. A number of further events are reportable under rules of practice, for example, where a death occurs within 24 hours of admission to hospital.⁽³⁹⁾

4.6 Mental Health Commission

The Mental Health Commission (MHC) is an independent statutory body which was set up under the Mental Health Act, 2001. The Mental Health Commission inspects mental health services and promotes high standards in the delivery of mental health services and ensures the interests of those involuntarily admitted to approved centres are protected. There are certain incidents that are required to be reported to the Mental Health Commission. For example, it is a legal requirement under the Mental Health Act 2001 (Approved Centres) Regulations 2006 that the registered proprietor shall notify the MHC of all deaths of any resident of an approved centre within 48 hours of the death occurring.⁽⁴⁰⁾

In line with the Mental Health Commission's risk management procedures, the registered proprietor of an approved centre shall maintain a record of all incidents and notify it of incidents occurring in the approved centre with due regard to any relevant codes of practice issued by the Mental Health Commission. Approved centres should use existing local incident reporting systems and associated forms to report incidents within their services. Local arrangements should be made with the

service that manages the local incident-reporting system to notify the Mental Health Commission about incidents they require to be notified.

There is no longer a requirement to notify the Mental Health Commission of all individual incidents as they occur. Instead of this, approved centres provide a six-monthly summary report of all incidents occurring in approved centres to the Mental Health Information Officer, Standards and Quality Division of the Mental Health Commission. The summary report should include details of how such incidents were managed. A six-monthly summary report should also be provided for all incidents occurring in day hospitals, day centres and 24-hour staffed community residences.⁽⁴⁰⁾

4.7 National Office of Clinical Audit

The National Office of Clinical Audit (NOCA) was established in 2012 as a result of collaboration between the HSE Quality Improvement Division (QID) and the Royal College of Surgeons in Ireland (RCSI). The primary purpose of NOCA is to establish sustainable clinical audit programmes at national level which will ultimately improve outcomes for Irish patients. Its Governance Board is an independent voluntary board which was convened to guide the clinical decision-making and strategic direction of NOCA. Should the Governance Board become aware of poor professional performance (under the Medical Practitioners Act 2007) or process which has not been satisfactorily addressed through the audit cycle, it has a duty to communicate such findings through the relevant channels available to the National Director of the Quality Improvement Division. The office 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 so that audit output is interpreted and used to direct quality improvement. The current national audits governed by NOCA are as follows:

- Major Trauma Audit
- Irish National Orthopaedic Register
- National Intensive Care Audit
- Irish Hip Fracture Database
- National Audit of Hospital Mortality
- National Perinatal Epidemiology Centre.⁽⁴¹⁾

4.8 National Perinatal Epidemiology Centre and Maternal Death Enquiry Ireland

The National Perinatal Epidemiology Centre (NPEC) operates as an audit stream within the National Office of Clinical Audit. NPEC was established to collaborate with Irish maternity services to translate clinical audit data and epidemiological evidence into improved maternity care for families in Ireland. Maternal Death Enquiry (MDE) Ireland aims to promote safer pregnancy by conducting confidential reviews into maternal deaths, identifying learning points, and using its findings to formulate and share recommendations. MDE Ireland was launched in 2009 and was developed with the support of the Institute of Obstetricians and Gynaecologists, the HSE, the Department of Health and Children and the State Claims Agency. In the event of a maternal death occurring during or within one year of pregnancy, a dedicated MDE Maternal Death Notification Form should be completed.⁽⁴²⁾

4.9 HSE Medical Exposure Radiation Unit

The HSE regulates patient radiation protection practices in radiological facilities, both private and public and receives advice from the National Radiation Safety Committee on the safety of these practices. The Medical Exposure Radiation Unit of the HSE was established to fulfil the regulatory functions assigned to the CEO of the HSE in SI 478 of 2002 and SI 303 of 2007. The HSE regulates to protect patients from the harmful effects of exposure to ionising radiation, whereas the Environmental Protection Agency (EPA) regulates to protect workers and members of the public from the harmful effects of exposure to all ionising radiation.

Among Medical Exposure Radiation Unit's functions is managing the statutory incident reporting system.⁽⁴³⁾ The National Radiation Safety Committee has produced guidance on the types of incidents that are notifiable to the Medical Exposure Radiation Unit and gives a guide on how non-notifiable incidents are defined.⁽⁴⁴⁾ An example of a notifiable incident is an 'Exposure Greater than intended, for example; Incorrect Radiopharmaceutical'. The Medical Exposure Radiation Unit has designed incident reporting templates and these are available here, <http://www.hse.ie/eng/>

4.10 Environmental Protection Agency

The Environmental Protection Agency (EPA) is the designated competent authority responsible for regulating the use of ionising radiation in Ireland. This function was formerly under the remit of the Radiological Protection Institute of Ireland (RPII)

which merged with the EPA in 2014. Following this, the office of radiological protection within the EPA is now responsible for ensuring that people and the environment in Ireland are protected from the harmful effects of ionising radiation.

Regulation of the use of ionising radiation is achieved through a system of licensing and inspection, which is designed to ensure that the risk to workers and members of the public from ionising radiation is kept to a minimum. The primary legislation governing safety in the uses of ionising radiation in Ireland is the Radiological Protection Act, 1991. The Radiological Miscellaneous Provisions Act 2014 provides the EPA with the functions and powers to regulate irradiating apparatus and radioactive materials used in Ireland.

The EPA's Office of Radiological Protection (EPA-ORP) regulates and licenses almost 1,700 practices in Ireland. These include hospitals, dentists, veterinary surgeons, universities, institutes of technology and industrial users. The EPA also regulates the exposure of aircrew to cosmic radiation, and, where appropriate, work activities involving naturally occurring radioactive materials (NORM).

The Irish population is exposed to radiation from several sources, which are present either naturally in the environment or have been produced artificially by man. The greatest health risk from radiation in Ireland is caused by radon which accounts for 56% of the total radiation dose received by the Irish population. The role of the EPA with regard to radiation is to ensure that Irish people and the environment are adequately protected from the harmful effects of ionising radiation. The EPA achieves this role by:

- providing advice to the public and the Government
- monitoring people's exposure to radiation
- regulating and licensing all those who use radiation
- providing technical support for Ireland's plan to deal with radiation emergencies
- cooperating with similar bodies internationally.

Generally, incidents involving workers, members of the public or the environment that are likely to give rise to public concern should be reported to the EPA regardless of their radiological significance. In accordance with Article 41 of SI No. 125 of 2000, there are several incidents that must be reported to the EPA. These include any incident involving the 'unintended exposure of a person arising from a design flaw, incorrect calibration or malfunction of a licensed item' and 'any incident arising from a diagnostic or therapeutic procedure in which a wrong patient receives a dose exceeding the dose limits of a member of the public'.

4.11 Health and Safety Authority

The Health and Safety Authority (HSA) is the national statutory body with responsibility for enforcing occupational health and safety law, promoting accident prevention, and providing information and advice to all companies, organisations and individuals. The aim of the HSA is to make occupational safety, health and welfare an integral part of doing business in every Irish workplace. The Safety, Health and Welfare at Work Act 2005 specify certain accidents and dangerous occurrences that must be reported to the HSA.

For example, any injury or accident to a member of the public caused by HSE work activities where medical treatment is received irrespective of its seriousness is to be reported to the HSA as soon as is practicable.⁽⁴⁵⁾ The HSA monitors compliance with legislation in the workplace and can take enforcement action (up to and including prosecutions). Incident reports can be submitted to the HSA via its online applications web page at www.hsa.ie.

4.12 Other sources of patient safety intelligence in Ireland

Other sources of patient safety intelligence in Ireland include the following:

- Office of the Ombudsman
- Irish Medical Council
- Bord Altranais agus Cnáimhseachais na hÉireann, or Nursing and Midwifery Board of Ireland (NMBI)
- Dental Council
- Pharmaceutical Society of Ireland
- Pre-Hospital Emergency Care Council
- health and social care professionals regulated by CORU.

4.12.1 Office of the Ombudsman

The function of the Ombudsman is to investigate complaints from members of the public who believe that they have been unfairly treated by certain public bodies such as the Health Service Executive (HSE). The public bodies whose actions may be investigated by the Ombudsman are:

- all Government departments
- HSE (and public hospitals and health agencies providing services on behalf of the HSE)
- local authorities.⁽⁴⁶⁾

In relation to patient safety, members of the public may make a complaint to the Office of the Ombudsman to review the issue if the complainant is not satisfied with the outcome of the HSE complaints management process.

4.12.2 Medical Council

The Medical Council regulates medical doctors in Ireland. Its purpose is to protect the public by promoting and better ensuring high standards of professional conduct and professional education, and training and competence among doctors. The Medical Council's responsibilities include:

- maintaining the Register of Medical Practitioners
- ensuring the highest standards of medical training and education in Ireland
- promoting good medical practice
- overseeing doctors' continuing professional development
- investigating complaints against medical doctors.⁽⁴⁷⁾

4.12.3 Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland, as described in the Nurses and Midwives Act, 2011, has two main objectives: to protect the public and to ensure the integrity of nursing and midwifery practices. The Board is the statutory body which sets the standards for the education, registration and professional conduct of nurses and midwives. It also advises on how nurses and midwives should provide care to patients, their families and society.⁽⁴⁸⁾

4.12.4 Dental Council

The Dental Council was established under the provisions of the Dentists Act 1985. It is responsible for promoting high standards of professional education and professional conduct among dentists. The main functions of the Council are:

- To establish, maintain and publish a register of dentists and dental specialists and to provide for the registration and retention of dentists' names in these registers.
- To satisfy itself as to the adequacy and suitability of the dental education and training provided in the State's dental schools and to the standards required at examinations for primary qualifications.
- To inquire into the fitness of a registered dentist to practise dentistry on the ground of alleged professional misconduct or unfitness to practise by reason of physical or mental disability and to take appropriate action. The Council has power, subject in some instances to confirmation by the High Court to advise,

admonish, censure, suspend, attach conditions to registration or erase a dentist's name from the register.

- To make, with the consent of the Minister, schemes for the establishment of classes of auxiliary dental workers.
- To discharge the duties assigned to the Council pursuant to the provisions of EU Dental Directives.
- To advise the dental profession and the public on all matters relating to dental ethics and professional behaviour.
- To advise the Minister on all matters relating to the functions of the Council under the Act.⁽⁴⁹⁾

4.12.5 Pharmaceutical Society of Ireland

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies.⁽⁵⁰⁾

4.12.6 Pre-Hospital Emergency Care Council

The Pre-Hospital Emergency Care Council regulates emergency medical services in Ireland and their role is to protect the public. The Council is an independent statutory agency with responsibility for standards, education and training in the field of pre-hospital emergency care. The Pre-Hospital Emergency Care Council also maintains a statutory register of emergency medical services practitioners.⁽⁵¹⁾

4.12.7 Health and social care professionals regulated by CORU

CORU is Ireland's multi-profession health regulator. Its role is to protect the public by promoting high standards of professional conduct, education, training and competence through statutory registration of health and social care professionals. CORU was set up under the Health and Social Care Professionals Act 2005 (as amended). It is made up of the Health and Social Care Professionals Council and 12 registration boards, one for each profession named in the Act. The professions to be regulated are clinical biochemists, medical scientists, orthoptists, physiotherapists, podiatrists, psychologists and social care workers. CORU currently has registers open for dietitians, occupational therapists, radiographers and radiation therapists, social workers and speech and language therapists.⁽⁵²⁾

Next steps

Having completed this 'As is' analysis of patient safety intelligence systems and structures in Ireland, in addition to an international review of patient safety surveillance systems, the next step for HIQA is to convene an advisory group to access expert opinion on the prevailing situation in Ireland.

Following input from the advisory group, the final stage and the overall aim of the project is to produce a set of recommendations to the Minister for Health on the coordination of patient safety intelligence in Ireland. The final recommendations to the Minister will be published on the HIQA website, www.hiqa.ie.

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6. Appendices

Appendix 1 — Glossary of associated abbreviations

Term	Explanation
CIDR	Computerised Infectious Disease Reporting System
CMO	Chief Medical Officer
CRA	Clinical risk advisor
DNF	Death and notification form
EMS	Emergency Medical Services
EPA	Environmental Protection Agency
GP	General Practitioner
HIQA	Health Information and Quality Authority
HPRA	Health Products Regulatory Authority
HPSC	Health Protection Surveillance Centre
HSA	Health and Safety Authority
HSE	Health Service Executive
IBTS	Irish Blood Transfusion Service
ICPS	International Classification for Patient Safety
IIMS	Incident Information Management System
MDE	Maternal Death Enquiry
MERU	Medical Exposure Radiation Unit
MHC	Mental Health Commission
NHO	National Haemovigilance Office

Term	Explanation
NIMLT	National Incident Management Learning Team
NIMS	National Incident Management System
NIRF	National Incident Report Form
NORM	Naturally Occurring Radioactive Materials
NPEC	National Perinatal Epidemiology Centre
NPOG	National Performance Oversight Group
NRSC	National Radiation Safety Committee
NTMA	National Treasury Management Agency
PHECC	Pre-Hospital Emergency Care Council
PI	Performance indicator
PPGs	Policies, procedures and guidelines
PSI	Pharmaceutical Society of Ireland
QAVD	Quality Assurance and Verification Division
QID	Quality Improvement Division
RDO	Regional Director of Operations
SADS	Sudden Adult Death Syndrome
SIDS	Sudden Infant Death Syndrome
SIMP	Safety Incident Management Policy
SRE	Serious reportable event
TSO	Transfusion surveillance officer
WHO	World Health Organization

Appendix 2 – Glossary of terms

Term	Explanation
Audit	The assessment of performance against any standards or criteria (clinical and non-clinical) in a health or social care setting ⁽⁵³⁾
Adverse event	An incident which results in harm to the patient. ⁽³¹⁾
Adverse incident	Any act, omission or other matter in relation to which a delegated claim has been made, or may, in the opinion of the State authority concerned, be made. ⁽²¹⁾
Benchmarking	A continuous process of measuring and comparing care and services with similar service providers. ⁽⁵³⁾
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. ⁽³¹⁾
Communication	Communication by the local manager to the next level of management refers to providing information about the incident so that the higher level of management is aware of it. There is no transfer of responsibility for the management of the incident to the next or any higher level of management. ⁽¹²⁾
Confidentiality	Privacy in the context of privileged communication (such as patient-doctor consultations) and medical records is safeguarded. (WHO) ⁽⁵⁴⁾
Data	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed. ⁽⁵⁵⁾
Escalation	Refers to the process whereby the local manager reports the safety incident to the management level above them and onward to the hospital group and or primary care area and or administrative area and national-director level as required. An incident is escalated when the local

Term	Explanation
	manager determines that additional support is required for managing and investigating the incident. ⁽¹²⁾
Healthcare	Services received by individuals or communities to promote, maintain, monitor and restore health. ⁽⁵⁵⁾
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. ⁽⁵⁶⁾
Healthcare organisation	Entity that provides, coordinates, and or insures health and medical services for people. (WHO) ⁽³¹⁾
Incident	An event or circumstance which could have, or did, lead to unintended and or unnecessary harm. Incidents include adverse events which result in harm; near misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service-user complaints which are associated with harm. Incidents can be clinical or non-clinical and include incidents associated with harm to: patients, service users, staff and visitors, the attainment of HSE objectives, information communications technology systems, data security and the environment. ⁽¹⁰⁾
Incident reporting	A system in many healthcare 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, the effectiveness of the incident reporting is limited, including fear of punitive action, reluctance of non-physicians to report incidents involving physicians, lack of understanding of what a reportable incident is, and lack of time for paperwork. ⁽³¹⁾

Term	Explanation
Information and communications technology (ICT)	The tools and resources used to communicate, create, share, store and manage information electronically. ⁽⁵⁷⁾
Just culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action. ⁽³¹⁾
Near miss	A deviation from best practice in healthcare 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. ⁽³¹⁾
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. ⁽¹⁰⁾
Patient safety	Actions undertaken by individuals and organisations to protect healthcare recipients from being harmed by the effects of healthcare services. ⁽³¹⁾
Patient safety data	The broad heterogeneous information that includes, but is not limited to, the description of incidents with medical errors and near misses, their causes, their follow-up corrective actions, interventions that reduce future risk, and patient safety hazards. ⁽³¹⁾
Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to the patient. ⁽³¹⁾
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. ⁽⁵³⁾
Regulation	A sustained and focused control exercised by a public

Term	Explanation
	agency over activities that are valued by a community. ⁽⁵⁵⁾
Risk	The likelihood of an adverse event or outcome. ⁽⁵⁵⁾
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. ⁽³¹⁾
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. ⁽⁹⁾
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 services. ⁽¹⁰⁾
Surveillance	Routine collection and review of data to examine the extent of a disease, to follow trends, and to detect changes in disease occurrence. ⁽³¹⁾
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. ⁽³¹⁾
Standard for reporting	Formally accepted or endorsed definition and rules regarding the types of events reported to patient safety reporting systems, the data and information collected on these events, and the reporting formats used. ⁽³¹⁾

Appendix 3 — Example of a balanced scorecard for acute services 2015⁽⁵⁸⁾

Quality		Target Year to date	Year to date	% Var Year to date
Serious reportable events (SREs)	Performance reporting under development.	New performance indicator	New performance indicator	New performance indicator
Surgery	Percentage day-case rate for elective laparoscopic cholecystectomy.	>60%	46%	23%
	Percentage emergency hip fracture surgery carried out within 48 hours.	95%	75%	-21.1%
Re-admission rates	Medical: percentage of emergency re-admissions within 28 days.	9.6%	11%	-14.6%
	Surgery: percentage of surgical re-admissions within 30 days.	Less than [$<$] 3%	2%	33.3%
Cancer services	Symptomatic breast: percentage of attendances whose referrals are triaged as urgent by the cancer	9.6%	11%	-14.6%

Quality		Target Year to date	Year to date	% Var Year to date
	centre and adhered to the HIQA standard of two weeks for urgent referrals.			
	Lung: percentage of patients attending lung rapid-access clinic who attended or were offered an appointment within 10 working days of receipt of referral in designated cancer centres.	Less than [$<$] 3%	2%	33.3%
National Early Warning Score (NEWS)	Percentage of hospitals with full implementation of NEWS in all clinical areas.	100%	100%	0%
Irish Maternity Early Warning Score (IMEWS)	Percentage of maternity units and or hospitals with full implementation of IMEWS.	100%	100%	0%

Appendix 4 — HSE Safety Incident Management Policy Communication and Escalation Form (two pages)

HSE Safety Incident Management (SIM) Policy Communication / Escalation Form (2 pages)									
(Please ensure this form is as complete as possible & and refer to the Safety Incident Management Policy 2014 for guidance)									
NAEMS (SCA) Reference	(State Claims Agency)								
IIMS Reference Number	(QPS)								
	(Other)								
Date incident occurred:	Date incident report form completed:								
Date incident inputted/reported on NAEMS (State Claims Agency) :	Date incident inputted/reported on IIMS :								
<p>The Form is Being Notified to the Next Level of Management to: (see section 7.2 of SIM policy)</p> <p>Communicate <input type="checkbox"/> Escalate <input type="checkbox"/> details of the management of the safety incident (with no transfer of responsibility for management)</p>									
<p>1. Impact assessment of incident according to the Impact Table (see appendix 1 of SIM policy)</p> <p style="text-align: center;">Negligible <input type="checkbox"/> Minor <input type="checkbox"/> Moderate <input type="checkbox"/> Major <input type="checkbox"/> Extreme <input type="checkbox"/> (please choose one)</p> <p>2. Is this incident a Serious Reportable Event (SRE) No <input type="checkbox"/> Yes <input type="checkbox"/> (if yes, see below & refer to appendix 5)</p>									
If yes, please write event type (care management etc.)									
If yes, please write the event sub-category (A, B etc.)									
<p>3. Briefly Describe the Safety Incident What (unintended / unnecessary) harm has occurred; include numbers of service users / staff involved?</p> <p style="font-size: x-small;">(do <u>not</u> include details that could identify a patient or person).</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>									
<p>4. Location & Contact Details</p> <p>Name of Service:</p> <p>Service location (Hospital Group/PCCC area):</p> <p>Section/Ward/Department/Service:</p>									
<p>5. Named Senior Accountable officer (or their delegate) with responsibility / accountability for managing this incident / service.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 20%;">Name</td><td></td></tr> <tr><td>Title</td><td></td></tr> <tr><td>Email</td><td></td></tr> <tr><td>Telephone</td><td></td></tr> </table>		Name		Title		Email		Telephone	
Name									
Title									
Email									
Telephone									
<p>6. Is there a requirement to report this Safety Incident to any external regulators / agencies / insurers (other than State Claims Agency)?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, see below) (see Appendix 7 HSE Safety Incident Management Policy)</p>									
If Yes: Name regulator(s)/agency (ies) reported / notified to	Dates of Notification (DD/MM/YYYY)								
1									
2									
3									
<p>7. Has a complaint been made under Your Service Your Say? No <input type="checkbox"/> Yes <input type="checkbox"/></p>									

8. Has this incident been assessed to determine the type of investigation required No Yes

Outcome of Assessment	No	Yes	
Decision to conduct a systems analysis investigation in line with HSE Guidance.			<i>If yes, please fill in section 9.</i>
Decision to analyse data for aggregate analysis			<i>If yes, aggregate should be reviewed by local quality & safety committee (or an equivalent)</i>
No further investigation required past assessment.			<i>If yes, this decision should be reviewed by local quality & safety committee (or an equivalent)</i>
Decision to conduct a look-back review			<i>If yes, decision communicated to the relevant national director.</i>
Incident Management team established			<i>If yes, please fill in section 10.</i>

9. Systems Analysis Investigation Details

	No	Yes	
Have investigator(s) been assigned?			<i>If yes, complete names below.</i>
Have terms of reference (TOR) been prepared in line with HSE Guidance			<i>If yes, please attach TOR.</i>
Were the investigator(s) directly involved in this incident or the management of the service / department <i>(please note HSE guidance specifies that investigators should not be)</i>			<i>If yes, please refer to HSE guidance.</i>
Name(s) of the Investigators & Date(s) investigator(s) assigned (DD/MM/YYYY)			
1			
2			
Anticipated completion date of the systems analysis investigation (DD/MM/YYYY)			

10. Safety Incident Management Team Details

Name / Title of Chairperson of the Safety Incident Management Team	
Email:	
Landline	
Mobile	
Date Established	

11. Is this incident being escalated to the next level of management for additional support? No Yes *(if yes, see below)*

Please chose from the following (you may chose more than one)	Yes	No
1 The incident involves more than one division / care group / hospital group.		
2 The local area has issues with capacity or capability to manage and investigate this incident.		
3 The HSE investigator(s) deem that external input to the investigation is required.		
4 The assessment of this incident has indicated that a look-back review is required.		
5 There is a significant risk to public confidence in services.		
6 An external investigation is being conducted (e.g. by Mental Health Commission, HIQA, HSA, Gardai.		
7 Other, please write.		

12. Has a draft media statement / communications plan been prepared with press office / communications manager? Yes No

13 Describe any service user / carer / public / staff other key holder needs & arrangements put in place to address these

14. Describe any public or staff confidence issues identified and actions taken including communication undertaken and planned / support provided / further support planned.

Appendix 5 — Agencies to whom the HSE reports

HSE agency	What to report	How to report	Legal requirement
Health Protection Surveillance Centre (HPSC)	Diseases that are identified by the HPSC as notifiable under legislation.	Notifications are made to the relevant medical officer for Health using the relevant form (downloadable from HPSC website www.hpsc.ie).	Yes
Medical Exposure Radiation Unit of the HSE	Radiation incidents to patients. Incidents above a threshold level where the wrong patient received a radiation dose or a dose much greater than intended.	Contact the Medical Exposure Radiation Unit	Yes
Clinical Indemnity Scheme (CIS)	Any incident directly related to service-user treatment or care which did or could have resulted in an adverse outcome (such as treatment error, medical equipment failure, and so on).	Via the National Incident Management System (previously STARSweb)	Yes
Coroner's office	There are a total of 32 instances in which deaths must be reported to the coroner.	The list of instances can be found on www.coroners.ie . Contact is made directly to the relevant local coroner.	Yes
Data Protection Commissioner via Consumer Affairs	All information breaches.	All information and or data breaches must be reported to the Consumer Affairs or ICT Division of the HSE immediately. Members of staff and their line manager must complete a data breach incident report and forward to their local consumer affairs officer.	Yes

External agency	What to report	How to report	Legal requirement
Environmental Protection Agency (EPA)	Radiation incidents to staff or members of the public.	Contact the EPA, see www.epa.ie	Yes
Health and Safety Authority (HSA)	Incidents in respect of accidents to employees.	IR1 form. On-line reporting available at www.hsa.ie .	Yes
HSA	Incidents in respect of accidents to non-employees.	IR1 form. On-line reporting available at www.hsa.ie .	Yes
HSA	Incidents in respect of events which are categorised as dangerous occurrence.	IR3 form. On-line reporting available at www.hsa.ie	Yes
Health Information and Quality Authority (HIQA)	Those in charge of a designated centre must ensure that HIQA is formally notified when certain events or incidents take place, known as 'notifiable events'.	Forms available on line at www.hiqa.ie .	Yes
HIQA	Children in childcare — certain deaths should be reported to the SSI within 48 hours of the death occurring.	Form is available in HIQA <i>Guidance for the Health Service Executive for the Review of Serious Incidents including Death of Children in Care</i> .	Yes

External agency	What to report	How to report	Legal requirement
Health Products Regulatory Authority (HPRA, formerly the Irish Medicines Board)	<ul style="list-style-type: none"> ▪ Any malfunction of or deterioration in the characteristics and performance of a device, as well as inaccuracies in the instruction leaflet which might lead to or might have led to the death of a service user or to deterioration in health. ▪ Any technical or medical reason due to a risk of serious injury or death resulting in the recall of a device from the market by a manufacturer or the issue of an advisory notice. 	Form available on line at www.hpra.ie .	Yes
HPRA	Serious adverse reactions (SARs) and serious adverse events (SAEs) related to the collection and transfusion/application of blood and tissues and cells.	Form available online at www.hpra.ie .	Yes
HSE's indemnifiers (State Claims Agency)	All non-clinical incidents deemed as having potential to result in a claim, such as public or employee liability.	Via relevant indemnifiers' reporting procedures.	Yes
National Perinatal Epidemiology Centre (NPEC)	Deaths including certain types of stillbirths, early neonatal deaths and late neonatal deaths.	Perinatal Death Notification Form available on the NPEC website: www.ucc.ie/en/npec/projects/ .	No
Maternal Death Enquiry (MDE) Ireland	Certain categories of maternal deaths.	Maternal Death Notification form available from: Maternal Death Enquiry office: University Maternity Hospital Cork.	No

External agency	What to report	How to report	Legal requirement
Mental Health Commission (MHC)	<ul style="list-style-type: none"> ▪ Death occurring in approved centres within 48 hours of the death. All sudden, unexplained deaths of persons attending a day hospital, day centre or currently living in a 24-hour staffed community residence within seven days of the death. ▪ Incident summary reports are required on a six-monthly basis. 	Via the MHC's Death and Notification Form (DNF) or approved centres may use their own existing notification form where such a form contains all the fields specified in the MHC's DNF.	Yes
National Haemovigilance Office	Incidents relating to severe adverse reactions and events relating to blood component administration.	Notifiable to the National Haemovigilance Office as soon as possible using the Initial Report Form, available at www.giveblood.ie . The National Haemovigilance Office also has a Rapid Alert Notification System to be used in rare circumstances.	Yes

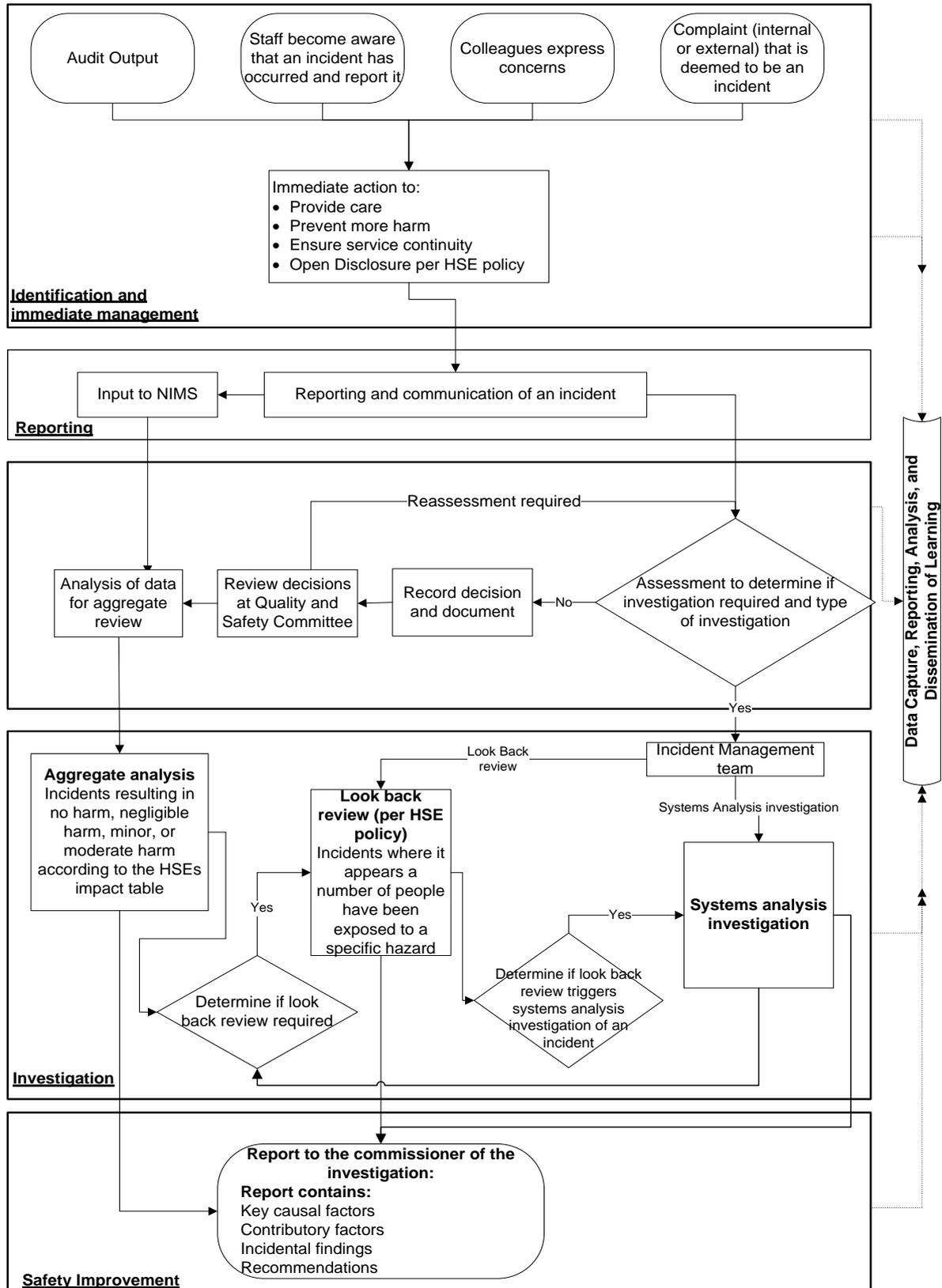
Appendix 6 – HSE impact table for clinical and non-clinical incidents

	Negligible	Minor	Moderate	Major	Extreme
Injury	Adverse event leading to minor injury not requiring first aid. No impaired Psychosocial functioning	Minor injury or illness, first aid treatment required. <3 days absence <3 days extended hospital stay. Impaired psychosocial functioning greater than 3 days less than 1 month.	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, An Garda Síochána (violent and aggressive acts). >3 Days absence. 3-8 Days extended hospital stay. Impaired psychosocial functioning greater than 1 month less than 6months.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling. Impaired psychosocial functioning greater than 6 months.	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public. Permanent psychosocial functioning incapacity.
Service User Experience	Reduced quality of service user experience related to inadequate provision of information.	Unsatisfactory service user experience related to less than optimal treatment and/or inadequate information, not being talked to & treated as an equal; or not being treated with honesty, dignity & respect, readily resolvable.	Unsatisfactory service user experience related to less than optimal treatment resulting in short term effects (less than 1 week).	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling. Impaired psychosocial functioning greater than 6 months.	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public. Permanent psychosocial functioning incapacity.

<p>Compliance with standards (Statutory, Clinical, Professional & Management)</p>	<p>Minor non compliance with internal standards. Small number of minor issues requiring improvement.</p>	<p>Single failure to meet internal standards or follow protocol. Minor recommendations which can be easily addressed by local management.</p>	<p>Repeated failure to meet internal standards or follow protocols. Important recommendations that can be addressed with an appropriate management action plan.</p>	<p>Repeated failure to meet external standards. Failure to meet national norms and standards / Regulations (e.g. Mental Health, Child Care Act etc). Critical report or substantial number of significant findings and/ or lack of adherence to regulations.</p>	<p>Gross failure to meet external standards. Repeated failure to meet national norms and standards / regulations. Severely critical report with possible major reputational or financial implications.</p>
<p>Objectives/Projects</p>	<p>Barely noticeable reduction in scope, quality or schedule.</p>	<p>Minor reduction in scope, quality or schedule.</p>	<p>Reduction in scope or quality of project; project objectives or schedule.</p>	<p>Significant project over – run.</p>	<p>Inability to meet project objectives. Reputation of the organisation seriously damaged.</p>
<p>Business Continuity</p>	<p>Interruption in a service which does not impact on the delivery of service user care or the ability to continue to provide service.</p>	<p>Short term disruption to service with minor impact on service user care.</p>	<p>Some disruption in service with unacceptable impact on service user care. Temporary loss of ability to provide service.</p>	<p>Sustained loss of service which has serious impact on delivery of service user care or service resulting in major contingency plans being involved.</p>	<p>Permanent loss of core service or facility. Disruption to facility leading to significant 'knock-on' effect.</p>

Adverse publicity/ Reputation	<p>Rumours, no media coverage. No public concerns voiced.</p> <p>Little effect on staff morale. No review/investigation necessary.</p>	<p>Local media coverage – short term. Some public concern. Minor effect on staff morale /public attitudes. Internal review necessary.</p>	<p>Local media – adverse publicity. Significant effect on staff morale & public perception of the organisation. Public calls (at local level) for specific remedial actions.</p> <p>Comprehensive review/investigation necessary.</p>	<p>National media/ adverse publicity, less than 3 days. News stories & features in national papers. Local media –long term adverse publicity. Public confidence in the organisation undermined. HSE use of resources questioned. Minister may make comment. Possible questions in Dáil. Public calls (at national level) for specific remedial actions to be taken possible HSE review/investigation.</p>	<p>National/International media/ adverse publicity, > than 3 days. Editorial follows days of news stories & features in National papers. Public confidence in the organisation undermined.</p> <p>HSE use of resources questioned. CEO's performance questioned. Calls for individual HSE officials to be sanctioned. Taoiseach /Minister forced to comment or intervene. Questions in the Dáil. Public calls (at national level) for specific remedial actions to be taken. Court action. Public (independent) Inquiry.</p>
Financial Loss	<€1k	€1k – €10k	€10k – €100k	€100k – €1m	>€1m
Environment	Nuisance Release.	On site release contained by organisation.	On site release contained by organisation.	Release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc).	Toxic release affecting off-site with detrimental effect requiring outside assistance.

Appendix 7 – Overview of safety incident management process



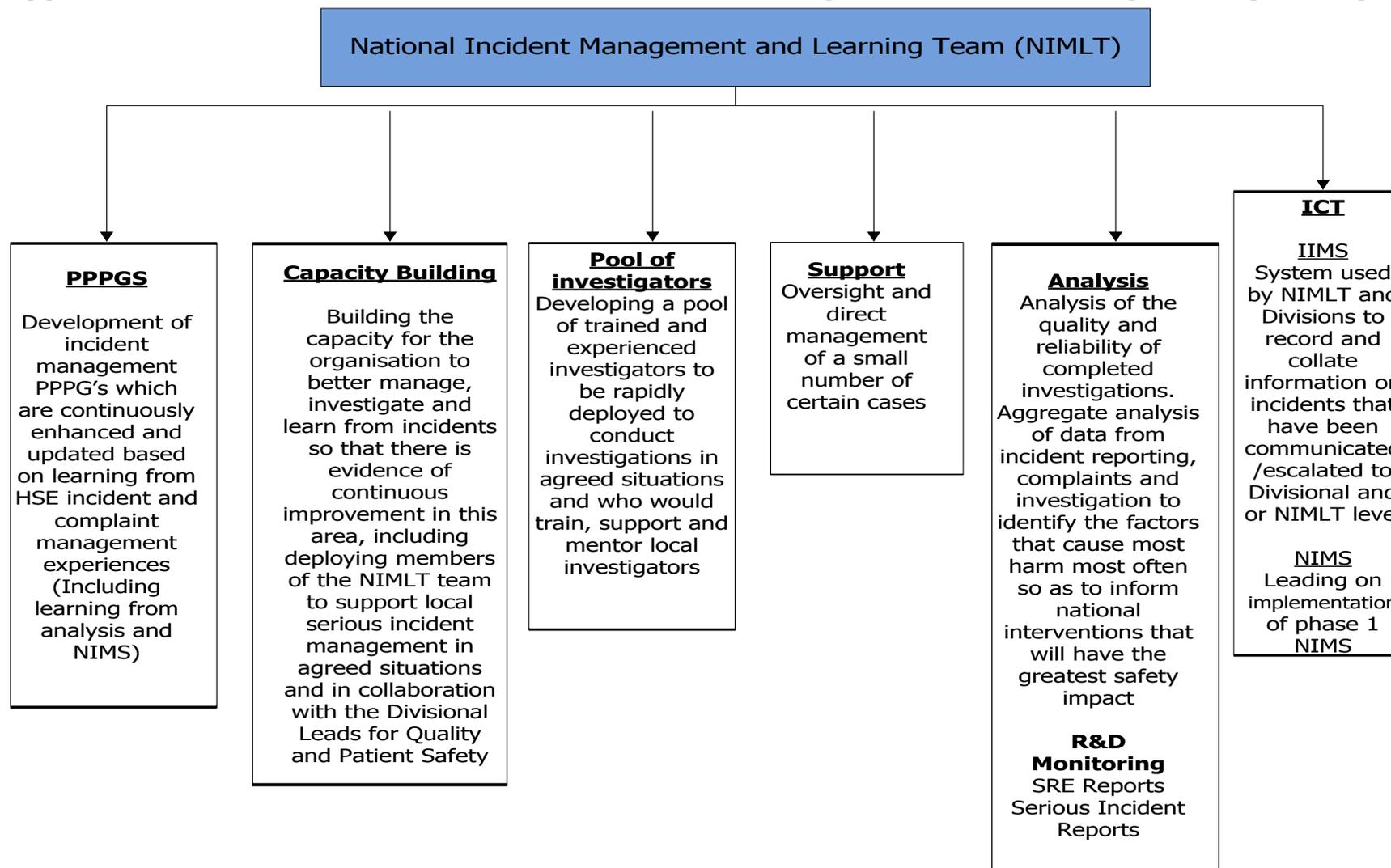
Appendix 8 – Serious reportable events summary list

1	Surgical events
1A	Surgery performed on the wrong body part by a healthcare service provider.
1B	Surgery performed on the wrong patient by a healthcare service provider.
1C	Wrong surgical procedure performed on patient by a healthcare service provider.
1D	Unintended retention of a foreign object in an enclosed body cavity in a patient after surgery or other procedure performed by a healthcare service provide
1E	Intra-operative or immediately postoperative death in a patient with no known medical problems (ASA Class I) occurring after surgery or other interventional procedure performed by a healthcare service provider.
2	Product or device events
2A	Patient death or serious disability associated with the use of contaminated medications, medical devices, or biologics provided by the healthcare service provider.
2B	Patient death or serious disability associated with the use or function of a medical device in which the medical device is used or functions other than as intended or anticipated in the care of a patient provided by the healthcare service provider.
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by a healthcare service provider but excluding death or serious disability associated with certain neurosurgical procedures or cardiac procedures known to present a high risk of intravascular air embolism.
3	Patient protection events
3A	Child or other dependent person discharged to the wrong person by a healthcare service Provider.
3B	Patient death or serious disability associated with a patient absconding from a healthcare service facility but excluding where a patient advises the healthcare service provider that he or she is leaving against medical advice.
3C	All sudden unexplained deaths or injuries which result in serious disability of a person who is an inpatient/resident in a mental healthcare facility.

4	Care management events
4A	Patient death or serious disability associated with a medication error by the healthcare service provider but excluding reasonable differences in clinical judgment involving drug selection and/or dose.
4B	Wrong formulation/route administration of chemotherapy by a healthcare service provider.
4C	Intravenous administration of mis-selected concentrated potassium chloride by a healthcare service provider.
4D	Patient death or serious disability due to the administration of incompatible blood or blood products by a healthcare service provider.
4E	Maternal Death for whom the hospital has accepted medical responsibility, registered with an independent midwife for pregnancy care/registered with a maternity hospital during pregnancy or within six weeks of delivery (whether in the hospital or not).
4F(i)	Perinatal death of a neonate occurring in a term infant or an infant weighing more than 2,500g.
4F(ii)	Death or encephalopathy of a normally formed neonate occurring in a term infant or an infant weighing more than 2,500g.
4G	Patient death or serious disability associated with severe hypoglycaemia (excluding neonates), the onset of which occurs while the patient is being cared for in a healthcare service facility.
4H	Death or serious disability (kernicterus) associated with non-detection by a healthcare service provider to identify and treat hyperbilirubinemia in neonates within the first 28 days of life.
4I	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare and social care residential facility.
4J	Patient death or serious disability due to spinal manipulative therapy by a healthcare service provider.
4K	Patient death or serious disability resulting from or associated with the use of restrictive interventions such a physical, mechanical, manual or environmental restraint (e.g. seclusion) to a patient while being cared for in a healthcare service facility.
4L	Diagnostic Error: Death or serious disability associated with a wrong diagnostic result e.g. mislabelled pathology specimen.

4M	The non utilisation of a donor organ deemed suitable for transplantation.
4N	Death of a living organ donor.
5	Environmental events
5A	Patient death or serious disability associated with an electric shock while being cared for in a healthcare service facility but excluding events involving planned treatments such as cardioversion.
5B	An incident in which a line designated for oxygen or other gas to be delivered to a patient while being cared for by a healthcare service provider contains the wrong gas or is contaminated by toxic substances.
5C	Patient death or serious disability associated with a burn incurred within a healthcare service facility.
5D	Patient death or serious disability associated with a fall– a. while being cared for in a healthcare service facility and/or b. during a clinical intervention from a healthcare professional (includes in the community setting, pre-hospital care and the Ambulance Service).
6	Criminal events
6A	Any instance of care ordered by or provided by someone impersonating a healthcare professional.
6B	Abduction of a patient of any age while being cared for in a healthcare service facility.
6C	Sexual assault on a patient or other person within or on the grounds of a healthcare service facility.
6D	Death or serious injury/disability of a patient or other person resulting from a physical assault that occurs within or on the grounds of a healthcare service facility.

Appendix 9 – Functions of the National Incident Management and Learning Team (NIMLT)



Appendix 10 — National Treasury Management Agency (Amendment) Act, 2000

Under the National Treasury Management Agency (Amendment) Act 2000,⁽²¹⁾
Section 11 (1) states that a State Authority shall –

- (a) Report any adverse incident to the Agency as soon as may be,
- (b) Furnish to the Agency in relation to any such incident such information as such an authority considers relevant and other information (if any) as the Agency considers relevant and specifies to such an authority.
- (c) In relation to the any such incident preserve and , if appropriate, furnish to the Agency such evidence as such as such an authority considers relevant and such other evidence (if any) as the Agency considers relevant and specifies to such an authority, and
- (d) Permit the Agency or any other person on behalf of the Agency to investigate any such incident in such a manner and to such an extent as the Agency considers appropriate.

Section 11 (2) defines an “adverse incident” as any act, omission or other matter in relation to which a delegated claim has been made, or may, in the opinion of the State authority concerned, be made.⁽²¹⁾

Appendix 11 — Risk management programmes undertaken by the State Claims Agency

Obstetrics

Obstetrics provides the most significant challenge from a risk management perspective, accounting for 54% of the State Claims Agency expenditure on clinical claims in 2014. In 2015, the clinical risk management unit is undertaking a programme of site visits to each of the 19 maternity units, following pre-site assessments. The purpose the pre-assessment is to identify those areas of maternity practice, in the 19 units, which require priority with management measures.

Pre- and post-graduate training

The State Claims Agency has developed a pilot undergraduate course on clinical risk management issues in collaboration with UCD. The aim of this pilot course is to roll it out to all universities nationwide in 2015. Similarly, the State Claims Agency has arranged with the Royal College of Physicians (RCPI) to assign and run a pilot course for medical postgraduates. The State Claims Agency hopes to roll out the pilot course to the remaining training bodies such as the Royal College of Surgeons (RCSI) in 2015.

Open disclosure

In collaboration with the HSE, the State Claims Agency has delivered 200 staff training sessions to 47 acute hospitals in relation to Open Disclosure. Further "train the trainer" programmes, which focus on building capacity and capability within the system, will continue throughout 2015. The General Scheme on open disclosure published in 2015⁽⁵⁹⁾ has provisions pertaining to the "protection of the apology" which is critical to have in place to protect front line workers and ensure open disclosure is fully adopted. HSE open disclosure policies and guidelines are detailed in Section 4.2.4 of this report.

The National Falls Prevention and Bone Health Implementation Project

The AFFINITY (Activating Falls and Fracture Prevention in Ireland Together) collaborative project between the State Claims Agency and the HSE aims to prevent harmful falls amongst persons aged 65 years and older, enhance the management of falls and improve health and wellbeing through a focus on bone health. Falls account for approximately one-third of fatal injuries in persons aged more than 60 years

Appendix 12 — Instances requiring notification to HIQA⁽³³⁾

Form	Nature of notification	Time frame	Person responsible
NF01	The unexpected death of any resident, including the death of any resident following transfer to hospital from the designated centre	Within three working days of the incident	Person in charge
NF02	Outbreak of any notifiable disease as identified and published by the Health Protection Surveillance Centre	Within three working days of the incident	Person in charge
NF03	Any serious injury to a resident which requires immediate medical or hospital treatment	Within three working days of the incident	Person in charge
NF05	Any unexplained absence of a resident from the designated centre	Within three working days of the incident	Person in charge
NF06	Any allegation, suspected or confirmed abuse of any resident	Within three working days of the incident	Person in charge
NF07	Any allegation of misconduct by the registered provider or by staff	Within three working days of the incident	Person in charge
NF08	Any occasion where the registered provider	Within three working days of	Person in charge

Form	Nature of notification	Time frame	Person responsible
	becomes aware that a member of staff is the subject of review by a professional body	the incident	
NF09	Any fire, any loss of power, heating or water, and any incident where an unplanned evacuation of the centre took place	Within three working days of the incident	Person in charge
NF20	When the person in charge proposes to be absent from a designated centre for a continuous period of 28 days or more	20 working days in advance of the change or within 3 working days if absence arises as a result of an emergency	Registered provider
NF21	Return of the person in charge after being absent for a continuous period of 28 days or more	Within three working days of return of the person in charge	Registered provider
NF30 DCOP Older People Services only	Change of the person in charge.	Within 10 working days of the change	Registered provider
NF30 DCD Disability Services only	Change of the person in charge.	Within 10 working days of the change	Registered provider
NF31 DCOP Older People services only	Change in people participating in management	20 working days in advance of the change	Registered provider
NF31 DCD	Change in people	20 working days	Registered

Form	Nature of notification	Time frame	Person responsible
Disability services only	participating in management	in advance of the change	provider
NF32 DCD Disability services only	Change in ownership of the Corporate body. The NF32 form is only applicable to designated centre for disability	8 weeks in advance of change	Registered provider
NF33 DCD Disability services only	Change to the Director, Manager, Secretary or any Similar Officer of the Corporate Body	8 weeks in advance of change	Registered provider
NF33 DCOP Older People services only	Change of Company Director	8 weeks in advance of change	Registered provider
NF34	Change of Company Details	8 weeks in advance of change	Registered provider
NF35	To cease to carry on the business of the designated centre and close the centre	Not less than six months	Registered provider
NF36	Change of partnership details	8 weeks in advance	Registered provider
NF37	Change of unincorporated body details	8 weeks in advance of change	Registered provider
NF38 DCD Disability services only	Change to the person responsible for the application on behalf	8 weeks in advance of change	Registered provider

Form	Nature of notification	Time frame	Person responsible
	of a partnership, company, unincorporated body or statutory body, a body established under the Health Acts 1947 to 2013 or a body established under the Health (Corporate Bodies) Act 1961		
NF38 DCOP Older People services only	Change of Contract Person or Provider Nominee	8 weeks in advance of change	Registered provider
NF60	Declaration of Occupancy for Billing Purposes The NF60 form is only applicable to designated centres for older people	<ul style="list-style-type: none"> • By the 15 January • By the 15 May • By the 15 September 	Registered provider
Quarterly Notifications Excel Spreadsheet (older people)	Any occasion when restraint was used Any occasion on which the fire alarm equipment is operated other than for the purpose of fire practice, drill or test of equipment A recurring pattern of theft or burglary Any death, including cause of death, other than those specified above	Submission dates for return of the quarterly notification spreadsheet form are: <ul style="list-style-type: none"> • 31 January (for incidents that took place in October, November and December) • 30 April (for incidents that took place in January, February and 	Person in charge

Form	Nature of notification	Time frame	Person responsible
		<p>March)</p> <ul style="list-style-type: none"> • 31 July (for incidents that took place in April, May and June) • 31 October (for incidents that took place in July, August and September). 	
<p>Quarterly Notifications Spreadsheet (disabilities)</p>	<p>Any recurring pattern of theft or reported burglary Any occasion on which a restrictive physical restraint was used Any occasion on which the fire alarm equipment is operated other than for the purpose of fire practice, drill or test procedure including Any injury to a resident, other than those previously notified in NF03 Any death, other than those previously notified in NF01, including cause of death</p>	<p>Submission dates for return of the quarterly notification spreadsheet form are:</p> <ul style="list-style-type: none"> • 31 January (for incidents that took place in October, November and December) • 30 April (for incidents that took place in January, February and March) • 31 July (for incidents that took place in April, May and June) • 31 October (for incidents that took place in July, August and September). 	<p>Person in charge</p>

Form	Nature of notification	Time frame	Person responsible
Follow-up Report	If additional information has been requested or is required in relation to notifications forms NF01, NF03, NF06 & NF07	As requested or required	Person in charge
Six-monthly nil-return notification	Where no incidents which require to be notified under Regulation 31 have taken place within the preceding six months	Submission dates for return of the six-monthly nil-return notification are 31 July (covering the period January to June) and 31 January (covering the period July to December)	Registered provider

Appendix 13 — Deaths which must be reported to a coroner

Sudden, unnatural, violent or unexplained deaths have to be reported to the Coroner. Doctors, funeral undertakers, the Register of Deaths, any householder and every person in charge of an institution or premises where the person who died was residing at the time of death have to inform the Coroner. Deaths are reported to the coroner under the Coroners Act, 1962 (rules of law); in addition, there are local rules which require that other deaths must be reported (rules of practice).

1. Sudden, unexpected or unexplained deaths.
2. Where the appropriate registered medical practitioner cannot sign a medical certificate of the cause of death (that is to say, a deceased person was not seen and treated within one month before death, or the cause of death is unknown or death may be due to an unnatural cause).
3. Even where the deceased had been attended by a registered medical practitioner for a documented illness, if the doctor is not satisfied in relation to the cause of death or death has occurred suddenly or unexpectedly, it must be reported.
4. Sudden infant death. Although the doctor may believe that an infant has died of sudden infant death syndrome (SIDS 'cot death'), such diagnosis can only be made following a post-mortem examination: this applies also to so-called 'sudden adult death syndrome' (SADS).
5. Where a death was directly or indirectly due to unnatural causes (regardless of the length of time between injury and death), including:
 - road traffic crash or collision
 - any accident in the home, workplace or elsewhere
 - any physical injury
 - falls and fractures
 - fractures in the elderly
 - drug overdose or drug abuse
 - neglect, including self-neglect
 - burns or carbon monoxide poisoning
 - starvation (including anorexia nervosa)
 - exposure and hypothermia
 - poisoning from any cause — occupational, therapeutic, accidental, suicidal, homicidal and also food poisoning
 - drowning
 - hanging

- firearms injuries.
- 6. Death resulting from an industrial or occupational disease or accident.
- 7. Deaths which are directly or indirectly the result of any surgical or medical treatment or any procedure. Where such treatment or procedure may have contributed in any way to death, the matter must be reported to the coroner regardless of the time that has elapsed between the event and death. Any allergic reaction to a drug administered therapeutically, and any toxic reaction or side-effect of a drug which may have caused or contributed to a death must be reported.
- 8. Where there is any allegation of medical negligence, misconduct or malpractice on the part of any registered medical practitioner, nurse or other person.
- 9. Septicaemia which may be caused by injury.
- 10. Death occurring during a surgical operation or anaesthesia.
- 11. Abortions (other than natural) and certain stillbirths.
- 12. Acute alcohol poisoning (chronic alcoholism is reportable, but a medical certificate of the cause of death will normally be accepted, unless there is some element of neglect [including self-neglect] or injury).
- 13. Deaths connected with crime or suspected crime.
- 14. Where death may be due to homicide or occurred in suspicious circumstances.
- 15. Death of a person in prison or legal custody, including deaths in hospital while sentence is being served and deaths in Garda stations.
- 16. Death of a patient in a mental hospital.
- 17. Death of a child in care or detention.
- 18. A death which may be due to CJD.
- 19. Where a person is found dead.
- 20. Where human remains are found.
- 21. Where the cause of death is unknown or obscure.
- 22. Where a body is to be removed from the State.
- 23. Where a person is brought in dead (BID or dead on arrival [DOA]) to the emergency department of a hospital.
- 24. Deaths occurring in an emergency department.
- 25. Where death occurs within 24 hours of admission to hospital.
- 26. Where death occurs within 24 hours of the administration of an anaesthetic, surgical procedure or any procedure. (Note where death may be due to a complication of an anaesthetic, surgical procedure, drug reaction or injury it must be reported to the coroner notwithstanding when death occurs, that is to say whether days, weeks, months or years after the event).
- 27. Certain deaths which occur in a department of a hospital, such as radiology department, outpatients, physiotherapy, electrocardiography (ECG), electroencephalography (EEG), and so on.

28. Maternal deaths.
29. Where a patient dies in hospital, having been recently transferred or discharged from a nursing home or other residential institution (including mental hospital or prison).
30. Where there is any doubt as to the cause of death.
31. A death in any public or private institution for the care of elderly or infirm persons.
32. Any death involving a Healthcare Associated Infection.

Appendix 14 — Agencies to whom the Health Service reports

HSE agency	What to report	How to report	Legal requirement
Health Protection Surveillance Centre (HPSC)	Diseases that are identified by the HPSC as notifiable under legislation.	Notifications are made to the relevant Medical Officer for Health using the relevant form (downloadable from HPSC website www.hpsc.ie).	Yes
Medical Exposure Radiation Unit (MERU)	Radiation incidents to patients. Incidents above a threshold level where the wrong patient received a radiation dose or a dose much greater than intended.	Contact the Medical Exposure Radiation Unit	Yes
Clinical Indemnity Scheme (CIS)	Any incident directly related to service user treatment or care which did or could have resulted in an adverse outcome (e.g. treatment error, medical equipment failure, etc.)	Via NIMS (previously STARSweb)	Yes
Coroner's office	There are a total of 32 instances in which deaths must be reported to the coroner.	The list of instances can be found on www.coroners.ie . Contact is made directly to the relevant local Coroner.	Yes
Data Protection Commissioner via Consumer Affairs	All information breaches.	All information/data breaches must be reported to the Consumer Affairs or ICT Division immediately. Members of staff and their line manager must complete a Data Breach Incident Report and forward to their local Consumer Affairs Officer.	Yes
Environmental Protection Agency (EPA)	Radiation incidents to staff or members of the public.	Contact the EPA- www.epa.ie	Yes

External agency	What to report	How to report	Legal requirement
Health & Safety Authority (HSA)	Incidents in respect of accidents to employees.	IR1 form. On-line reporting available at www.hsa.ie .	Yes
HSA	Incidents in respect of Accidents to non-employees.	IR1 form. On-line reporting available at www.hsa.ie .	Yes
HSA	Incidents in respect of events which are categorised as dangerous occurrence.	IR3 form. On-line reporting available at www.hsa.ie	Yes
Health Information and Quality Authority (HIQA)	Those in charge of a designated centre must ensure that HIQA is formally notified when certain events or incidents take place - known as 'notifiable events'.	Forms available on line at www.hiqa.ie .	Yes
HIQA	Children in Childcare - certain deaths should be reported to the SSI within 48 hours of the death occurring.	Form is available in HIQA Guidance for the HSE for the Review of Serious Incidents including Death of Children in Care.	Yes
Health Products Regulatory Authority-HPRA (formerly Irish Medicines Board)	<ul style="list-style-type: none"> ▪ Any malfunction of or deterioration in the characteristics and performance of a device, as well as inaccuracies in the instruction leaflet which might lead to or might have led to the death of a service user or to deterioration in health. ▪ Any technical or medical reason due to a risk of serious injury or death resulting in the recall of a device from the market by a manufacturer or the issue of an advisory notice. 	Form available on line at www.hpra.ie .	Yes

External agency	What to report	How to report	Legal requirement
HPRA	Serious adverse reactions (SARs) and serious adverse events (SAEs) related to the collection and transfusion/application of blood and tissues and cells.	Form available online at www.hpra.ie .	Yes
HSE's Indemnifiers (State Claims Agency)	All non-clinical incidents deemed as having potential to result in a claim e.g. Public/Employee liability.	Via relevant indemnifiers reporting procedure.	Yes
National Perinatal Epidemiology Centre (NPEC)	Deaths including certain types of still births, early neonatal deaths and late neonatal deaths.	Perinatal Death Notification Form available on the NPEC website: www.ucc.ie/en/npec/projects/ .	No
Maternal Death Enquiry (MDE)	Certain categories of maternal deaths.	Maternal Death Notification form available from: Maternal Death Enquiry office: University Maternity Hospital Cork.	No
Mental Health Commission (MHC)	<ul style="list-style-type: none"> ▪ Death occurring in approved centres within 48 hours of the death. All sudden, unexplained deaths of persons attending a day hospital, day centre or currently living in a 24 hour staffed community residence within 7 days of the death. ▪ Incident summary reports are required on a 6 monthly basis. 	Via the MHC's Death and Notification Form (DNF) or approved centres may use their own existing notification form where such a form contains all the fields specified in the MHC's DNF.	Yes

External agency	What to report	How to report	Legal requirement
National Haemovigilance Office	Incidents relating to severe adverse reactions and events relating to blood component administration.	Notifiable to the NHO as soon as possible using the Initial Report Form, available at www.giveblood.ie . The NHO also has a Rapid Alert Notification System to be used in rare circumstances.	Yes

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