Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

Review of information management practices for the National Incident Management System (NIMS) within the HSE

May 2021

Safer Better Care

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

- **Regulating health services** — Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Overview of the health information function of HIQA

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[(1)], the Health Information and Quality Authority (HIQA) 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 (ICT) 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 ICT infrastructure in health and social care services in Ireland is highly fragmented with major gaps and silos of information. This results in individuals being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is an 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, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders — patients and service users, health professionals, policy makers and the general public — to make choices or decisions based on the best available information. This is a fundamental requirement for a highly reliable healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services.

HIQA has a broad statutory remit, including both regulatory functions and functions aimed at planning and supporting sustainable improvements. In 2017, HIQA published standards in the area of health information — *Information management standards for national health and social care data collections*[2] — as per HIQA's remit under the Health Act 2007.[1] The standards provide a framework of best practice in the collection of health and social care data. HIQA has developed a structured review programme of assessing compliance with standards.[3] The aim of this review programme is to improve information management practices of national health and social care data collections in Ireland by assessing compliance with the standards in each national data collection. Ultimately, the review programme will drive improvements by identifying areas of good practice and areas where improvements are necessary across the range of national data collections.

Glossary of abbreviations

Abbreviation	Explanation
AMA	Authority Monitoring Approach
CAWT	Cooperation and Working Together
CEO	Chief Executive Officer
CHO	Community Healthcare Organisation
CIS	Clinical Indemnity Scheme
CMO	Chief Medical Officer
CPRI	Claims Previously Reported as Incidents
DoH	Department of Health
DPA	Data Protection Act
DPC	Data Protection Commission
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
DPSD	Danish Patient Safety Database
DSA	Delegated State Authority
ePOE	Electronic Point of Entry
GDPR	General Data Protection Regulation
GIS	General Indemnity Scheme
HIQA	Health Information and Quality Authority
HIPE	Hospital In-Patient Enquiry Scheme
HPRA	Health Products Regulatory Authority
HSA	Health and Safety Authority
HSE	Health Service Executive
ICPS	International Classification for Patient Safety
ICT	Information and Communications technology
IG	Information Governance
IHFD	Irish Hip Fracture Database
IIMS	Incident Information Management System
IMF	Incident Management Framework
ICPS	International Classification for Patient Safety
IRM	Integrated Risk Management
KPI	Key Performance Indicator
MERU	Medical Exposure Radiation Unit
MOU	Memorandum of Understanding
NAEMS	National Adverse Event Management System
NAS	National Ambulance Service
NE	Neonatal Encephalopathy
NIMS	National Incident Management System
NIRF	National Incident Reporting Form
NPOG	National Performance Oversight Group
NRLS	National Reporting and Learning System
NTMA	National Treasury Management Agency
PCRS	Primary Care Reimbursement Service
PIA	Privacy Impact Assessment

PUTZ	Pressure Ulcers to Zero
QAV	Quality Assurance and Verification
QPS	Quality and Patient Safety
SAO	Senior Accountable Officer
SCA	State Claims Agency
SIMT	Serious Incident Management Team
SRE	Serious Reportable Event

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Executive summary

The aim of this review is to assess the compliance of the National Incident Management System (NIMS) within the Health Services Executive (HSE) with the *Information management standards for national health and social care data collections.*[2] This review is part of an overall review programme being undertaken by HIQA to assess compliance with the Information Management Standards in all major national health and social care data collections within the HSE in Ireland. The Sláintecare report recognises the importance of quality health data and information to drive improvements in the future of healthcare in Ireland.[4] It is, therefore, very important that information is managed in the most effective way possible in order to ensure a high-quality safe service. Ultimately, the review programme aims to drive quality improvements by identifying areas of good practice and areas where improvements are necessary across national data collections.

In healthcare, incident management plays a vital role in patient safety surveillance and learning. There is an obligation on all health and social care services to identify, report, manage and review incidents, to facilitate and support a culture of learning, openness and transparency in relation to incidents. To this end, the HSE has developed a national policy for incident management called the Incident Management Framework (IMF), first published in 2018, and updated in 2020.[5] The purpose of this framework is to ensure that all health and social care incidents are identified, reported and reviewed so that learning from incidents can be shared. The framework sets out the principles, governance requirements, roles and responsibilities, and processes to be applied for the management of incidents in all service areas. In order to support the implementation of the IMF, it is necessary to have an information system in place. In 2015, the Department of Health (DoH) made the decision to use the NIMS system for this purpose and it was adopted as the single designated national information system for incident management and patient safety and learning within the HSE and HSE-funded services. Since 2015, the functionality of NIMS has significantly expanded, and it has evolved from being a system through which services fulfilled their statutory requirement to report adverse incidents directly to the State Claims Agency (SCA), to one which includes end-to-end risk management using additional functions such as, incident review screens, complaints modules, and dashboards to improve analysis and reporting of all incidents. The IMF underlines the requirement for all HSE and HSE-funded services to use NIMS for these purposes. Since the adoption of NIMS, there has been an increase in the reporting of incidents within the HSE, from approximately 125,000 incidents in 2014 to almost 205,000 incidents in 2020.

The importance of the NIMS system is further emphasised in light of the draft Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.[6] Once enacted, this will specify that health service providers must report notifiable incidents to HIQA and to the Mental Health Commission through NIMS, the National Treasury Management Agency's (NTMA) current incident management system. Furthermore, it is expected that the new National Patient Safety Surveillance System* being developed within the National Patient Safety Office in the Department of Health will incorporate NIMS as a key source of patient safety intelligence.[7] With these significant developments underway, it becomes ever more important that NIMS is fully fit-for-purpose and functional, as the single national incident report and learning system across all HSE and HSE-funded health and social care services in Ireland.

NIMS is a key national repository of data and information. Currently incident data is captured across all HSE services, including at acute hospital and community health organisation level, human resources (HR), and by the National Ambulance Service (NAS). This data is entered onto NIMS and available for use locally by HSE and HSE-funded services, and nationally by HSE Quality Assurance and Verification (QAV) and the SCA. NIMS data is used by the HSE to improve the quality and safety of services through the monitoring of incident data, risk management and using this data to gain insights and learning to improve patient safety. The data is also used to handle risk management, litigation and claims by the SCA. Given its importance, it is essential that the data and information held in NIMS is comprehensive and of the highest possible quality.

Owing to the complexity of the system, there are a significant number of stakeholders involved, and there is a unique model in place, with the system being hosted outside of the HSE by the State Claims Agency (via a third party system provider) who has a legal remit in this regard under the NTMA Act†. Viewed within an international context, Ireland's model for incident reporting is unusual compared with many international systems (including the UK, Canada, and Denmark). In general, these systems are sector-specific reporting systems, focused only on reporting incidents in relation to healthcare. Furthermore, such systems are usually held with the national patient safety organisation within the particular jurisdiction, and not within the national litigation agency. In Ireland's case, NIMS is held within our national litigation authority, the SCA, and used by all state sectors for reporting incidents.

As will be described in the following sections, the model in place in Ireland in relation to incident management has implications at oversight level in relation to governance, leadership and management, and additionally at service level in relation

** A patient safety surveillance system will pool information from a wide range of information sources to form intelligence to act as an early warning for patient safety risks in a service
† National Treasury Management Agency (Amendment) Act 2014.

to information management practices, trust in the system and data quality. The findings of this review of information management practices for NIMS within the HSE focus on three key areas: governance, leadership and management; information governance; and use of information. A summary of these findings are detailed below, followed by a summary of recommendations.

Governance, leadership and management

Strong governance, leadership and national oversight arrangements are essential to ensure that NIMS is meeting its objectives as an incident reporting and learning system for the HSE and all HSE-funded services.

As previously highlighted, how NIMS has evolved as a system within the HSE is unusual compared to other jurisdictions. The HSE is the 'owner' of NIMS data and is responsible for the effective management of incidents, the legal reporting of incidents via NIMS to the SCA, as well as the appropriate management of incident data within their services to support learning and quality improvement. The NIMS system and platform is owned, managed and maintained by the SCA. The SCA therefore has a dual role, firstly they have a legal responsibility to be notified of incidents under the NTMA Act. However, the functionality of NIMS is wider than just incident reporting; it is also a system for incident reviews, learning and risk management. The HSE therefore requires this system to support learning and quality improvement as well as being a mechanism through which to report incidents to the SCA. The second role of the SCA is the provision of a service to the HSE through technical support and management of their data, however this data is broader than incident data and includes more extensive information in relation to incident reviews and learning. The complexity of the current model, and the number of stakeholders involved across the HSE and the SCA, underpins the requirement for robust governance arrangements and also rigorous information management practices in relation to the NIMS system within the HSE.

Arising from this review, HIQA has concluded that while there are clear project teams and structures established in relation to the implementation of NIMS within the HSE, these need to be strengthened and further clarified. While there was evidence of governance structures in place around the current implementation of NIMS, the governance arrangements in relation to the long-term operational aspects of NIMS need to be more established. Additionally, within the current structures, clarity is needed on roles and responsibilities for NIMS within local and national HSE arrangements. Roles and responsibilities for the SCA in relation to NIMS also need to be clarified and clearly documented. In addition, the HSE needs to be assured by the SCA how their incident data, and in particular the broader and more in-depth incident review data, collected on NIMS is being managed appropriately.

As a result of the current model in place, there are complexities in relation to the governance of NIMS across the two agencies. Currently, the joint governance model and respective governance teams for NIMS tend to focus on the technical and project implementation aspects of NIMS. However, there is ambiguity regarding national responsibility for the governance of incident management data within the HSE. There is a need for national level coordination and leadership for the system. For example, although the National Director of QAV is identified as the NIMS 'Information Owner' within the HSE, HIQA was not able to identify who has overall responsibility for assuring and driving the quality of NIMS data across the HSE. In interviews with the QAV team, it was acknowledged that this responsibility ultimately lies at a service level under the role of senior accountable officer, but responsibility for national oversight and coordination of this requires further clarity.

While acknowledging that there is a Statement of Partnership in place between the two organisations under the joint governance arrangements, HIQA identified that this does not provide adequate clarity on who has ownership of the specific elements of information management and NIMS across the key partners. For example, responsibility for the development of long-term strategic and business planning; data quality; the development of guidance for specific areas of information management; as well as risk management for the effective collection and use of NIMS data. This gap in governance for NIMS has resulted in some key challenges facing the full implementation and effective use of NIMS within the HSE including: the use of alternative incident management systems at a local level; a strong reliance on paper-based data collection in some large acute hospitals; and challenges with local ICT connectivity and infrastructural weaknesses impacting on use of the NIMS system. It is essential for HSE leadership to take a national approach to NIMS to drive learning and improvement and to ensure that NIMS data are used to their full potential.

While HIQA also recognises the extent of stakeholder engagement undertaken since the inception of NIMS within the HSE, it has identified a lack of trust in the system among users at local level due to a lack of transparency as to who has access, at a national and SCA level, to the information entered on NIMS. This has resulted in a reluctance amongst some users to enter additional data to the mandatory data on NIMS, as well as the use of secondary incident management systems at a local level. As a result, there is a pressing need for a comprehensive engagement with service users and an evaluation of their use of the system and requirements. This evaluation would help to inform a strategic approach to ensure the national mandate for the use of NIMS as the single system for incident management within the HSE is achieved.

The review has also highlighted the need for a vision for the long-term collection of NIMS data. Although HIQA, in a 2016 report[8], previously recommended the move to electronic Point of Entry (ePOE) for all services, it is acknowledged that currently, different models of NIMS data collection are in place according to the infrastructure and resources available to each service that best support that service in meeting the requirements of compliance with the Incident Management Framework. However, regardless of current practices, HIQA identified through interviews that there was no consistent view as to what the optimal model regarding the effective and efficient collection of incident data would look like in the long-term, nor as to what the recommended information governance model to support such an approach would be. There has never been an evaluation or a cost-effectiveness analysis to establish the different options for a nationally recommended approach as part of a long-term strategic plan. HIQA was unable to conclusively establish who is responsible for taking responsibility for such a significant issue in the HSE, highlighting again a gap in relation to the current governance arrangements.

In relation to performance management, HIQA recognised as positive the use of key performance indicators (KPIs) reported in national and management level reports to drive improvement in the management of incidents and data quality locally. However, HIQA has noted that these KPIs relate specifically to severe incidents. They do not include KPIs for less serious events and near misses which can provide a rich source of learning to services in relation to quality and patient safety. In relation to audit, another key component of measuring performance, HIQA noted a lack of a formal schedule of audits. Without this it is difficult for senior management to be fully assured of the performance of NIMS and of data quality.

In addition to KPIs and audits, a third important measure of performance is risk management in relation to incident management. While the HSE have an integrated risk management policy, there is no specific joint risk register in place between the HSE and the SCA for NIMS within the HSE. Additionally, risk management is not a standing item on the agenda of any of the NIMS governance meetings. A system of this importance and scale should have in place a specific risk management approach for information management. Not having this in place results in risks not being identified, managed and controlled to prevent issues with NIMS arising or to mitigate same.

At the time of the review, HIQA identified that the HSE did not have a Statement of Purpose developed or published for NIMS. A Statement of Purpose is important in order to provide transparency and to enhance the confidence of those collecting and using NIMS data. Furthermore, HIQA identified a lack of NIMS-specific data sharing agreements to support the appropriate sharing of data from the HSE to the SCA or back to the HSE.

The gaps in governance, leadership and management for NIMS identified through this review have resulted in some major challenges facing the full implementation and effective use of NIMS within the HSE including: the use of alternative incident management systems at a local level; a strong reliance on paper-based data collection in some large acute hospitals; challenges with ICT connectivity and infrastructural weaknesses affecting use of the NIMS system; understanding of users' needs; trust issues at a local level; and low compliance with KPI targets for incidents. These findings are a symptom of lack of clear governance, leadership and management for NIMS within the HSE. The HSE owns this data and should be taking responsibility for leading a long-term strategic approach to ensure the effective collection and use of this data. This is essential not only from an efficacy and efficiency point of view, but also to support good data quality and effective use of NIMS data.

Use of information

In the health and social care sector, effective use of information is key to driving quality improvements. Timely access to good quality information benefits a range of stakeholders including health and social care professionals, managers, policy makers and ultimately health and social care services users. In order to gain the greatest benefit from health and social care data and information, the data must be accurate, complete, legible, relevant, timely and valid. NIMS is a very rich source of data which should be used to improve the quality and safety of services provided across health and social care, through monitoring incident data and using this data to manage associated risks.

Through this review, HIQA identified a high level of awareness of the importance of data quality and a number of data quality activities being undertaken by HSE QAV, Acute and Community Operations in the HSE and the SCA. However, the review found that the lack of clarity regarding specific roles and responsibilities in relation to information management has a direct impact on the quality of NIMS data and some key challenges were identified.

There is no specific individual or HSE department with overall responsibility for NIMS, nor any forum within the HSE that provides specific oversight for data quality for NIMS. Additionally, there is no data quality framework in place at a national level, nor a strategic approach to data quality that would help to guide data quality activities, including formal evaluations of data quality, and enhance compliance with KPIs for NIMS. Locally, the lack of clear national guidance on data quality can have an impact on the standardisation of data quality activities across services. Additionally, while there are a number of training initiatives in place for NIMS within the HSE, HIQA did not find evidence of a formal training needs analysis having been carried out. HIQA identified through interviews that NIMS users would benefit from

additional training, as well as a more coordinated approach to this area of information management.

The review also identified the use, by some services, of a secondary system alongside NIMS as a key challenge. This can cause backlogs and duplication of data input, and lead to a reduction in the quality of data reported on NIMS. In addition, the review found that a more tailored National Incident Report Form is required for reporting healthcare-specific incidents.

HIQA acknowledges as good practice by the HSE and the SCA, the dissemination of NIMS data through a number of regular reports for key stakeholders. However, it also identified that there is scope for a more coordinated and strategic approach to improving the dissemination and use of incident and patient safety learning data to maximise its use and benefit for all key stakeholders.

Through the review, HIQA recognised the efforts undertaken by the HSE and SCA to date in engaging with NIMS users and in providing support with technical aspects of the system, as well as addressing issues with access and general queries. However, there is no overarching stakeholder engagement strategy in place to ensure a coordinated approach to these activities.

Information governance

Under the joint governance arrangements in place between the HSE and the SCA, both organisations recognise that they have individual responsibilities in relation to information governance. However, HIQA identified a lack of clarity on who has overall responsibility for information governance for NIMS within the HSE and for specific areas of information governance such as information security, data quality, data protection and the secondary use of information. Furthermore, there is no governance team in place for NIMS which has a specific responsibility for information governance. At a minimum, within a joint governance model, one would expect to see responsibilities for information governance clearly outlined within a Data Sharing Agreement. Without clear documentation in place, it is challenging for an organisation to respond effectively to information governance issues, such as data quality, breaches, complaints or the need to safeguard the data protection rights of individuals.

Although QAV is involved in elements of information governance, such as arranging and controlling access to NIMS for staff, managing setting up locations within NIMS for the HSE and HSE-funded services and the development of the policy document 'HSE Guidance for NIMS to include access and control', it does not have a role in coordinating a national approach to information governance for NIMS within the HSE.

In addition, under the joint governance arrangements HIQA was informed that both the HSE and the SCA have dual roles of data processor and data controller as defined in the General Data Protection Regulation (GDPR), but there was a lack of clarity on the specifics of these roles. This is an important area to address given that the obligations of both of these roles are clearly laid out under GDPR legislation. As well as there being no NIMS specific data sharing agreement in place between the two organisations, there is also no NIMS privacy statement or statement of information practices for NIMS.

HIQA found that there was a good understanding among staff at local level in hospitals and Community Health Organisations (CHOs) in relation incident management reporting, sign-off and escalation and the principles of information governance. However, HIQA identified there were still some gaps in understanding of some areas of information governance. HIQA also found that information governance practices are currently developed and implemented at a local level, in the absence of a coordinated national approach. In addition through site visits, HIQA identified some information governance risks including issues in relation to local IT connectivity, data quality issues, and risk of unauthorised access to paper-based records. However, there is no risk on the HSE QAV risk register in relation to information governance for NIMS.

In relation to information security and access control, HIQA identified a well-developed process in place for controlling access to NIMS within the HSE as per the policy document 'HSE Guidance for NIMS to include access and control'.

HIQA noted that although the SCA has undertaken a Data Protection Impact Assessment (DPIA) for the broader NIMS system, this DPIA does not encompass the full flow of data from the specific perspective of the HSE and HSE-funded services. It is important that the HSE ensures that a comprehensive DPIA is in place to reflect the full flow of data and covers all potential data protection and privacy issues that currently exist for NIMS within the HSE.

While there is evidence of good practice in relation to information governance for NIMS within the HSE, it is important that the joint governing organisations address the gaps identified through this review.

Summary

Incident management plays a vital role in patient safety surveillance and learning. NIMS, as the system underpinning incident management across the public health and social care system in Ireland is therefore an extremely important national health data collection. This review recognises the progress made by the HSE in its efforts to embed NIMS as the single designated national information system for incident management, patient safety, and learning across the HSE and HSE-funded services.

HIQA also acknowledges the examples of good information management practices highlighted throughout this review, particularly in relation to information governance and use of information.

However, the complexity of the joint governance arrangements between the SCA and the HSE, and gaps in governance, leadership and management for NIMS identified through this review, have resulted in some significant challenges facing the full implementation and effective use of NIMS within the HSE. The forthcoming legislation in relation to Patient Safety Incidents and the development of a new National Patient Safety Surveillance System within the DoH, puts an added focus on NIMS as a key source of patient safety intelligence. With these significant developments underway, it is important that NIMS is fully fit-for-purpose and functional as the single national incident report and learning system across all HSE and HSE-funded health and social care services in Ireland.

The ten recommendations outlined in this report should be considered in conjunction with the overall findings of this review, in order to improve information management practices for NIMS within the HSE. Under the joint governance arrangements, the HSE and SCA should continue to work together to support the implementation of NIMS across the HSE. In addition, the HSE should continue to assess their adherence to the Information Management Standards between reviews by HIQA, to ensure that they are consistently meeting the requirements of these standards.

Summary of recommendations

Governance, leadership and management	
1.	**Joint governance arrangements for NIMS**
	HSE QAV and the SCA should enhance the current governance arrangements in place for NIMS. This is to ensure that NIMS is fit for purpose as the single system for incident management, reporting and learning within the HSE and HSE-funded services and will support the implementation of the Incident Management Framework. The enhanced arrangements should: ▪ define clear and distinct responsibilities in relation to governance, leadership and management for HSE QAV and the SCA in relation to all aspects of information management for NIMS in the HSE. ▪ provide clarity on the responsibilities of the SCA as service provider for the NIMS platform, software and IT support; in addition, appropriate arrangements should be put in place to provide assurance to the HSE that NIMS is being effectively managed and supported within these arrangements, through audit schedules, access control and identification of key risks. ▪ review and clearly outline the terms of reference of each of the current joint governance groups in place: NIMS Sponsorship Group; NIMS Steering Committee; NIMS Project Team and working groups. ▪ provide clarity in relation to the strategic direction of NIMS through the development of clear project plans for the next phases of NIMS implementation and identification of specific roles and responsibilities for both organisations.
2.	**Governance, leadership and management of NIMS within the HSE**
	An enhanced governance, leadership and management model needs to be put in place internally by the HSE to support the efficient and effective collection and use of NIMS data within the HSE and HSE-funded services. The National Director of QAV, in association with Acute and Community Operations, should ensure that the structures of governance, leadership and management for NIMS in the HSE are

	fit for purpose, and support the implementation of the HSE's Incident Management Framework. Current arrangements should be enhanced to: ▪ provide a detailed scheme of delegation showing clearly defined roles and responsibilities for HSE QAV, HSE Acute and Community Operations, and the Senior and Local Accountable Officer (SAO/LAO) roles at local service level, in relation to information management for NIMS within the HSE ▪ work to align HSE QAV with HSE Acute and Community Operations and provide clarity on specific responsibilities in relation to NIMS within the HSE and to ensure that all HSE-funded services including Section 39 agencies, have access to the NIMS system for incident reporting, management and learning.
3.	**Strategy for information management**
	HSE QAV, in collaboration with the SCA, and HSE Acute and Community Operations, and other key stakeholders, should lead on the development of an organisation-wide strategy for NIMS within the HSE that addresses: ▪ the advancement of NIMS to ensure it is fully implemented as the single incident management system used by all HSE and HSE-funded services ▪ a long-term vision for the collection, use and sharing of NIMS data. This should include the phased introduction of electronic point of entry reporting across the HSE and HSE-funded services, where this option is feasible and necessary ▪ data quality and assurance ▪ risk management ▪ stakeholder engagement/system evaluation in relation to meeting the needs of users ▪ the development of guidance in key areas of information management such as information governance and data quality ▪ effective use of NIMS data and information.

4.	**Performance assurance framework**
	HSE QAV in collaboration with HSE Acute and Community Operations should develop a performance assurance framework for NIMS within the HSE that builds on current KPI practice and addresses: ▪ national oversight for KPIs and quality assurance across HSE services ▪ the addition of KPIs beyond those related to Serious Reportable Events (SREs) and Category 1 incidents that focus on all five dimensions of data quality; relevance, accuracy and reliability, timeliness and punctuality, coherence and comparability and accessibility and clarity the need for a formal schedule of audits specifically for NIMS within the HSE covering all aspects of information management including data security, data quality, accessibility and use of information ▪ as part of current Performance Agreements, clear pathways and mechanisms for escalation of local issues and risks in respect of information management of NIMS.
5.	**Risk management framework**
	As part of the joint governance arrangements for NIMS, HSE QAV in collaboration with the SCA should implement a NIMS Risk Management Framework, including the development of a joint NIMS Risk Register, to ensure that all risks relating to the system's use within the HSE are identified, monitored and controlled. The framework should address: ▪ specific roles and responsibilities in relation to risk management ▪ the need for a forum to discuss risk within the reviewed joint governance groups.
6.	**Statement of purpose**
	HSE QAV, in collaboration with the SCA and HSE Acute and Community Operations, should develop and publish a statement of purpose that accurately describes the aims and objectives of NIMS within the HSE.
7.	**Data sharing agreement**

	As part of the joint governance arrangements for NIMS, HSE QAV and the SCA should develop a detailed data sharing agreement that clearly outlines the appropriate sharing of NIMS between the HSE and the SCA.
Use of information	
8.	**Data quality framework and arrangements**
	HSE QAV should develop and implement a data and information quality framework for NIMS to systematically address and improve data quality of NIMS across all HSE and HSE-funded services. This framework should include an accessibility and dissemination plan to optimise the use of NIMS as a key source of patient safety intelligence. This would ensure that the benefits of incident and patient safety and learning data is maximised for all stakeholders. Additional data quality arrangements to complement the framework should be implemented by HSE QAV in collaboration with HSE Acute and Community operations to include: ▪ assigning an individual with overall responsibility for data quality in relation to NIMS within the HSE ▪ clearly outlining responsibilities for data quality at every level through a scheme of delegation for the HSE in line with the HSE's Incident Management Framework ▪ developing a stakeholder engagement plan in collaboration with HSE Acute and Community Operations to address the needs of all NIMS users. This should include a survey of NIMS users to assess the usefulness and usability of the system and their requirements of the system. ▪ a review of current National Incident Report Forms (NIRF) to ensure that they are fit for purpose for health and social care services ▪ a formal Training Needs Analysis to be carried out across acute and community services to identify training needs and a more coordinated approach to training to ensure all NIMS users who require training are receiving it.
Information governance	
9.	**Effective arrangements for information governance**

	As part of a strategy for NIMS within the HSE, HSE QAV in collaboration with HSE Acute and Community operations, should lead on the establishment of more effective arrangements for information governance that include: ▪ assigning an individual within the HSE overall responsibility for information governance who can take a national approach to key aspects of this area, such as data quality, data security, and ensuring privacy and confidentiality of data in respect of NIMS ▪ ensuring responsibility for information governance is assigned to one of the NIMS governance groups ▪ clearly defining roles and responsibilities for information governance for NIMS from local to national level across the HSE ▪ addressing specific aspects of information governance in services where an electronic Point of Entry model has been implemented ▪ the assessment and management of information governance risks through the joint risk register ▪ audits in relation to information governance that form part of an overall schedule of audits for NIMS ▪ a formalised approach to providing and keeping records of information governance training.
10.	**Compliance with legislation and privacy risk assessment**
	HSE QAV should develop a Data Protection Impact Assessment (DPIA) for NIMS within the HSE to: ▪ cover the entire flow of NIMS data from the perspective of the HSE and HSE-funded bodies to ensure HSE-specific data protection and privacy risks can be identified and mitigated ▪ provide clarity in relation to data retention and destruction. HSE QAV, in collaboration with HSE Acute and Community Operations, should also develop a Privacy Statement or Statement of Information Practices specifically for NIMS within the HSE.

1. Background to HIQA's review programme for national data collections

This review is part of an overall programme being undertaken by HIQA to assess compliance with the *Information management standards for national health and social care data collections*.[2]

A considerable amount of data are collected on a regular basis about health and social care services in Ireland. These data are used for many important purposes, such as to guide clinical decision-making, monitor diseases, organise services, inform policy making, conduct high-quality research and plan for future health and social care needs, both at national and local levels.

All stakeholders (the general public, patients and service users, health professionals, researchers and policy makers) need access to high-quality information in order to make choices and decisions. It is vital that there is confidence in this information as the delivery of safe and effective healthcare depends on, access to and use of, information that is accurate, valid, reliable, timely, relevant, legible and complete.

Based on international best practice, four key overarching objectives relating to health information have been identified to maximise health gain for the individual and the population:

1. Health information is used to deliver and monitor safe and high-quality care for everyone.
2. Health information should be of the highest quality and, where appropriate, collected as close as possible to the point of care.
3. Health information should be collected once and used many times.
4. Data collection should be 'fit for purpose' and cost-effective.

National health and social care data collections are national repositories of routinely collected health and social care data, including administrative sources, censuses, surveys and national patient registries, in the Republic of Ireland.

Managing organisation is defined as the organisation, agency, managing unit, institution or group with overall responsibility for the national health and social care data collection.

National health and social care data collections provide a national overview of data relating to a particular health or social care service. Examples of national data collections include BreastCheck, the Hospital In-Patient Enquiry (HIPE) scheme and the Computerised Infectious Disease Reporting System (CIDR). There is little point in investing considerable time, effort and resources into producing a high-quality data

collection if the data are not used to the maximum benefit of the population it serves. Therefore, it is essential to promote, encourage and facilitate the use of data.

HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information under the Health Act 2007.[1] A number of key documents have been published by HIQA in recent years in relation to national health and social care data collections (Appendix 1).

Furthermore, the *National Standards for Safer Better Healthcare,* published in 2012, describe a vision for quality and safety in healthcare which includes the use of accurate and timely information to promote effectiveness and drive improvements.[9] One of the eight themes, 'Use of Information', emphasises the critical importance of actively using information as a resource for planning, delivering, monitoring, managing and improving care. These nationally mandated standards apply to all healthcare services (excluding mental health) provided or funded by the Health Service Executive (HSE).

In 2017, HIQA published specific standards in the area of information management — *Information management standards for national health and social care data collections.*[2] The purpose of these standards is to improve the quality of national health information. The standards provide a framework of best practice in the collection of health and social care data. The *Information management standards for national health and social care data collections,* therefore, complement the *National Standards for Safer Better Healthcare.*[2, 9] Together, these standards provide a roadmap to improve the quality of health information and data, which should ultimately contribute to the delivery of safe and reliable healthcare.

HIQA has developed a structured review programme to assess compliance with the *Information management standards for national health and social care data collections.*[2] Prior to commencing the review programme, the *Guide to the Health Information and Quality Authority's review of information management practices in national health and social care data collections* was published by HIQA.[3]

For the remainder of the report:

Information Management Standards will be used for the *Information Management Standards for National Health and Social Care Data Collections*

Review Programme will be used for the review programme to assess compliance of national health and social care data collections against the Information Management Standards

1.1 Aims of the review programme

The aim of this review programme is to improve information management practices of national health and social care data collections in Ireland by assessing compliance with the Information Management Standards in individual national data collections. Ultimately, the review programme was developed to drive improvements by identifying areas of good practice across national data collections and identifying areas where improvements are necessary.

1.2 Assessment and judgment framework

HIQA has adopted a standard Authority Monitoring Approach (AMA) to carry out its functions. HIQA staff involved in the review programme use this approach and any associated procedures and protocols. HIQA's monitoring approach does not replace professional judgement. Instead, it provides a framework for staff to use their professional judgement and supports them in reviewing compliance against the standards. The use of AMA and an assessment and judgment framework ensures:

- a consistent and timely assessment of compliance with standards
- a responsive approach to performing reviews.

1.3 Review programme methodology

Due to the large number of national data collections, the review programme is being carried out using a phased approach. Phase 1 included major national data collections within the HSE; Phase 2 includes national data collections with a governance arrangement in place between the HSE and an external agency. Prioritisation criteria were developed to determine the schedule for reviews within the review programme, which included the quality and safety impact, the policy impact and other operational factors which may impact on the review programme.

There are five stages involved in this review process:
1. Self-assessment tool
2. Information request
3. On-site assessments and additional evidence gathering
4. Report of findings
5. Factual accuracy.

Stage 1: Self-assessment tool

The self-assessment tool is a questionnaire which enables national health and social care data collections to determine the extent of their compliance with the Information Management Standards. The tool highlights areas where action is

required and where improvements can be made. All of the national data collections in the initial phase of the review programme were contacted and asked to complete the self-assessment tool. The designated contact person in each organisation was asked to complete and return the self-assessment tool within three weeks.

Based on the findings of the prioritisation criteria, HIQA agreed to perform a focused review of the HSE National Incident Management System (NIMS).

Stage 2: Information request

As part of the review methodology, a detailed request for key documentation and information relating to NIMS was sent to the Quality Assurance and Verification (QAV) team in the HSE and the State Claims Agency (SCA). The information was returned to HIQA within 15 working days. The information received was used to identify areas of good practice and potential gaps in the evidence in order to provide clarity of focus for the on-site assessment.

Stage 3: On-site assessment and additional evidence gathering

An on-site assessment was conducted at the QAV offices in Dublin. The aim of the on-site assessment was to gather additional evidence to assess compliance of NIMS with the Information Management Standards through further documentation reviews, observations and interviews with management and staff. Interviews were also held with representatives from the SCA.

The HIQA review team also conducted interviews with key staff from within the HSE (Acute Operations, Community Operations, Acute Hospitals and Community Health Organisations) in relation to the use and implementation of NIMS within those services.

Stage 4: Report of findings

The findings of the assessment of compliance with the Information Management Standards for NIMS are outlined in this report.

1.4 Quality improvement plans

The HSE, supported by the SCA, is responsible for preparing and implementing quality improvement plans in respect of NIMS within the HSE to provide assurance that the findings relating to areas for improvement are prioritised and implemented to comply with the Information Management Standards.

The HSE, supported by the SCA, should continue to assess their adherence to the standards in between reviews by HIQA to provide assurance that they are meeting the requirements of the Information Management Standards in respect of NIMS.

Where opportunities for improvement have been identified by the review team during the review, checks will be carried out during future reviews to ensure that the necessary improvements have been implemented.

1.5 HIQA's legislative remit

HIQA has a specific remit in relation to health information as laid out in the Health Act 2007.[1] The review programme falls within this legislative remit. The relevant Sections of the Act are as follows:

- Section 8(1)(k) — to set standards as the Authority considers appropriate for the Health Service Executive, the Child and Family Agency and service providers respecting data and information in their possession in relation to services and the health and welfare of the population
- Section 8(1)(l) — to advise the Minister, the Minister for Children and Youth Affairs, the Executive and the Agency as to the level of compliance by the Executive and service providers with the standards referred to in paragraph (k)
- Section 12 — the Authority may require the Executive, the Agency or a service provider to provide it with any information or statistics the Authority needs in order to determine the level of compliance by the Executive, the Agency or by service providers with the standards set by the Authority in accordance with Section 8.

1.6 Scope of this review

The aim of this review is to examine the findings of compliance with the Information Management Standards for the NIMS within the HSE. The review team examined the implementation of NIMS within the HSE and HSE-funded acute and community services. As there is a joint governance arrangement in place for the NIMS system between the HSE and SCA, the governance structures were examined from both the perspective of the HSE and the SCA.

2. Overview

Under the National Treasury Management Agency Act (NTMA) 2000, all state authorities are required to report incidents to the NTMA. The NTMA is designated as the State Claims Agency (SCA) when performing the claims management, risk management and legal cost management functions.[10]

The system used for this mandatory reporting of incidents is termed the National Incident Management System (NIMS). This is a risk management platform provided to the SCA by a third party system provider. NIMS has over 2,000 users and captures data from 146 Delegated State Authorities (DSAs).[11] The HSE is one of these DSAs; since 2015, NIMS has been endorsed by the DoH and the HSE as the single and primary system for incident reporting for HSE and HSE-funded services. NIMS supports the HSE's Incident Management Framework (IMF) while in parallel ensures the statutory reporting of adverse incidents to the SCA.

This chapter provides an overview of the use of NIMS within HSE and HSE-funded services in Ireland. Specifically, this chapter will:

- Describe the history and current practices of incident management in HSE and HSE-funded services in Ireland
- Provide an overview of the HSE Quality Assurance and Verification (QAV) team and the SCA
- Provide a summary of the core functions of NIMS
- Describe the implementation of NIMS in HSE and HSE-funded services
- Present an overview of international evidence on incident management
- Detail the importance of good information management practices for NIMS.

2.1 Incident management in health and social care in Ireland

2.1.1 Background

Historically in Ireland, healthcare professionals reported incidents to their respective medical malpractice insurers/indemnifiers. In 2002, the Clinical Indemnity Scheme (CIS) was set up and in 2004, the introduction of the CIS STARSweb system provided organisations with a central point for the recording of clinical incidents and near misses, as well as healthcare worker incidents and incidents involving members of the public.[12] There were two phases to the introduction of STARSweb, phase 1 was to address the issues of data quality and reliability and phase 2 was the development of a quality assurance tool.

In 2014, the 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 (NPSSS) in Ireland.

While such a system is not formally defined in the CMO's report, reference is made to a need for 'an overall process of pooling of risk information and intelligence in order to create a composite risk file for the health care systems'.[13] In addition, the CMO chaired a group involving the DoH, HSE and the SCA to support the implementation of NIMS as part of the proposals in relation to the NPSSS.

In November 2015, the then Minster for Health announced a number of patient safety reforms, which included plans to establish a new National Patient Safety Office within the DoH.[8] It was announced that the office would include a system for the coordination of patient safety surveillance. In addition, an independent National Advisory Council for Patient Safety was set up in 2016, to provide advice and guidance to inform the policy direction for the National Patient Safety Office. In December 2019, draft patient safety legislation was approved by the government. The yet to be enacted Patient Safety (Notifiable Patient Safety Incidents) Bill 2019[6], provides for the mandatory open disclosure of serious patient safety incidents to those who have been harmed by them. The Patient Safety Bill also provides for reportable incidents to be notified to HIQA and extends HIQA's current remit for monitoring against national standards to private healthcare services. Furthermore, it specifies that health service providers report notifiable incidents through the NTMA incident management system. The NTMA's current system for incident management is NIMS. Figure 1 provides a timeline of incident management in health and social care in Ireland.

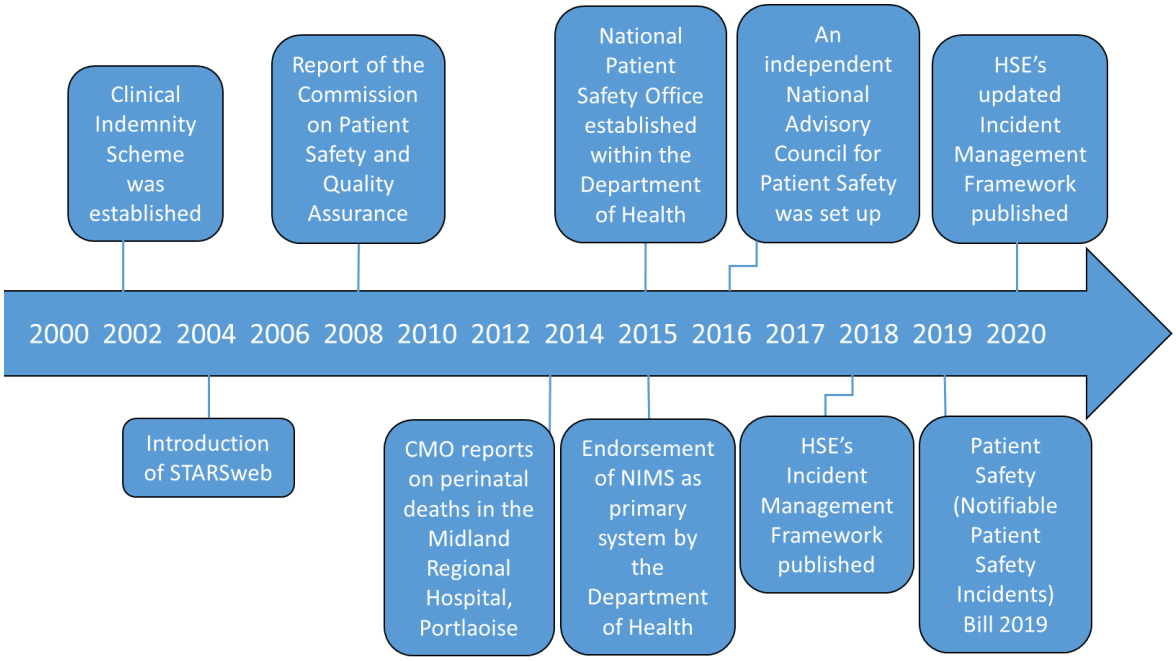


Figure 1: Timeline of incident management in health and social care in Ireland

Within the HSE, an internal (Excel-based) Incident Information Management System (IIMS) was also previously in place that recorded and collated relevant information regarding serious incidents, that were communicated to the Divisional Quality and Patient Safety Lead and, where necessary, escalated to the QAV National Incident Management and Learning Team. The IIMS was closed to new incidents in January 2018 at the end of Phase 2 of NIMS implementation.[14]

2.1.2 Current incident management arrangements in health and social care services in Ireland

2.1.2.1 Incident Management Framework

The HSE published an Incident Management Framework (IMF) in 2018. This framework built on the HSE's previous Safety Incident Management Policy. It was developed to provide an overarching practical approach, based on best practice, to assist providers of HSE and HSE-funded services to manage all incidents (clinical and non-clinical) in a manner that is cognisant of the needs of those affected and that supports services to learn and improve.[15] The purpose of the framework is to ensure that all health and social care incidents are identified, reported and reviewed so that learning from incidents can be shared. The framework sets out the principles, governance requirements, roles and responsibilities and process to be applied for the management of incidents in all service areas. The IMF clearly articulates that NIMS is the single and primary designated system for the reporting of all incidents for HSE and HSE-funded services.[5] The IMF is the primary initiative driving improvements in incident management in the HSE and HSE-funded services and is therefore enabled by the implementation of the NIMS system across the sector.

An updated version of the IMF was published in 2020. The revised IMF outlines that the primary responsibility and accountability for the effective management of incidents lies with the Senior Accountable Offier (SAO) for that service. A new role of Local Accountable Officer (LAO) has also been included in the IMF. An LAO reports to the SAO and is responsible for promoting compliance with the IMF in their area. The framework sets out an overview of the incident management process, the implementation of which is supported by NIMS[5] (see Appendix 2 for an overview of this process). The Incident Management Framework is intended to cover all publicly-funded health and social care services provided in Ireland including:

- Hospital Groups
- Community Healthcare Organisations (CHOs)
- National Ambulance Services
- National Services, for example, National Screening Services, National Transport Medicine Programme
- HSE-funded care, for example, Section 38/39 agencies.[5]

2.1.2.2 HSE Performance and Accountability Framework

The Performance and Accountability Framework[16] sets out the means by which the HSE and in particular the Hospital Groups, CHOs, the National Ambulance Service (NAS), the Primary Care Reimbursement Service (PCRS), the heads of other national services and individual managers are held to account for their performance.[16]

2.1.2.3 HSE National Performance Oversight Group (NPOG)

The National Performance Oversight Group (NPOG)[16] has delegated authority from the HSE CEO to serve as a key performance and accountability oversight group for the health service. It is the responsibility of the National Performance Oversight Group, as a part of the overall HSE accountability process, to scrutinise the performance of the health service provider organisations, in particular Hospital Groups, CHOs, NAS, PCRS and other national services, to assess performance against the National Service Plan. The NPOG meets on a monthly basis to review performance across the health service.

The standing membership of the Group is the:

- Chief Operations Officer (Chair)
- Chief Strategy and Planning Officer
- Chief Clinical Officer
- Chief Financial Officer
- National Director Human Resources
- National Director Acute Services Operations and Performance
- National Director Community Services Operations and Performance
- National Director National Services.

2.1.2.4 Senior Accountable Officer

NIMS in the HSE is a decentralised system, meaning data entry, management of incidents and review, data quality management and reporting, occur at local service level and are the responsibility of the SAO.

Therefore in the context of the management of an incident within acute and community services, the SAO is the person who has ultimate accountability and responsibility for the services within the area where the incident occurred. In a hospital group, it would be a person with delegated responsibility for a service and reporting directly to the Hospital Group CEO, for example, a hospital manager or the person delegated with overall responsibility for the management of a clinical directorate or service. In a CHO it could be the Head of Service and in the case of the NAS, it could be the NAS corporate area manager.[5] From a governance perspective, the SAO is described as being responsible for having in place systems and processes for the:[5]

- governance of information arising from incident management processes
- notification of Category 1 incidents to them within 24 hours of occurrence in order for them to gain assurance on immediate actions taken and to convene a meeting of the Serious Incident Management Team (SIMT)
- verification of compliance with the requirements of the IMF for managing incidents within services in their area of responsibility
- monitoring implementation of recommendations made as a consequence of incident reviews
- integration of information relating to incident management within the service's overall governance arrangements for quality and safety to enable learning from the review of incidents to inform quality and safety improvement programmes
- monitoring key performance indicators relating to incident management.

These governance arrangements at a service level are required to support the timely and effective management of incidents, as well as a management commitment to safety that promotes a culture of openness, trust and learning.

2.2 Overview of Quality Assurance and Verification Team, HSE

The Quality Assurance and Verification team (QAV - previously QAVD) was established within the HSE in 2015 to, amongst other responsibilities, monitor and report on the quality and safety of health and social care services, by building on the capacity of the HSE to respond to and learn from service user and service provider feedback, as well as risk and safety incident management.[17]

The role and function of QAV is to promote, assure and encourage high-quality and safety standards at all times, as well as carrying out interventions and improvements, when deemed necessary. QAV has functions in terms of assuring performance within the HSE, the risk management policy for the HSE and maintaining the HSE's Corporate Risk Register for, among others, all hospitals, hospital groups and CHOs. [8] The following list of functions forms part of QAV:[17]

- Risk Management
- Incident Management
- Healthcare Audit
- Protected Disclosures
- Appeals Service
- Complaints and Governance Learning Team.

2.2.1 HSE Quality Assurance and Verification (QAV) team - NIMS responsibilities

In line with the functions outlined above, QAV has a leadership role within the HSE for NIMS. QAV's role includes:[18]

- Leading on systems developments and changes
- Maintaining and managing a list of all service user systems change requests
- Providing support to users, as required, which includes a NIMS helpdesk
- Engagement with QPS advisors/managers and other managers across the HSE
- Providing guidance and training material for users
- Producing corporate reports
- Producing specialised reports on an ad-hoc basis
- Managing user access and location hierarchy of the system.

QAV work with the SCA to provide support to users of NIMS. This responsibility includes managing, authorising and controlling access to NIMS for staff in the HSE and HSE-funded services. The HSE uses NIMS data in the following ways:[18]

- incident and risk management
- incident analysis and trend analysis
- identifying incidents requiring review/investigation
- tracking progress and capturing outcomes of incidents
- to understand and learn from incident data
- to fulfil the statutory requirement to report incidents to the SCA.

2.3 Overview of the State Claims Agency (SCA)

The NTMA is the State body that provides asset and liability management services to Government. The NTMA is designated as the SCA when performing the claims management, risk management and legal cost management functions delegated to it under the National Treasury Management Agency (Amendment) Act 2000 and the National Treasury Management Agency (Amendment) Act 2014. This includes the management of personal injury and third party property damage claims against DSAs and the underlying risks.[10]

The SCA has three core areas of work:

- Claims management
- Risk management
- Legal costs management.

It is a legal requirement for all DSAs including the HSE, to notify the SCA of adverse incidents. The Irish government made the decision to implement one common system across all DSAs to capture these notifications. NIMS is the current system in place. It is hosted by the SCA via a third party system provider and is a national end-to-end risk management and claims management web-based tool. It is used by over 2,000 users across 146 DSAs to record and manage risk. Users include Government Departments, An Garda Síochána, the HSE, the Prison Service, the Defence Forces, public hospitals, Section 38 funded bodies and a number of Section 39 funded bodies.[11]

The SCA's vision for NIMS is to:[19]

- Standardise the approach and language around end-to-end incident management across the State and Public Healthcare Sector
- Engage at all levels in the reporting and lessons learned risk processes
- Provide an IT solution (NIMS) that is owned by each enterprise in the State Sector and Public Healthcare Sector to support their risk management processes
- Provide a national platform for the development of other risk initiatives.

2.3.1 Claims and risk management

The SCA provides claims and risk management services through two State indemnity schemes, namely the clinical indemnity scheme (CIS) and the general indemnity scheme (GIS). Under the CIS, the SCA manages clinical negligence claims taken against healthcare enterprises, hospitals and clinical, nursing and allied healthcare practitioners covered by the scheme. Under the GIS, the SCA manages personal injury and third party property damage claims taken against the State bodies covered by the scheme; this includes injuries to healthcare workers and to patients or service users that are not clinically caused, such as abuse, failure to provide care, and approach and loss to relatives when death occurs. The HSE, section 38 hospitals and disability services are covered by both schemes operated by the SCA. At the end of 2018, the SCA was managing 10,658 active claims. Although clinical claims comprise only 29% of the overall number of active claims at end of 2019, they comprise 75% of the overall estimated outstanding liability.[20]

2.4 Overview of the National Incident Management System (NIMS)

NIMS supports the management of risk and safety within State authorities including publicly-funded health and social care services in Ireland. As stated earlier, all State authorities are required to report incidents to the SCA via NIMS. NIMS is an end-to-

end risk management tool that allows DSAs to manage incidents throughout the incident lifecycle. It facilitates the identification of emerging trends in incidents both locally and nationally, raising awareness of patient safety risks.[21] NIMS also supports reviews of incidents, as well as recording complaints and monitoring the implementation of recommendations. A table detailing the purpose of NIMS is presented in Appendix 3 of this report.

The types of incidents that are reported to NIMS are as follows:[21]

- 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) is described by the Health and Safety Authority (HSA) or any other reportable circumstance, as prescribed and or deemed appropriate by the DSA
- a 'complaint' made about any action and or inaction of the DSA.

As described previously in section 2.1.1, the HSE's IIMS was closed to new incidents in 2018. Therefore, the functionality of NIMS within the HSE has expanded from a system of incident reporting to include the following functionalities: incident review screens; complaints modules; dashboards to improve analysis and reporting of incidents. Through its functionalities, NIMS supports the implementation, management and monitoring of the Incident Management Framework (described in section 2.1.2.1) and enhances learning from incidents. There is a joint governance model currently in place, whereby both the HSE QAV and the SCA (described in sections 2.2 and 2.3) are responsible for the implementation, management and maintenance of the system within the HSE and funded services.

2.4.1 Categories of incidents on NIMS

When an incident occurs, services are required to categorise the incident, so as to inform the level of review required. The types of incidents captured include those involving service users, patients, healthcare workers, members of the public, contractors, volunteers, as well as property loss or damage including to vehicles or service user belongings. NIMS captures both clinical and non-clinical incidents. Failure to recognise and respond to clinical deterioration is an example of a *clinical incident*. If a service user were to fall in an older persons residential setting while not under clinical supervision it would be classed as a *non-clinical incident*.[15] The level of harm experienced informs the categorisation of the incident. As per the HSE's Risk Impact Table, clinical and non-clinical incidents are categorised as follows:[5]

- Category 1 Major/Extreme – rated as major or extreme
- Category 2 Moderate – rated as moderate
- Category 3 Minor/Negligible – rated as minor or negligible.

Serious Reportable Events (SREs) are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. SREs are mandatorily reportable by services to the SAO. NIMS will auto generate the category of the incident (Category 1, 2 or 3) when the outcome of the incident is entered from either the hard copy or online National Incident Reporting Form (NIRF) or through ePOE.[5]

2.4.2 Data collection and reporting on NIMS

Incident information is collected at hospital, CHO and National Service level, which includes for example the National Ambulance Service and the National Screening Service. Information is then entered onto NIMS and is available to use locally, by HSE and HSE-funded agencies and nationally, by the HSE QAV team and the SCA. Figure 2 illustrates data collection and reporting in NIMS.

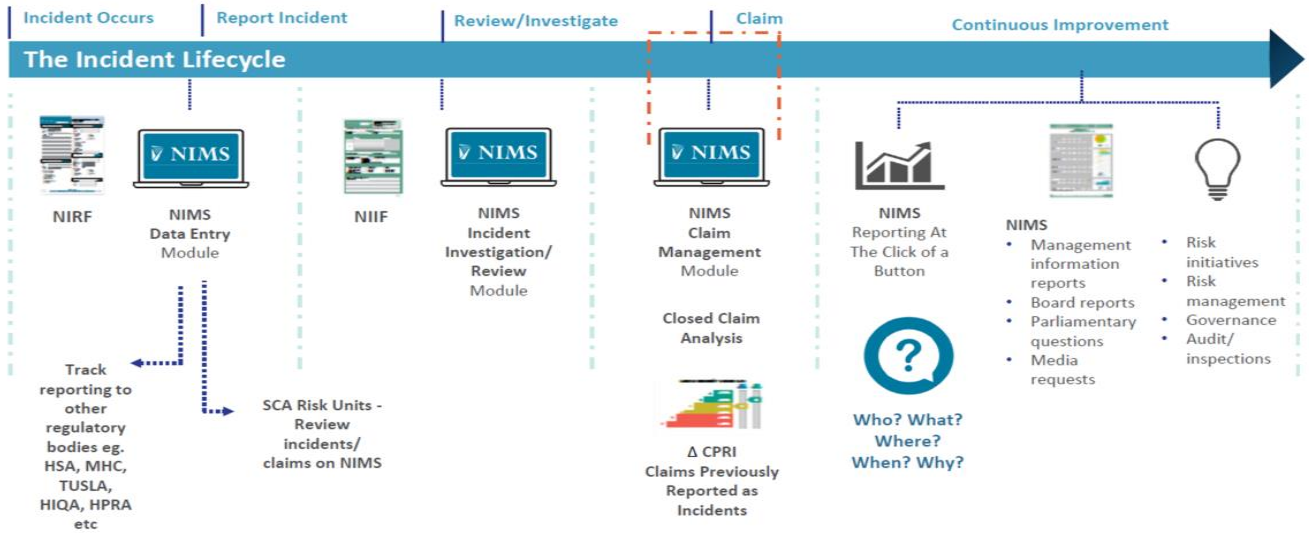


Figure 2: NIMS data collection and reporting, Incident Life Cycle [19]

2.4.3 Data entry on NIMS

When an incident occurs, it is the responsibility of the staff member identifying the incident to report the incident either by completion of the appropriate NIRF (paper or online version) or direct entry to NIMS, as part of the initial notification and reporting stage. There are four separate NIRFs available for reporting incidents.

Recently, a fifth NIRF was developed to capture information on healthcare-acquired COVID-19 cases in healthcare workers (HCW).

- Person NIRF
- Property NIRF
- Crash or collision NIRF
- Dangerous occurrence (reportable circumstance) NIRF
- HCW COVID-19 Acquired NIRF - completed where a staff member/volunteer/external contractor/work placement student acquires COVID-19.

The vast majority of healthcare-related incidents are recorded on NIMS using the 'Person' NIRF. Table 1 details the three ways information is currently collected and entered on NIMS. The method of data collection varies between health and social care services depending on the absence or presence of NIMS ePOE[‡] reporting, or the use of alternative incident management systems. Where paper-based and or two-system models are in place, the process for collecting and recording incident data can be extremely resource intensive at a local level with varying numbers of steps involved. Dedicated resources within hospitals and CHOs have to manage the manual inputting of data, from NIRFs onto NIMS or from an alternative system on to NIMS. Paper-based models where there are large volumes of incidents to report can often cause backlogs of incidents and impact on timeliness of reporting.

Table 1: Data collection process for NIMS

	Data collection process	Method of recording information
1	Paper/editable pdf	Reporter completes a paper/fillable pdf form and that data are then manually entered on NIMS
2	Use of two incident management systems	Input information at point of occurrence on a local incident management systems (for example. Datix and QPulse) and also manually enter the information on NIMS [§]
3	Electronic Point of Entry data collection	ePOE on NIMS

Once the incident information is entered onto NIMS, it is then available to the relevant service with varying levels of access to this information at national levels,

[‡‡] Electronic point of entry is where frontline staff enter incident reports directly on to the incident management system database eliminating the need for paper and duplicate data entry.
[§] This is contrary to the national mandate for all HSE and HSE-funded services to use NIMS as the single, primary incident management system.

including national Operations Teams and the HSE QAV team. It is also available to the SCA.

2.5 Implementation of NIMS system in HSE and HSE-funded services in Ireland

The implementation of NIMS across health and social care services has evolved over time. Figure 3 illustrates the timeline of the development of NIMS. A national incident reporting system (STARSweb) was first established in Ireland in 2003. It was an incident reporting and claims administration system used within the public healthcare system. National rollout of STARSweb commenced in November 2003, and coverage was extended to the entire acute public health sector by the end of 2006.[22] Originally, the primary objective of the reporting system was to build a risk management system for risk managers/subject matter experts to manage their harmful incidents also known as 'adverse events'.

The SCA informed HIQA that in 2010, in consultation with DoH, the HSE and SCA lead on a series of stakeholder engagements. From a number of major themes that arose for the re-design of the STARsweb system, one was that an upgraded database should capture all incident types and use an international standard as a basis for definition, so that data could be compared internationally as well as nationally. Based on this consultation the scope was expanded to allow the system to cater for no-harm incidents, near misses, dangerous occurrences and complaints, as well as adverse events, in line with the WHO definition of an incident and the HSE Safety Incident Management Policy at the time. In 2014, the reporting system was briefly named the 'National Adverse Event Management System' (NAEMS) and in 2015 was once again re-branded as the National Incident Management System (NIMS). NIMS was rolled out to most healthcare enterprises by June 2015 and further phases of implementation have been actioned since then. Details of the phases of the NIMS implementation project are outlined in Section 2.5.1 below.

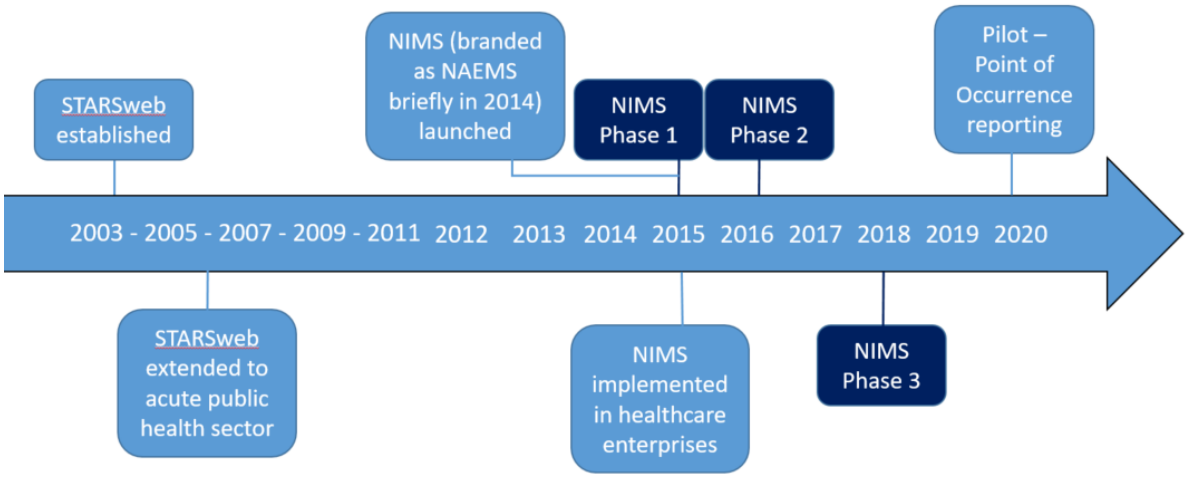


Figure 3: Timeline for the establishment of NIMS

2.5.1 NIMS implementation project

The National Incident Management System (NIMS) Implementation Project has three phases as illustrated in Figure 4. Phase 1 and 2 are complete and phase 3 began in March 2018.

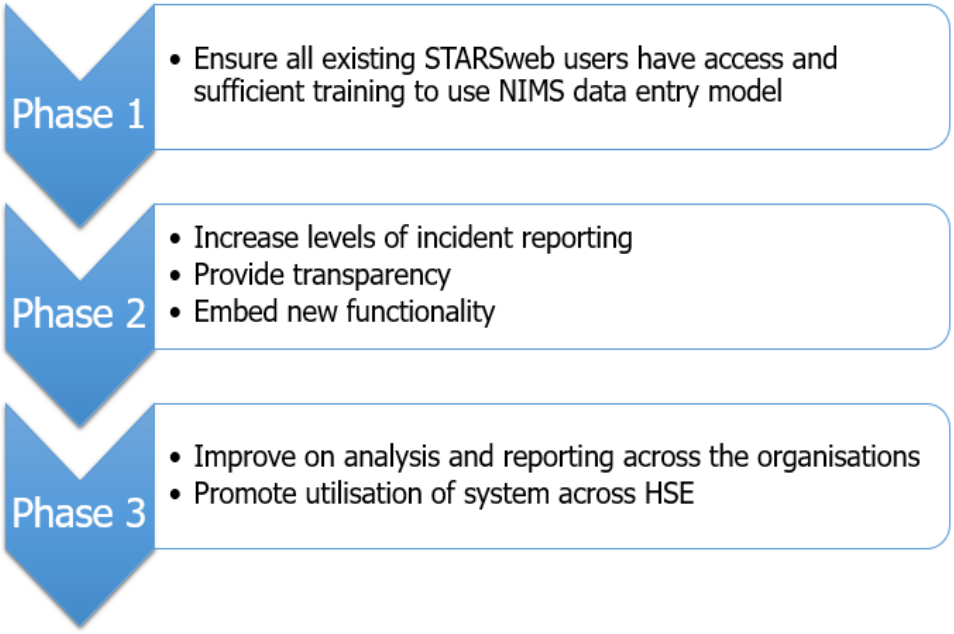


Figure 4: NIMS Implementation Project Phases 1-3

Phases 1 and 2 are described in more detail in Appendix 4.

2.5.1.1 Current Phase of NIMS Implementation (Phase 3)

In March 2018, the Project Initiation Document for Phase 3 of NIMS detailed the scope and deliverables to be achieved in Phase 3. This phase is currently underway and deliverables include the following:[23]

- Improve the HSE's capability to analyse and report on quality and safety data from across the organisation
- Deliver activities which are deemed crucial for the ongoing maintenance and support of the NIMS system by the Project Team in conjunction with the SCA
- Promote utilisation of the system across the HSE and encourage uptake in locations, such as HR.

Phase 3 focuses on Reporting and Data Analysis, System Maintenance and System Utilisation. In particular, there is a focus on developing NIMS dashboards to meet user needs, reviewing potential future requirements for NIMS and the potential expansion of electronic point of entry NIMS reporting. Further information on the plans for Phase 3 are outlined in Appendix 5.

2.6 International evidence on incident management

In 2000, the publication of the Institute of Medicine's 'To Err is Human' report made the case for national mandatory reporting systems which would collect standardised information on adverse medical or patient safety events in healthcare, in order to prevent similar errors occurring into the future.[24] Incident management systems are an essential part of measuring and improving safety, and managing risks. Benefits of incident management systems include increased understanding of predisposing factors, risks and circumstances to managing and resolving the harm relating to the incident.[24] Following on from the 'To Err is Human' report, many countries established national or regional patient incident reporting systems. Summary details of the national and regional incident reporting systems included in this review are outlined in Appendix 6 of this report. While variations exist between many of the reporting systems used internationally, most international incident reporting systems have sector-specific reporting systems, these are incident reporting systems focused only on healthcare. Ireland's incident reporting system differs from those internationally in this regard. NIMS is used by all State sectors for reporting incidents and where the ePOE model is not in use, generic National Incident Reporting Forms (NIRFs) are used by all sectors to report incidents to NIMS.

The international incident management systems reviewed vary in terms of how reports are made, by whom, whether reporting is mandatory or voluntary, whether reports can be made anonymously, what incidents are reportable, the classification of incidents, the level of follow up and the use made of the data. Extensive reviews

have indicated that, at present, there is no one perfect system and that patient incident reporting systems face a range of challenges which limit the overall reporting levels and effectiveness of these systems.[25] There was a high degree of consistency across all reviews stating the main challenges faced by incident reporting systems. A summary of these challenges is outlined in Table 2.

Table 2: Common challenges found in reviews of incident management systems

Challenges	Description
Systems not fit for purpose	▪ Many systems collect more data than the system can handle, making the system overly bureaucratic and demanding for healthcare professionals ▪ Pressure on patient reporting systems to provide both a reporting system and a surveillance and learning system, creating confusion.
Blame culture	▪ Fear of retribution, blame or adverse consequences for reporters ▪ Lack of anonymity and privacy in the reporting system.
Governance; lack of clarity around roles and responsibilities	▪ Lack of clarity about what should be reported and who is responsible for reporting. ▪ Reporters not understanding the importance of organisational learning.
Taxonomy	▪ Lack of clarity about what incidents and adverse events should be reported and poor classification of information on the incident form.
Data collection	▪ Some of the information which would be most useful for root cause analysis can only be included in a free text section of the form.
Use of information	▪ Poor processing of incident reports (triaging, analysis, recommendations) ▪ Insufficient resources allowed for the timely collection and analysis of data.
Implementing learning and quality improvement actions	▪ Recommendations arising from reviews are often considered to be poor in terms of their feasibility for practical settings ▪ Failure to provide feedback to those who submit reports ▪ Lack of remedial or quality improvement actions ▪ Failure to use health information technology effectively.

Overall, healthcare personnel are unwilling to invest time in reporting unless they receive feedback and can see incidents they report translated into improvements in quality and patient safety.

These studies also highlighted factors/opportunities that increase reporting and confidence in the system, some of which include:

- the confidentiality of the system
- regular analysis of incidents
- the provision of prompt feedback to staff and the promotion of change
- the establishment of a system which is fair to all (patients and healthcare staff) and which seeks to promote learning rather than blame.

Similarly, in order to maximise uptake and minimise stakeholder resistance, the Organisation for Economic Co-operation and Development (OECD) encourages a system where:[26]

- Information is not published for comparison purposes, but is reported back to all relevant stakeholders for learning purposes, to promote a positive safety culture and as a way of spreading good practice
- Accountability for implementing mitigation strategies is emphasised
- Providers, clinicians and patients are engaged in the development and implementation of the system.

In 2016 an international review of national patient reporting systems was published.[7] A summary of the key findings of this review can be found in Appendix 7.

2.7 Importance of information management for NIMS in the HSE and HSE-funded services

Within the health and social care system in Ireland, incident management plays a significant role in patient safety surveillance and learning, so there is an obligation on all services to identify, report and review incidents in a timely manner to drive a culture of quality and patient safety. In order to ensure services can fulfil this obligation, it is important that good information management practices are in place.

The benefit of good information management practices in health and social care services is to instil confidence in service users, clinicians and all other stakeholders and that decisions are made based on high-quality information, the availability of which will ultimately improve patient outcomes.[2] It is widely recognised that effective information management improves quality through enhanced knowledge and understanding for all involved in generating and using the data. Furthermore, good information management promotes assurance that information will be held securely; it puts in place the necessary precautions to maintain individuals privacy and confidentiality; it facilitates greater empowerment and involvement by communicating effectively with stakeholders including the public; and, ultimately, it creates a culture in which information can be used more effectively.[5]

As the primary incident management system for the HSE and HSE-funded services, NIMS is an extremely valuable source of data. As NIMS is the core system to facilitate the management of healthcare-related incidents, it is of significant importance that stakeholders are assured that the data held within NIMS is of good quality, in order to facilitate appropriate management of incidents and associated learning.

NIMS is used to enable the management of incidents throughout the incident lifecycle in line with the HSE Incident Management Framework. Data from NIMS is used to identify emerging trends in patient safety and incident management while also fulfilling the legal requirement to report incidents to the SCA.[27] The HSE also uses NIMS data to understand and learn from incidents. The effective use of NIMS data has the ability to contribute to improvements in patient safety and ultimately improve patient outcomes. It is widely accepted that the vast majority of incidents which occur in healthcare are due to failures or weaknesses in the systems of care or management, rather than the actions of an individual.[15] It is therefore imperative that information in relation to incidents within healthcare is captured locally and available to those who need it in a timely manner.

A well designed incident management system, which holds high-quality data, has the ability to positively influence patient and service user safety and support a culture of safety in healthcare.

The benefits of appropriate management of information for NIMS allows for:

- Prompt identification of local hazards and appropriate responses: accurately capturing incidents as they arise within the healthcare setting enables risk personnel to put measures in place to manage the incident and reduce the chance of the risk occurring in the future.
- Shared learning within and across services: significant learning opportunities can be generated from review and investigation of incidents both locally and nationally. By identifying the factors which led to the occurrence of an incident, this learning can be shared with others, to reduce or prevent the occurrence of similar incidents within services. Identification of trends in incident data and evaluation of practices as part of the incident review process assists management in identifying the need to develop targeted training programmes.
- Informed development of local policies and procedures and identification of the need for policy and guidance at a national level: the availability of complete and accurate data on NIMS enables stakeholders to identify trends in incidents occurring. The availability of such a rich source of data should highlight problematic or high-risk areas, and thus inform the need for targeted policies and procedures.

- Identification of key trends to inform patient safety: Accurate and timely submission of incident reports to NIMS facilitates trending of incidents, and can point to areas where challenges are occurring. This data, combined with other sources of data, can assist in informing the need to target resources to a particular service area, in order to reduce risk to patient safety.

3. Governance, leadership and management

To achieve compliance with the Information Management Standards[2], the managing organisation of a national data collection must have effective governance, leadership and management structures in place. These structures should promote good information management practices throughout the organisation. Effective governance arrangements for information management are necessary to ensure that processes, policies and procedures are developed, implemented and adhered to in respect to information management.

Features of good governance, leadership and management include:

- A well-governed managing organisation is clear about what it does, how it does it and is accountable to its stakeholders. The managing organisation should be unambiguous about who has overall executive accountability for the national data collection, and there should be identified individuals with responsibility for information governance and data quality. There is also an onus on senior management to develop the required knowledge, skills and competencies among personnel within the organisation to manage information effectively to ensure compliance with the relevant legislation.
- Managing organisations should demonstrate strong leadership by strategically planning and organising resources to achieve their objectives. Strategic and business planning needs to specifically address the area of information. These plans should be aligned with the broader health information strategies in Ireland.[28-31] The strategy should set out how the organisation aims to improve the management of information in order to achieve its overall strategic objectives. This should include consideration of information technology, information governance, data quality and the use of information.
- A well-governed and managed service can only be achieved if the managing organisation has robust processes in place to monitor its performance. Senior management require information on performance to be assured that practices are consistently of a high standard within the national data collection. This involves using key performance indicators to measure and report on performance, undertaking regular audits to assess practice and having a comprehensive risk management framework in place throughout the entire organisation to help identify, manage and control information-related risks.
- Data sharing agreements are necessary to support the provision of good quality data, and the legal and secure handling of data. The agreements outline the responsibilities of both parties and the associated timelines for the completion of tasks.
- Managing organisations with robust governance structures promote transparency by informing those individuals about whom data are being shared about any data

sharing agreements in place. They accurately describe the aims and objectives of the national data collection in a published statement of purpose.

The HIQA review team assessed the governance, leadership and management arrangements for NIMS within the HSE against Standards 2, 3 and 4 of the Information Management Standards. The findings of governance, leadership and management will be presented in the following sections:

- Overview of governance structures for NIMS within the HSE
- Strategic vision, planning and direction
- Risk and performance management
- Transparency.

3.1 Findings — Overview of governance structures for NIMS within the HSE

It is current national policy by the Irish government and HSE, to use one national system for the capture and notification of incidents. This is appropriate from a governance and risk management point of view as, if implemented correctly, it should: ensure national level oversight for incident management; generate national data to trend incidents and disseminate learning; standardise data collection and practices, and in turn promote the generation of high-quality data; promote efficiencies in the collection and use of data; facilitate learning and reflection; and ultimately improve patient safety.

In line with this national agenda, HIQA was informed that NIMS was adopted within the HSE as the software to provide an end-to-end risk management system for the HSE and HSE-funded services to manage incidents throughout the incident lifecycle and identify emerging trends, while also fulfilling the legal requirement to report incidents to the SCA.

In relation to DSAs, the HSE is by far the largest user of the NIMS system due to the volume and nature of health and social care related incidents. This reinforces the need for robust structures to be in place to ensure effective governance and management of NIMS within the HSE. HIQA has identified the uniqueness of the model in place in Ireland in respect of incident management, compared to international models for incident management (including the UK, Canada, and Denmark) where the system is usually held within the National Patient Safety Organisation in the particular jurisdiction and not within the national litigation authority (see Appendix 6 for further details in relation to international models).

As previously described (Section 2.3), the NIMS system is hosted outside of the HSE. There are two key organisations involved in the governance of NIMS, namely the HSE and the SCA, each with different levels of responsibility. In addition, within the HSE there are different levels of accountability at a national and local level. With the complexity of the governance arrangements in place in respect of NIMS, it is critical that appropriate, clear and effective governance structures are in place and that the functions of each stakeholder are clear and transparent to the end users of the system. The governance structures for NIMS within the HSE involves a number of key stakeholders including the SCA, QAV and HSE Acute and Community Operations. The respective roles of each of these entities will be explored in further detail in the following sections.

3.1.1 HSE Quality Assurance and Verification (QAV) team

The HSE QAV (formerly QAVD) team was established in 2015 by the HSE to monitor and report on the quality and safety of health and social care services. An overview of the functions of the QAV team is provided in Section 2.2.

QAV has overall lead responsibility for NIMS within the HSE and the QAV team liaises with the SCA as the central point of contact for NIMS within the health services. In interview, HIQA were informed that the QAV team has specific responsibility for managing and delivering on the phased implementation projects as described in Section 2.5.

At the time of the review, HIQA was informed that the National Director of QAV was the designated 'NIMS Information Owner', with responsibility for managing, authorising, and controlling access to the NIMS system across the HSE and HSE-funded services. The National Director reports to the Chief Clinical Officer, who reports to the HSE CEO who in turn reports to the HSE Board. Figure 5 illustrates where QAV is positioned within the overall HSE governance structure.

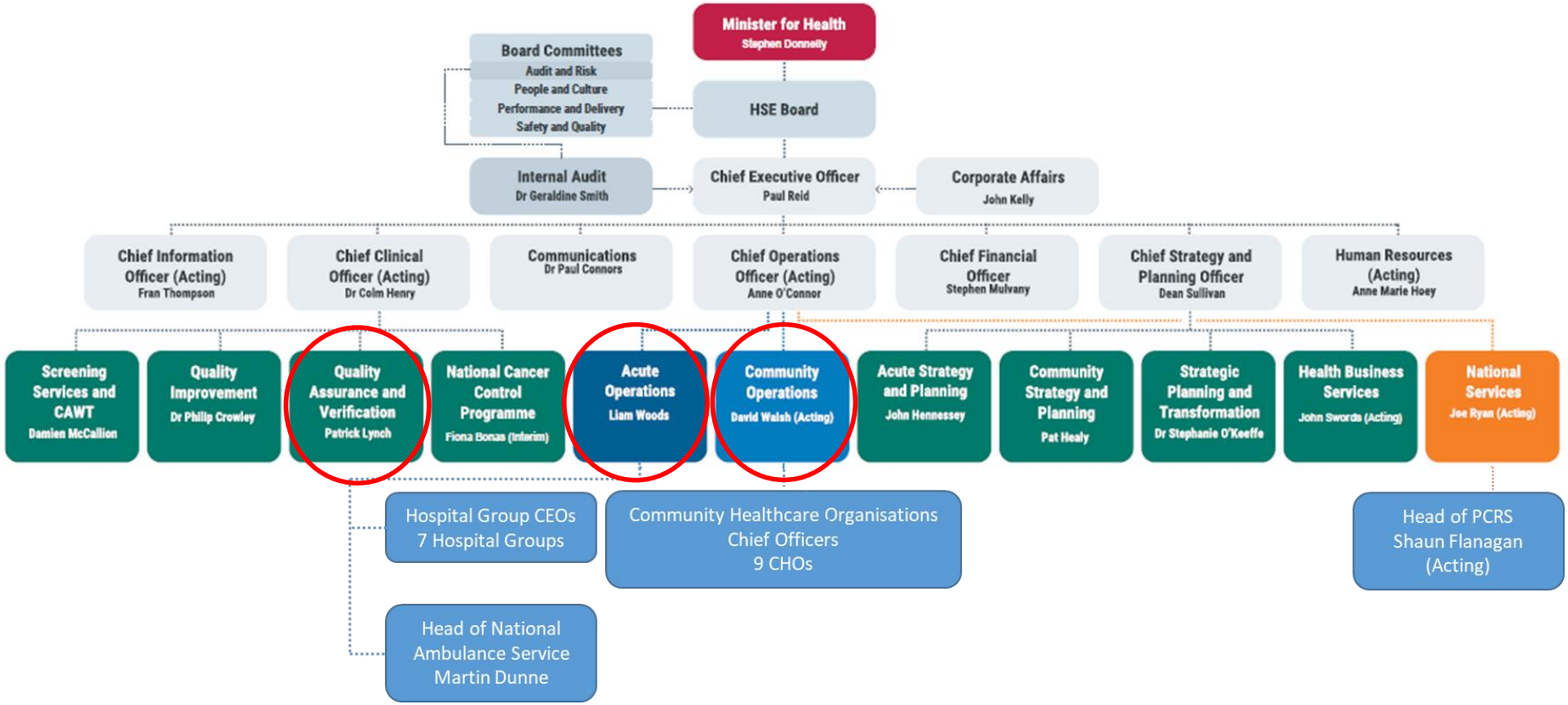


Figure 5: Position of QAV and Acute and Community Operations within the HSE governance structure[32]

3.1.2 State Claims Agency (SCA)

An overview of the functions of the State Claims Agency is provided in Section 2.3.

HIQA was informed through interview that the SCA is the managing organisation for NIMS across all State authorities and the Deputy Director, the Head of IT Operations and Business System of the SCA, have overall responsibility for the governance of the database, including the management of the technical aspects of NIMS. The SCA's statutorily mandated risk management role within the HSE is to support and assist the HSE in the management of risk associated with incidents and claims. The SCA does this by providing a platform (NIMS) for incident management which is then configured and designed by the HSE to facilitate its needs according to its Incident Management Framework (IMF- see section 2.1.2.1). The risk management software is provided to the SCA by a third party system vendor.

The SCA owns, manages and maintains the overall NIMS platform. They are responsible for the technology, as well as associated IT developments and upgrades. In relation to the HSE's information management practices and compliance as set out in the IMF, for example, incident capture, data quality, management reporting - while the SCA's interests are served by supporting compliance with the IMF, HIQA was informed by the SCA that its role in relation to the IMF is relatively minor.

The SCA therefore has both a legal remit to be notified, through NIMS, of all adverse incidents that occur in the HSE and HSE-funded organisations for risk and claims management purposes, while also under its risk mandate, providing a service to the HSE in terms of advice and assistance in the management of risk. This includes continuously improving NIMS and engaging in activities to enhance the reporting and use of the system.

3.1.3 Service-level governance arrangements within the HSE

As described in Chapter 2, all services are required to set out their governance arrangements for incident management in a manner which is consistent and in compliance with the approach outlined in the IMF. It was beyond the scope of this review to ascertain compliance with this requirement. While the IMF is clear about the responsibility for incident management at the organisational level at which an incident occurs, there is a lack of clarity in relation to national oversight of NIMS as the system supporting the implementation of the IMF. In addition, although Section 39 agencies are among the services expected to comply with the IMF, HIQA was informed through interview that not all of these services currently have access to the NIMS system. It was unclear from interview who, within the governance structure for NIMS, is responsible for this issue and whether or not it is being strategically addressed.

3.1.3.1 Service Level Agreements

The HSE has Service Level Agreements in place with organisations and agencies that are funded to provide services on behalf of the HSE. A specific obligation of all service providers under these agreements is to use NIMS as the primary ICT system to report and manage incidents.[33-35] These agreements also clearly specify that the NIMS system should be used to assist in complaints and risk management, as well as the appropriate notification of these issues to the HSE and SCA.

3.1.3.2 Acute Operations governance arrangements

As outlined in the IMF, the primary responsibility and accountability for the effective management of incidents, remains with the organisational level at which the incident occurs. The SAO of each hospital therefore has the responsibility and accountability for the effective management of incidents, the reporting of such incidents into NIMS, as well as the appropriate management of incident data within their service.

Within the broader structures of the HSE, the governance and management of incidents within hospitals is the responsibility of Acute Operations within the HSE for which the Chief Operations Officer has overall accountability. The executive management of all hospitals is the responsibility of the National Director of Acute Operations. The National Director of Acute Operations delegates responsibility for managing services to the Chief Executive Officer (CEO) of each hospital group, who in turn, delegates responsibility for the management of individual hospitals to the relevant hospital CEO or general manager (see Figure 5 for illustration of how Acute Operations is positioned within the HSE structure).

3.1.3.3 Community Healthcare Organisations (CHOs) governance arrangements

Similarly for CHOs, as outlined in the IMF, the primary responsibility and accountability for the effective management of incidents, remains with the organisational level at which the incident occurs. The SAO of individual services has the responsibility and accountability for the effective management of incidents, the reporting of such incidents onto NIMS, as well as the appropriate management of incident data within their service.

Within the broader structures of the HSE, the governance and management of incidents within CHOs is the responsibility of Community Operations within the HSE for which the Chief Operations Officer has overall accountability. The executive management of all CHOs is the responsibility of the National Director of Community Operations. The National Director of Community Operations delegates responsibility for managing services to the CHO Chief Officers for each of the 9 areas, who in turn, delegate responsibility for the management of individual services to the relevant manager (see Figure 5 for illustration of where CHOs are positioned within the

overall HSE governance structure). The service areas covered by CHOs are primary care services, social care services (which include disability services and older persons services), mental health services, and health and wellbeing. All have their own head of service.

3.1.4 National governance teams for NIMS

HIQA was informed that the QAV and SCA operate a joint governance model for the management of NIMS within the HSE. The governance teams for NIMS consists of a Sponsorship Group, a National Steering Committee and a HSE Project Team. Table 3 provides additional information on the functionality of the governance teams. These governance structures were put in place by the HSE supported by the SCA to oversee the delivery of the previously described phased NIMS implementation plan (see section 2.5 for summary). At the time of writing, the HSE is now in phase 3 of this implementation plan for which the QAV team have specific responsibility for managing and delivering.

3.1.4.1 HSE/SCA National Joint Governance Group

To reflect the overarching joint working arrangements between the HSE and SCA, a National Joint Governance Group is in place. This group was established to provide a communications forum in order to discuss the overall partnership and common priorities between the HSE and the SCA and to have high-level oversight of the work carried out between the two organisations. The focus of this group is therefore broader than the arrangements in place for governance of NIMS. The Joint Governance Group, which meets at least twice a year, is jointly chaired by the HSE's National Director for QAV and the Director of the SCA.

A Statement of Partnership is in place to underpin these joint working arrangements and will be discussed in Section 3.1.5.1. In addition, a Joint SCA/HSE Clinical Risk Forum is in place where aspects of NIMS data are discussed, as outlined in the following section.

3.1.4.2 HSE/SCA Clinical Risk Forum

A joint HSE/SCA Clinical Risk forum has also been established and meets quarterly. This group is chaired by SCA's Head of Clinical Risk. The role of this group is to provide a forum for the HSE and the SCA to identify emerging or concerning trends of a clinical nature identified by analysis of data recorded on NIMS, to consider risk mitigation strategies related to any risks identified and to escalate to the HSE, service user risks in health/social care enterprises or hospital groups, which it believes have not been or are not being addressed satisfactorily at local or hospital group level. The focus of this group is also broader than the arrangements in place for governance of NIMS.

In relation to the specific joint governance arrangements for NIMS within the HSE, the following three groups/committees are in place addressing aspects of information management for NIMS; these will now be discussed in turn.

- The NIMS Sponsorship Group
- The NIMS Steering Committee
- The NIMS Project Team.

3.1.4.3 NIMS Sponsorship Group

The NIMS Sponsorship Group is responsible for overall direction of the 'NIMS project', sign off on Phase 3 project scope, and resolving any issues that cannot be resolved by the Steering Committee. Therefore, information management aspects of the NIMS system are discussed at this forum. The Sponsorship Group escalates issues, as required, to the HSE Leadership Team and the Management Team of the SCA. The review team did not receive Terms of Reference for this group. Details regarding the group, its membership and meetings can be seen in Table 3.

The sponsorship group is co-chaired by the National Director of QAV and the Deputy Director of the SCA. The group also includes the Head of Operations/NIMS Project Lead, QAV, HSE; the NIMS Project Manager, QAV, HSE; and the Head of Business Systems and IT Operations and NIMS Programme Manager, SCA and Head of the Clinical Risk, SCA.

3.1.4.4 NIMS Steering Committee

The NIMS Steering Committee is responsible for ensuring delivery of the detailed plan to be developed in accordance with the scope and deliverables of each phase of the NIMS implementation plan.

The Steering Committee is chaired by the Head of Operations/NIMS Project Lead, QAV, HSE. HIQA was provided with the Terms of Reference for the Steering Committee for Phase 3 of the project. This outlines that the Steering Committee is composed of representatives from the HSE Project Team, Acute Operations, Hospital Groups, CHOs, Human Resources (National Health and Safety Function) and the SCA. Further details regarding this committee, its membership and meetings can be seen in Table 3.

3.1.4.5 NIMS Project Team

The NIMS Project Team is responsible for driving the achievement of the scope, deliverables and detailed plan for each phase of NIMS.

The Project Team is led by the NIMS Project Manager. The Project Team also includes; QAV Head of Operations/NIMS Project Lead, SCA Programme Manager/Head of Business Systems and IT Operations, QAV Business Performance Information Manager, and QAV Business Manager. The review team received a schedule of meetings up to August 2019. Five meetings were scheduled to take place between February and August 2019. Four meetings took place and HIQA received evidence in relation to three of these.

A number of working groups feed into the work completed by the Project Team, including a CHO working group, Hospital working group, HR working group and Systems Maintenance (see Figure 6). HIQA noted that the CHO working group met twice in 2019 in March and June and that the Hospital Group NIMS working group met twice in 2018 in July and October. No information on 2019 meeting dates was received for the NIMS Hospital Group working group.

Table 3: Evidence and documentation for the NIMS governance teams

	The NIMS Sponsorship Group	The NIMS Steering Committee (Phase 3 Implementation)	The NIMS Project Team *
Lines of reporting	**Chair:** Co-chaired by the National Director, QAV and the Deputy Director, SCA **Reporting to:** The HSE Leadership team and the Senior Management Team of the SCA through the Chairperson (as required).	**Chair:** QAV Head of Operations/NIMS Project Lead **Reporting to:** The Sponsorship Group through the Chairperson.	**Chair:** NIMS Project Manager **Reporting to:** The Steering Committee through the Chairperson.
Responsibilities	The overall direction of the project sign off on phase 3 project scope and resolving any issues that cannot be resolved by the Steering Group.	Responsible for overseeing delivery of the project plan and in particular to: ▪ review progress reports from the Project Manager ▪ provide guidance and support to the project team ▪ oversee delivery of the project plan and consider and resolve any issues arising ▪ act as an advocate for the systems roll out ▪ escalate to the sponsorship group any key issues it is unable to resolve.	Responsible for driving the achievement of the scope, deliverables and detailed plan for each phase of NIMS, and in particular to: ▪ support and maintain the system, supported by their colleagues in the SCA ▪ support and drive the work of the Steering Committee ▪ work closely with business owners and supported by the SCA, deliver on system developments and report in the context of the systems potential and constraints; and escalate issues as required to the Chair of the Steering Group.

	The NIMS Sponsorship Group	The NIMS Steering Committee (Phase 3 Implementation)	The NIMS Project Team *
Membership	▪ National Director, QAV ▪ Head of Operations/NIMS Project Lead, QAV ▪ NIMS Project Manager, QAV ▪ Deputy Director, SCA ▪ Head of Business Systems and IT Operations, NIMS Programme Manager, SCA.	▪ Head of Operations/NIMS Project Lead, QAV ▪ NIMS Project Manager, QAV ▪ NIMS Project Team Rep, QAV ▪ Quality, Risk and Safety Rep, QAV ▪ Head of Business Systems and IT Operations, NIMS Programme Manager, SCA ▪ Hospital Group Rep, HSE ▪ Acute Operations QPS Lead, HSE ▪ CHO QPS Rep, HSE ▪ HR Rep, HSE ▪ Section 38 Rep, HSE ▪ National Complaints and Governance Learning Team (NCGLT) Rep, HSE ▪ Clinical Risk rep (x2), SCA ▪ Enterprise Risk (x2), SCA.	▪ Head of Operations/NIMS Project Lead, QAV ▪ Head of Business Systems and IT Operations, NIMS Programme Manager, SCA ▪ Business Performance Information Manager, QAV ▪ Business Manager, QAV ▪ Community Operations QPS. Membership of the Project Team can be supplemented by other representatives, as required.
Other details	**Frequency:** 3 times/year **Documentation:** Minutes and agenda **Quorum:** Not stated.	**Frequency:** 3 times/year **Documentation:** TOR, Minutes and agenda **Quorum:** Not stated.	**Frequency:** Monthly **Documentation:** Minutes and agenda **Quorum:** Not stated.

	The NIMS Sponsorship Group	The NIMS Steering Committee (Phase 3 Implementation)	The NIMS Project Team *
Functionality	**Meeting dates**: Since March 2018, the group has met three times: ▪ March 2018 ▪ January 2019 *(10 months since previous)* ▪ April 2019 *(3 months since previous)* **Attendance:** Evidence of good attendance provided for April 2019 (n=7) **Focus:** Provided with evidence of minutes from two meetings. One had specific focus to review birth-specific and clinical procedures approach. The other meeting reviewed progress of deliverables, under-reporting, point of occurrence implementation, national view of all information, approach by SCA to review birth-specific and clinical procedures, content of performance reports, recording screening incidents, communication process for claims/incidents, and severity algorithm.	**Meeting dates**: Since September 2018, the group has met three times: ▪ September 2018 ▪ December 2018 *(3 months since previous)* ▪ June 2019 *(6 months since previous)* **Attendance:** Evidence of good attendance provided for Sept 2018 and Dec 2018 meeting (n= 15) **Focus:** Corporate update: NIMS reports, training, access, review screen participation, severity algorithm, birth-specific and clinical procedures, incidents created by SCA, complaints on NIMS, GDPR, open disclosure, achievements update.	**Meeting dates**: Since December 2018, the team met seven times: ▪ December 2018 ▪ Jan 2019 ▪ Feb 2019 ▪ April 2019 ▪ May 2019 ▪ August 2019 **Attendance:** Evidence of good attendance provided for meetings in April, May and August (n= 5-6) **Focus:** Change of NIRF (remove complaints), severity algorithm, communication for SCA created claims, reviewed change requests, reviewed recommendations from review, point of entry, 2020 KPIs.

***** The Project Team has a number of sub-teams including the CHO working group, the HR working group, the Hospital Group working group and systems maintenance. Both the NIMS project manager and NIMS project lead sit on these additional groups.

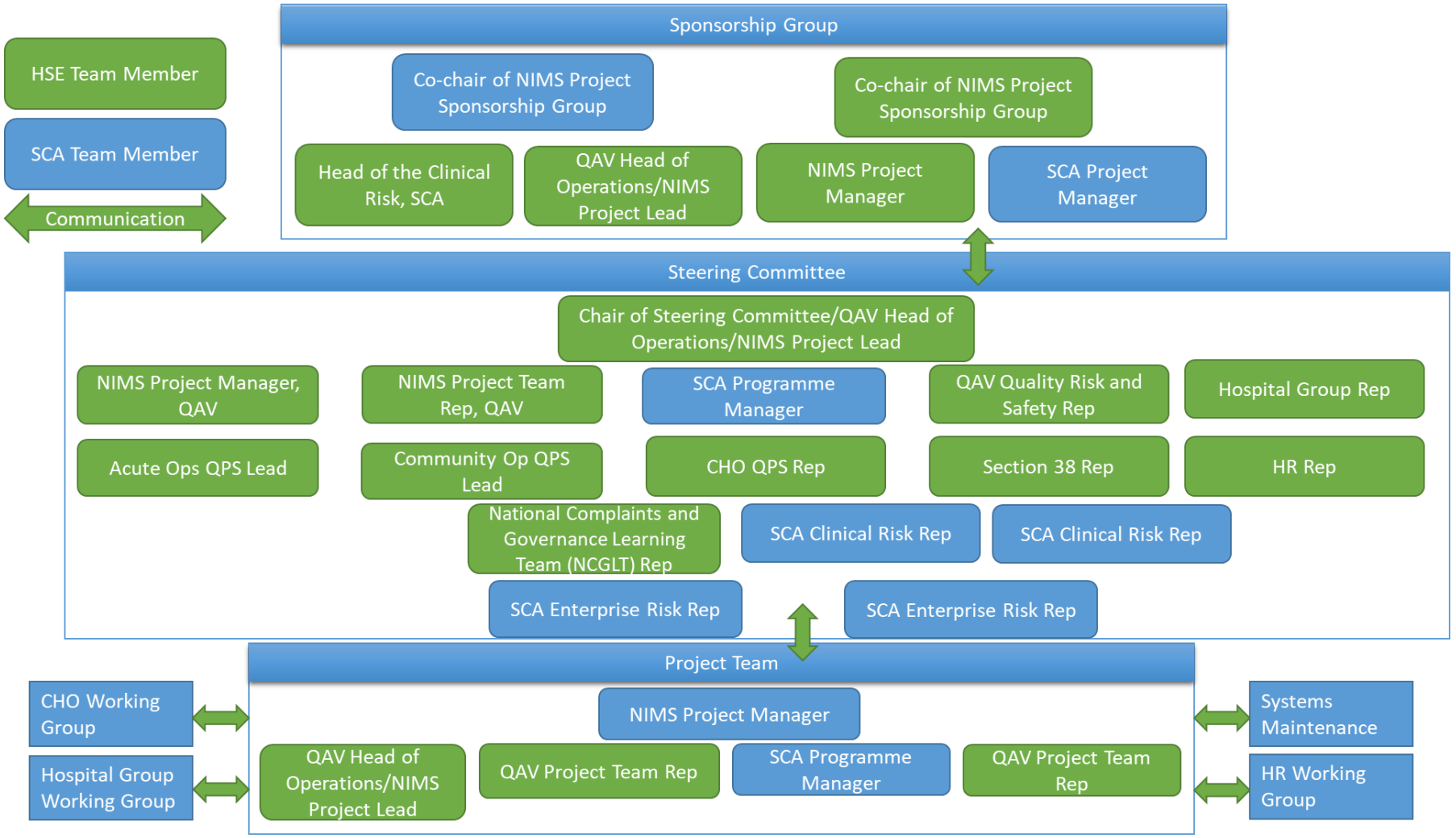


Figure 6: Governance structure for implementation of NIMS

3.1.5 Governance responsibilities for NIMS

3.1.5.1 Statement of Partnership

HIQA was provided with a Draft Revised Statement of Partnership between the HSE and SCA, dated September 2019. This Statement of Partnership is intended to enable and enhance the delivery of each organisation's respective statutory mandates. This is a high-level document which reflects a shared overarching vision and goals and a commitment to working together to: support improvement in the quality and safety of services delivered by providers of publicly-funded health and social care services; and to ensure the safety, health and welfare of all HSE employees and third parties in compliance with legislation, by implementing targeted personal injury and property damage risk work programmes.

The Statement of Partnership sets out:

- The context of service provision by the HSE and learning from incidents through reporting on NIMS.
- The shared vision and goals which involves working together to improve the safety of health services for the users of those services, in addition to the health and safety of the employees, members of the public and third parties.
- The high-level roles of both organisations as set out in legislation and the statutory basis for working together.
- Underlying statements of commitment including: focusing on patients, service users, employees and third parties, showing compassion, minimising duplication, improving capability, being considerate, sharing of intelligence, communicating and managing concerns.
- Governance arrangements (as outlined in Section 3.1.3), as well as escalation procedures, agreement regarding reporting of incidents and monitoring performance through KPIs.

3.1.5.2 Partnership roles and responsibilities

Although, the Statement of Partnership provides a positive basis for the working relationship between the HSE and SCA, HIQA identified that the detailed roles and responsibilities for each organisation are not clearly documented. This is important given the complexity of the management of incidents and NIMS across the organisations involved in the joint governance model (the QAV and the SCA). In addition, within the HSE, there are responsibilities at different levels within the HSE governance structure (as outlined in Figure 5), across QAV, Acute Operations and Community Operations. As a result, through interviews with each organisation, HIQA identified that there was a lack of clarity in respect of specific roles and responsibilities for NIMS across the key partners.

- In interview, the National Director of QAV outlined that he had responsibility for the 'programme of work' which involves the governance and management of the NIMS implementation plan.

- The Head of the SCA noted that the SCA has responsibility for the technical aspects of NIMS and working with the QAV as the central point of contact for NIMS within the HSE. The SCA manages the relationship with the third party system vendor who provides the NIMS platform and data hosting.

Currently, the joint governance model and respective governance teams for NIMS tend to focus on the technical or project implementation aspects of NIMS. However, contrary to what is required under the Incident Management Framework and service level agreements, there is ambiguity regarding who has national responsibility for the governance of the incident management data within the HSE. There is a need for national level coordination and leadership for this system. For example, although the National Director of QAV is identified as the NIMS "Information Owner" within the HSE, HIQA was not able to identify who has overall responsibility for assuring and driving the quality of NIMS data across the HSE. In interviews with the QAV team, it was acknowledged that this responsibility ultimately lies at a service level, but responsibility for national oversight of this was not clear.

Furthermore, throughout the interviews there was a lack of clarity regarding the oversight responsibilities for NIMS within the HSE to address some of the significant issues that currently exist. These include:

- Use of alternative incident management systems for recording incidents
  This is at variance with the national mandate for all services to use one common system and can impact on quality of data affecting: timeliness of data due to backlogs of data being entered onto NIMS as a result of organisations electing to report on an alternative system as well as on NIMS; accuracy of data due to higher risk of errors when entering data twice; and completeness of data as not all data are entered onto the national system. In addition, and of significance, the HSE was unable to provide HIQA with precise details in relation to the number of services that are currently using alternative systems.

- Over-reliance on paper-based data collection
  In settings where large volumes of incidents are reported, it can be challenging to generate real-time data to assist in the management of incidents and risks. This can result in lack of access to timely data to monitor, track and trend incidents and manage risk on a daily basis as incidents occur.

- Local ICT infrastructural and connectivity issues
  Problems with local ICT connectivity, due to local infrastructural weaknesses, were reported during interviews with NIMS users and have resulted in significant challenges, with users in one region being unable to connect to NIMS. This can lead to delays in incidents being inputted onto NIMS or data having to be input twice. HIQA was informed that this has been recognised at national level with a group, made up of QAV/SCA/HSE IT/Local Service users, set up to resolve the issue.

- Lack of adequate stakeholder engagement and support
  While HIQA acknowledges the considerable work and engagement that has been carried out by the SCA, in collaboration with the HSE, in designing and implementing the system and establishing senior stakeholder support, the HSE has not, to date, undertaken comprehensive engagement with all NIMS users to understand their needs and requirements in relation to the system. Ongoing engagement can also ensure that NIMS users are informed and kept updated in relation to the full capabilities of the NIMS system

These issues are examples and symptoms of a lack of a coordinated approach to resolving NIMS challenges, which is posing challenges to the full implementation and effective use of NIMS within the HSE. A strategic national level approach is required to adequately address these issues.

3.1.5.3 Responsibility for leadership

Within the HSE, the QAV explained that there was a decentralised model in place where the governance and management of NIMS data was the responsibility of the SAO for that service (for example, a hospital) in the HSE (further details on the role of SAO can be found in Section 2.1.2.4). At a local level, the Incident Management Framework provides clarity regarding roles and responsibilities for the management of incidents and related learning from a quality and patient safety perspective. However, as noted previously, the challenges currently facing the system need to be addressed at a national level.

HIQA learned that there are roles at a national level, for example the QPS Lead and Risk and Incident Officer roles in Acute Operations, with responsibilities for promoting the appropriate submission of data, data quality and use of data. However, HIQA also learned in interview that more integration of local level practices within these Quality and Patient Safety functions is necessary. Staff members identified that there is a need to coordinate and integrate their functions in relation to NIMS, in order to identify the most effective and efficient ways of working.

In relation to the collection of NIMS data, currently there are various models in use across the health service (these are described in Chapter 2). There are significant implications on resources at a local level with each hospital and CHO having dedicated resources to manage the inputting of data, in some cases into two systems. As explained, some organisations have moved to electronic point of entry (ePOE) data collection, using alternative systems, as their understanding is that currently ePOE is not supported by NIMS. However, HIQA was informed by the SCA that during the first months of COVID-19, ePOE was rolled out across 21 private hospitals within two weeks as part of their involvement in the pandemic response. In addition, the review team was informed that since the commencement of this review, ePOE has been implemented in 25 locations with another 30 locations due to go live in April 2021. This evidence demonstrates the capacity of the NIMS system to support ePOE. However, HIQA identified through interviews that there was no consistent view as to what the optimal model regarding the effective and efficient collection of incident data would look like in the long-term, nor as to what the recommended information governance model to support such an approach would be. There has never been an evaluation or a cost-effectiveness analysis to establish the different options for a nationally recommended approach. HIQA was unable to conclusively establish who is responsible for taking responsibility for such a significant issue in the HSE, which highlights a gap in relation to the current governance arrangements.

The lack of clarity around roles and responsibilities and leadership, the presence of the current challenges facing NIMS and the absence of a long-term strategy for the system suggests that current governance structures for NIMS within the HSE are not adequate for ensuring it is successfully embedded as the single national system for incident management across the HSE and HSE-funded services.

3.2 Findings – Strategic vision, planning and direction

Strategic plans are the foundation on which all business activities can be connected and aligned. In order to effectively deliver a strategy, it is necessary to specify how the national data collection is going to achieve their strategic objectives by producing regularly updated business plans.[36] Developing and implementing business plans is an essential process to translate strategies into realistic work targets, and this process also provides a basis to monitor progress to ensure that key outcomes are achieved within the specified timelines.

The last Corporate Plan published by the HSE covered the period from 2015 to 2017; this sets out the strategic direction for the HSE.[37] The Strategic Approach 2020-2024 sets out goals and strategic objectives for the next five years.[38] These goals

include improving the patient experience, improving clinical expertise and improvement and assurance. The National Service Plan is the annual business plan which sets out the type and volume of services against which the HSE's performance is measured.[31] The HSE Corporate and Service plans outline high-level strategic objectives and outcomes. These plans do not address the specific requirements for any of the national data collections, including NIMS. Therefore, it is the responsibility of the managing organisation, with input from key stakeholders, to develop detailed strategic and business plans to outline the aims and objectives, legal responsibilities and future developments in order to adequately consider how the management of the national data collection, NIMS, needs to evolve along with wider system changes and in line with the HSE Corporate Plan.

A strategic plan for NIMS is necessary to address each aspect of information management, such as developments in ICT, data quality, information governance and the effective use of information.

3.2.1 Strategic Direction for NIMS

HIQA identified evidence of high-level strategic plans to address incident management within the HSE. However, details regarding the strategic direction of NIMS are not included within these plans. The Corporate Plan 2015-2017 outlined that the HSE would put processes in place so that all safety incidents are effectively managed, reported, investigated and the learning from such incidents is shared and implemented.[37] The aim of this is to ensure that all serious incidents and events are reported, managed and investigated in a timely manner.

HIQA learned through interviews with both the QAV and SCA that there is no coordinated approach to long-term strategic planning for NIMS within the joint governance model. Instead, there is more of a project management style approach to the development of short-term goals such as software development, and with a lack of strategic focus on overarching developments such as change management. This was particularly evident when HIQA asked about the strategic approach to dealing with the large backlogs in the system, the approach to dealing with alternative systems for managing incidents at a local level, the duplication of work as a result, and the plans to implement ePOE nationally. There was no clarity as to who held the responsibility to take leadership for the strategic plans for NIMS within the HSE.

3.2.2 Business planning for NIMS

The HSE National Service Plan (NSP) 2019[30], outlined that the HSE would, as a priority, establish a programme to facilitate learning from the National Patient Experience Survey, Your Service Your Say and complaints mechanisms, Your Voice Matters (Patient Narrative Project) and the Incident Management Framework 2018.

The plans also outlined that it would progress the implementation and evaluation of the Incident Management Framework 2018 in order to report, manage, review, disseminate and implement learning from safety incidents. KPIs in relation to incident management feature strongly within the NSP and which emphasises the need for good quality data in this regard.

In addition to this, both the QAV and SCA have documented plans for programmes of work with regard to NIMS as outlined below. These plans are developed in consultation with the Steering Committee which has representation from services and NIMS users within these services. However, HIQA did not see evidence of extensive consultation undertaken with stakeholders beyond the Steering Committee to understand the existing challenges facing the system before the rollout of any further modules was decided upon.

3.2.2.1 QAV: Operation Plan 2019

This plan outlines a number of priorities linked to NIMS:

- to develop reporting and data analysis capabilities on NIMS
- patient safety surveillance and intelligence: develop a framework for shared learning for patient safety and develop audit tools to assess compliance with IMF and Integrated Risk Management policy
- NIMS Phase II+ complaints management database: to continue training and establishment of a governance structure.

3.2.2.2 QAV: NIMS Implementation project- Phase 3

The QAV have developed Project Initiation Documents for each phase of the implementation of NIMS, as outlined in Section 2.5. HIQA was provided with the current NIMS implementation plan (Phase 3 Scope and Deliverables).[23] The purpose of this project plan is to provide succinct, informative and accurate interpretation of NIMS data from all user sites in a coherent and structured framework. Details of the scope of Phase 3 of the implementation of NIMS are provided in Section 2.5.1.

3.2.2.3 SCA: Goals 2019 - 2023

This document was provided by the SCA as part of HIQA's information request and outlines the annual targets and set deliverables for 2020, in relation to all work for DSAs, and not just the HSE. Goal 8 as set out in the document, is to advise and assist in the management of litigation risks to a best practice standard, in order to enhance the safety of employees, service users/patients and other third parties and to minimise the incidence of claims.

A number of the goals for this period are directly linked to NIMS including:

- reducing the number of claims previously reported as incidents

- producing and publishing key risk management and data reports as per the agreed schedule.

Some of the relevant deliverables for 2020 include achieving target reductions in claims previously reported as incidents and implementing NIMS continuous improvement programme. Previous relevant deliverables for 2019 included the design and pilot of point of occurrence (kiosk) incident entry solution by Quarter 3.

HIQA noted that this evidence is positive as it portrays that development work and progress to enhance NIMS is ongoing both within the QAV and SCA.

However, although development work is progressing, there is no comprehensive strategy to deal with the major challenges that have been facing NIMS. There is an urgent need for the HSE to undertake comprehensive stakeholder engagement to understand the requirements of users, particularly those who are using alternative systems, to ensure that NIMS is used as the single system by all services. Findings from this engagement should form the basis for a long-term strategy for NIMS to ensure its use as the primary incident management system in place across all HSE and HSE-funded services. Any engagement should ensure that all services fully understand how NIMS is capable of meeting their requirements. There is also a need for a unified approach across the HSE and SCA, as joint partners to address the requirements of system users.

In summary, HIQA has identified that strategic and business plans need to be developed for NIMS in conjunction with all key partners, and through comprehensive stakeholder engagement with a focus on the greatest need and impact in terms of patient safety.

3.3 Findings – Performance and risk management

Robust performance and risk management promotes accountability to all stakeholders by facilitating informed decision-making and improvements through continuous and rigorous self-assessment.[39] Performance and risk management involves using the appropriate tools to produce the necessary information to assure senior management that NIMS is being managed effectively at an operational level. Effective performance management can be achieved by employing the use of a number of key tools, including identifying and reviewing KPIs, commissioning necessary internal and external audits to assess compliance with relevant legislations and the organisation's policies and procedures, and reviewing the risk management policy and risk register. The use of KPIs, audit and risk management for NIMS within the HSE will be detailed in the following sections.

The HSE has a Performance and Accountability Framework in place which sets out the means by which named individuals, who have delegated responsibility and accountability, are held to account for the performance of services within their allocated budget.[16] The principles of this framework are to outline, without ambiguity, what is expected of those that are held to account and what actions they should take if targets are not achieved. It is the responsibility of managers to proactively identify issues of underperformance and to act upon them promptly as an effort to avoid the need for escalation within the organisation. As previously stated, performance and risk management are closely aligned with clear governance structures: explicit lines of reporting and clarity regarding specific accountabilities are essential. For example, in line with the HSE's Performance and Accountability Framework, National Directors and hospital group CEOs are required to sign a performance agreement which sets out the scope of what they are responsible for and against which they will be held to account. As the SAOs of each hospital have delegated responsibility for the governance and management of NIMS within hospitals, it is within their remit to ensure that the data are consistently of a high-quality and to create a patient safety culture of no blame and learning from incidents to ensure they meet their mandated responsibilities. It is also seen as best practice that organisations prepare data quality statements to clearly demonstrate the quality of the data by reporting against pre-defined indicators.[2] This should be similar for CHOs and there should be someone with specific responsibility for reviewing performance of NIMS across acute hospitals and CHOs at a national level.

3.3.1 Key performance indicators

KPIs can be a valuable tool to assess performance if used effectively: they can be used to monitor how effectively an organisation is reaching targets. In accordance

with best practice, a systematic process is required to identify, develop, collect and review KPIs for information management. Senior management need assurance that there is a carefully planned process in place to gather the appropriate KPIs as relevant, reliable and accurate indicators, which are essential for good governance. A performance report detailing the KPIs should be reviewed regularly at management and senior management meetings with responsibility for NIMS, and actions should be decided upon if performance drops below the pre-specified target at any point.

As noted in 3.2.2, the incidents captured through NIMS feature strongly as KPIs for the system within the Service Plan[30], including KPIs for the National Scorecard and the National Performance Indicator Suite. However, although HIQA acknowledges the use of these KPIs for reporting purposes (this will be discussed further in Chapter 4), HIQA could not identify who has overall responsibility nationally within the HSE for overseeing and driving improvements in performance in terms of reviewing and improving the quality of NIMS data.

In interview, the National Director of QAV explained that the KPIs are reviewed by the HSE National Performance Oversight Group (NPOG – see Section 2.1.2.3). HIQA received evidence that the KPIs on timeliness of incident data are used in all national level reports and also used to drive practice locally:

- Percentage of reported incidents entered onto NIMS within 30 days of occurrence by CHO/ Hospital Group/NAS
- Percentage of serious incidents being notified within 24 hours of occurrence to the SAO
- Percentage of serious incidents requiring review completed within 125 calendar days of occurrence of the incident.

During site visits and interviews, HIQA identified that there was a high level of awareness of the use of KPIs at a national level, as well as the requirement for services to meet national targets.

HIQA was informed that the KPIs in relation to incidents are viewed as the 'single source of truth' by NPOG. The performance process that is in place is expected to scrutinise the data using a 'REDI' [Review, Enquire, Diagnose, Improve] process model which expects services to 'diagnose' the reason for poor reported performance.

Phase 3 of the NIMS implementation plan focuses on developing analysis and reporting functionality through the use of dashboards. Through interviews, the QAV

informed HIQA that the Project Team has a role in promoting better analysis and reporting, and therefore supports the development of performance reports and encourages the use of dashboards at a service, group and national level. The effective use of dashboards easily enables decision makers and management to breakdown and manipulate statistics like KPIs according to their needs. However, HIQA was unable to establish who holds an oversight role, focusing on assurance regarding the quality of the data underpinning the KPIs.

Regarding performance and in line with the Incident Management Framework, HIQA was informed that Acute Operations and Community Operations are responsible for managing the incidents and related data under the performance and accountability structure. Therefore, reviewing and managing the KPIs falls under the responsibility of the National Directors for the respective service. For example, HIQA was informed that the National Director for Acute Operations monitors KPIs across the hospital groups. This activity focuses specifically on serious incidents and SREs. National Directors in turn report to the Chief Operational Officer (also Chair of NPOG) and where necessary, could report upwards to the HSE CEO or the HSE Board. Follow up regarding performance occurs through Quality and Patient Safety Leads for outlying incidents.

HIQA must highlight that the use and availability of KPIs is a very positive development covering two aspects of the dimensions of data and information quality, timeliness and completeness. However, although HIQA identified that value is placed on reviewing these KPIs, there is an ongoing issue with assurance for NIMS data as targets are not being met and also not improving over time (details will be discussed in Chapter 5 Use of Information). The indicators are used to monitor safety, particularly focusing on Category 1 or SREs at a high level. HIQA was assured that incidents are being managed effectively at a local level, however the poor compliance with targets is a symptom of poor quality data. While various initiatives have been introduced to drive improvements in this area, the strategic approach underpinning this work is unclear. Additionally, there is a large amount of data related to less severe incidents for which there is no KPI and for which data is not being effectively used or evaluated in terms of data quality. These include data on near misses, for which there is a huge learning potential from a quality and patient safety perspective.

Although HIQA notes good practice in relation to activities around KPIs, there are still some issues that need to be addressed:

- There is an ongoing issue with assurance for NIMS data as targets are not being met and also not improving over time. Therefore, there is a need to question who is responsible for assuring the quality of these indicators and

what is being done at a national level to improve compliance to targets for KPIs and hence data quality.

- While acknowledging that there is a REDI process in place by NPOG to 'diagnose' the reason for poor compliance with national KPIs, it has been accepted by the HSE that this has not led to sufficient improvements in this area.
- HIQA could not identify who has overall responsibility within the HSE for overseeing and driving improvements in performance in terms of management of incidents and improving the quality of the data.

3.3.2 Internal and external audit

Audit plays an important role in providing assurances to senior management as to the adequacy of their internal controls. It also brings a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes. Audit schedules, including external audits, should be reviewed and agreed by senior management. External audits should be commissioned when a specific area of expertise, which may not be available in house, is required or when an extra level of independence is considered necessary. The findings of the audits should be presented regularly to senior management to highlight areas of good practice and to identify areas which need improvements. Audits should also be used to identify specific training needs and to ultimately identify and implement improvements to information management practices.

3.3.2.1 Internal Audits

The HIQA review team was provided with evidence from QAV of one internal audit carried out in 2017, that looked at compliance with section 7.2.3 of the safety incident management policy 2014.[(14)] This was in relation to the decision not to proceed to investigation of SREs. The desktop audit was carried out on six Hospital Groups and three CHOs. One of the two recommendations that came from the report was for the National Director of QAV to ensure that a communication is issued/re-issued to all services drawing attention to the use of the NIRF as the single incident report form and NIMS as the primary incident reporting system for the HSE and HSE-funded agencies. HIQA was not provided with evidence of any other internal audits of the management of incidents or review of data quality at a local level or national level by the QAV, Acute Operations or Community Operations.

The Incident Management Framework outlines that compliance with key elements of the Framework will be subject to verification audits. HIQA was informed that the Head of Healthcare Audit in the QAV team has planned to undertake an audit of compliance with the Incident Management Framework in 2020, but no further

information on dates or specific details of this audit were provided to HIQA when requested. Acute operations informed HIQA that they have a role in Quality and Patient Safety and through this function, they follow up on the management of serious incidents. They do not undertake specific validation of the data, but recognise the need for good quality data to support surveillance. Therefore, in recent months, Acute Operations have begun sending reports on SREs to hospital group CEOs which highlights gaps in evidence which has led to a focus on data quality and improvements in the timeliness and completeness of data.

HIQA was informed that the SCA have an audit function and often perform an annual site visit to hospitals where they could enquire about the management of certain incidents. SCA audits focus on local risk management systems in place and on particular risks that are of concern and do not extend to reviewing data quality or the compliance with the Incident Management Framework. No evidence of a formal audit or audit report was provided to HIQA. In interview, the SCA stated that internal audits are carried out by a contracted auditor on SCA systems. These audits encompass some areas of NIMS, such as review of the system vendor; review of data service unit; review of data and information management.

3.3.2.2 External Audits

HIQA was not provided with any copies of the findings of external audits in relation to NIMS. However, in interview the SCA stated that audits have been carried out by the Comptroller and Auditor General's Office and that aspects of NIMS would fall under these audits. The SCA also has a detailed audit programme in place in relation to information security aspects of NIMS in conjunction with the system vendor. The details of these information governance-related audits can be found in Section 5.4.

In relation to the arrangements within the current joint governance model for NIMS, one would expect to see a regular schedule of audits documented and implemented for NIMS within the HSE. Although HIQA was provided with some evidence of audits, a more structured approach to this area of governance would provide assurance to stakeholders that NIMS is being effectively managed.

3.3.3 Risk management

Senior management needs regular assurance that the risk management policy is being implemented within the organisation by regularly reviewing the risk register at the senior management team meetings and assessing whether risks are being managed appropriately within the organisation.

3.3.3.1 Risk management within the HSE

All HSE and HSE-funded services are required to follow the HSE Integrated Risk Management Policy.[40] This policy encourages management to adopt a proactive approach to risk management by identifying risks that threaten the achievement of objectives and compliance with governance requirements. An example of such risks is the failure to comply with legal and regulatory requirements. The policy clearly outlines that it is the responsibility of all staff members to identify and manage risk within the context of their work. Furthermore, it is the line manager's responsibility to manage and control risk. In order to manage risk, formal identification of risks and implementation of controls should be part of the daily working flow and a risk register should be systematically maintained and reviewed by management.

3.3.3.2 QAV Risk Register

QAV provided a copy of their risk register for the period Q3 2019. This included a risk related to incident management which outlines the risk to a timely and proportionate response to incidents, due to the failure to have in place a consistent decision-making framework that can be proportionately applied at all stages in the incident management process. The existing controls included having the Incident Management Framework in place and related guidance and training to support implementation of the framework. The controls did not include specific audits to monitor compliance with the framework.

In interview, HIQA was informed that QAV did not at the time of the review have a risk on their register specifically relating to NIMS. This is despite a number of current challenges being identified throughout this review, as detailed in section 3.1.5.2.

Furthermore, although a joint governance model is in place between the HSE and SCA for NIMS, there is no joint risk register to identify and manage risks. It is clear from interviews carried out by HIQA that there is awareness about the issues that exist in relation to NIMS, but there was no evidence of them being strategically addressed within the current governance structures. Risk management is not a standing agenda item on any of the governance teams for NIMS. Although the review team was informed that the issues highlighted in this report are identified by the Project Team and Steering Group and that appropriate actions are taken accordingly, HIQA did not review any formally documented examples of this.

The review team was also informed that information governance risks may be raised through a briefing by the SCA to the QAV National Director and NIMS project manager. However, there was no indication on the frequency of these briefings or a record of the risks discussed. The above is significant given that there are so many stakeholders involved in the management of NIMS and also given that the specific roles and responsibilities are not clearly documented. These factors reduce the

likelihood of risks being mitigated effectively, due to miscommunication or misunderstanding regarding ownership of the risk across organisations and services.

3.3.3.3 Risk management within the SCA

The SCA provided a risk register report filtered for risks specific to NIMS. The three areas of risk listed were: IT systems - Data Breach; Protection of data; and IT systems - system availability. Under the system availability risk description it is noted that potential outcomes of the unavailability of systems included: systems that are not user-friendly resulting in poor uptake and loss of data; and intermittent outages or poor system performance causing reduction in user confidence and consequent poor uptake (these have been noted as low risk). Existing controls included formal communication via: Governance groups (HSE & other key clients) and Working groups (HSE/SCA); the DoH issued a Directive to the HSE CEO that NIMS be the sole/primary adverse events system; maintenance of liaison and good communication through several layers of client organisation - Heads of Function, Senior Risk Managers & advisors; SCA staff act as ambassadors for NIMS.

It is unclear from the document how often the register is reviewed and updated. However, HIQA was informed by the SCA that it is reviewed at least annually. In interview, the SCA noted that a joint approach to risk management and a joint risk register would be beneficial for the management of NIMS.

3.4 Findings — Transparency

Organisations with robust governance structures promote transparency by publicly reporting a statement of purpose which clearly outlines the aims and objectives of the national data collection. Furthermore, data sharing between organisations is encouraged if it is for the benefit of the service user and public health and in line with legislation and best practice guidelines. The use of data sharing agreements is recognised as good practice in this area. The governance of data sharing should ensure personal information is shared in a way that is fair, transparent and in line with the rights and expectations of the individuals whose information is being shared. Data sharing is encouraged if it is for the benefit of the service user and public health and in line with legislation and best practice guidelines.

Data sharing agreements define a common set of rules to be adopted by the various organisations involved in a data sharing operation. It is essential that robust governance structures are in place to allow appropriate data sharing to occur. These include having oversight, assurance and transparency for all data entering and leaving the organisation.

3.4.1 Statement of purpose

At the time of the review, the HSE did not have a statement of purpose published for NIMS. This document is a fundamental requirement for a national data collection, as it clearly outlines the aims and objectives of the national data collection, and helps to build a culture of transparency which builds confidence in those collecting and using the data. Although aspects of the required details of a Statement of Purpose are contained within the NIMS terms and conditions, it is best practice to develop and publish a Statement of Purpose for NIMS within the HSE.

3.4.2 Data sharing agreements for NIMS

The collection and sharing of incident data with key agencies is essential in order to monitor and promote patient safety and learning across the HSE.

HIQA identified through the information request that the SCA receives incident data from all public hospitals, Section 38 hospitals and services under the governance of CHOs. HIQA identified that although data sharing arrangements are set out in the NIMS Terms and Conditions for DSAs (including the HSE) there did not appear to be a specific data sharing agreement in place in relation to the sharing of data from the HSE to the SCA, or back to the HSE in terms of the national database. A data sharing agreement defines a common set of rules to be adopted by the various organisations involved in a data sharing operation. Although, as already noted,

documentation is in place demonstrating that there are data sharing obligations between the two organisations and that both organisations are compliant with relevant legislation, a data sharing agreement would strengthen these arrangements and provide full clarity and transparency for all stakeholders.

3.5 Significance of Findings — Governance, Leadership and Management

Joint governance arrangements for NIMS

- The management of any national data collection requires two important aspects: the management of the information system, and the management of the process for collection and use of the data. The governance of NIMS within the HSE is unique when compared with international models for incident reporting. It involves an arrangement for which the SCA hosts, manages and maintains the information system (via a third party system provider); and the HSE manages the process of collecting and using the data. The SCA not only has a legal remit to be notified of all adverse incidents, they also provide a service to the HSE in terms of managing the system software which includes the technical support and development of NIMS. However, the HSE is the 'owner' of the data held on the system, and is responsible for the effective management of incidents, the reporting of such incidents onto NIMS, as well as the appropriate management of incident data within their services to support learning and quality improvement. In order for this complex joint governance arrangement to be robust and effective, it requires very clear and distinctive responsibilities.

- HIQA identified that there are clear project teams and structures in place in relation to the implementation of NIMS within the HSE. HIQA acknowledged that this is positive in terms of having a structured approach to the implementation phases. However, HIQA also identified that the scope of these teams is currently too narrow, that they did not comprehensively cover the broader governance, leadership and management of NIMS within the HSE. The governance of NIMS within the HSE therefore requires more than a project implementation approach and needs appropriate governance for the long-term management of the collection and use of data, and the system itself to ensure an adequate system is in place to support and facilitate compliance with the Incident Management Framework.

- In summary, currently the joint governance model for NIMS tends to focus primarily on the information system and the technical aspects of NIMS. However, the governance needs to cover the long-term operational aspects of incident management and related data as a whole within the HSE, for example, the effective collection and use of data.

Governance responsibilities for NIMS

- In line with clarity regarding governance arrangements, although the Statement of Partnership provides a positive basis for the working relationship between the HSE and SCA, HIQA identified that the detailed roles and responsibilities for each organisation are not clearly documented. This is important given the complexity of the management of incidents and NIMS across the organisations involved in the joint governance model (the HSE and the SCA) and also more broadly within the HSE, given there are responsibilities at different levels within the HSE governance structure across QAV, Acute Operations and Community Operations.

- HIQA identified that there is a lack of clarity in respect of specific roles and responsibilities for NIMS across the key partners; for example, responsibility for the development of long-term strategic and business planning, data quality, as well as risk management for the effective collection and use of NIMS data. This gap in governance for NIMS has resulted in some major challenges facing the full implementation and effective use of NIMS within the HSE including: the use of alternative systems at a local level; a strong reliance on paper-based data collection in some large acute hospitals; and challenges with local ICT connectivity and infrastructural weaknesses.

- HIQA also found that the lack of a comprehensive evaluation of NIMS and engagement with NIMS users to fully understand their needs and requirements of the system, poses a significant challenge to the comprehensive implementation of NIMS as the single mandated system for incident reporting.

- HIQA identified that these findings are a symptom of a lack of robust governance, leadership and management for NIMS. The HSE owns this data and should be taking responsibility for leading a strategic approach to ensure the effective collection and use of this data. This is not only essential from an efficacy and efficiency point of view, but also to support good data quality and use of information.

Internal governance and management arrangements for NIMS within the HSE

- HIQA was informed that there is a decentralised model in place, whereby data input, management of incidents and reviews, data quality management and reporting occurs at local service level for Acute and Community Operations

under the responsibility of the SAO as outlined in the Incident Management Framework. HIQA notes as positive that these responsibilities in relation to information management at a local service level are clearly laid out within this framework, however, further clarity is required to address the national oversight of key aspects of information management including data quality, information governance and use of information at a national level. A lack of clear delineation of responsibility and accountability makes it difficult to fully address the challenges facing NIMS.

- As a basic requirement, a national system needs a national approach by leadership to developing guidance in areas, such as data quality and information governance, as well as strategies to appropriately address the challenges facing the system within the HSE. This is essential to drive the appropriate collection and use of incident data, and in essence to ensure that these data are used to their full potential, to learn from incidents and near-misses and drive a culture of quality and patient safety. NIMS needs more effective leadership in relation to structures in place to govern and assure the quality of NIMS data to create a high level of confidence in the data to drive learning and improvement.

- Furthermore, HIQA identified a need for clear direction in respect of the long-term vision for the collection of NIMS data within the HSE. Currently, there are a number of models used across the health service for the collection of NIMS data. There are significant implications on resources at a local level, with individual hospitals and CHOs having dedicated resources in place to manage the inputting of data, often into two separate systems. Although currently different models of NIMS data collection are necessarily in place according to the resources of each service, HIQA identified through interviews that there was no consistent view as to what the optimal model regarding the effective and efficient collection of incident data would look like in the long-term, nor as to what the recommended information governance model to support such an approach would be. HIQA was unable to establish whose role it is to take responsibility for such a significant issue in the HSE. Leadership in this area is essential, not only to ensure effective and efficient data collection but also to support data quality and use of information. The move to NIMS, from alternative systems currently in use within some services, must be supported and effectively managed to prevent the unnecessary duplication of work which can cause inefficiencies and backlogs and impact the quality of data.

Strategic and business planning

- HIQA identified that currently there is no strategic plan for NIMS which would ensure the effective implementation of NIMS within the HSE covering both the technical aspects (system) and the process (collection and use of NIMS data) within the HSE.

- HIQA acknowledges some positive evidence of development work through the joint work of the QAV and SCA in relation to the technical and project implementation aspects of NIMS. However, the current approach is too narrow to deal with all the issues, as documented in this report, to implement NIMS across all health and social care services.

HIQA has concluded that a strategy needs to be developed to deal with the significant issues that face the full implementation of NIMS as the system for incident management within the HSE in line with national policy. This needs to include a plan to properly evaluate the NIMS system and to undertake comprehensive stakeholder engagement to understand the needs and requirements of all NIMS users.

Performance and risk management

KPIs

- HIQA identified that the use of KPIs for NIMS feature strongly within national performance reports and reports generated for management at each level within the HSE. However, these KPIs focus primarily on two dimensions of data quality (timeliness and completeness) and specifically on serious incidents, which are only a small proportion of data collected. There is a large amount of data related to less severe incidents for which there is no KPI and for which data are not being effectively used or evaluated in terms of data quality. These include data on near-misses for which there is a huge learning potential from a quality and patient safety perspective.

Audit

- Apart from one internal national QAV audit carried out in 2017, HIQA was not provided with evidence of internal or external audits to assess the management of incidents or review the data quality at a local level or national level by the HSE. In addition, although the SCA carry out internal and external audits which encompass data security elements of the NIMS system as a

whole, there was no evidence of any formal schedule of NIMS audits in place. Audits are an important element for the governance of any system. Without a schedule of audits in place, it is difficult to see how senior management can be fully assured of the performance of NIMS and of data quality.

Risk management

- HIQA was informed that the QAV does not currently have any risks listed on the HSE QAV register specifically relating to NIMS within the HSE. This is despite a number of significant challenges being identified throughout this review for NIMS as detailed throughout this report: use of multiple systems to manage incidents; reliance on paper-based data collection; poor connectivity to NIMS; understanding of user needs**;** trust issues at a local level; low compliance with KPI targets for incidents

- In addition, although a joint governance model is in place between the HSE and SCA for NIMS within the HSE, there is no joint risk register in place to identify and manage risks appropriately. Furthermore, risk management is not an agenda item on any of the governance team meetings for NIMS which provides evidence that risks are not discussed routinely at a senior management level. Although the team was informed that issues are discussed by the Project Team and Steering Committee, the lack of a joint risk register and a formal focus on risk at leadership and governance level and a lack of clarity on roles and responsibilities in this area, increases the likelihood of risks not being identified and managed in the timely manner. This can lead to significant information governance challenges as identified through this review. Risk management should therefore be a standing item on the relevant governance group agendas and risks should be tracked and managed on a joint risk register.

- These findings on performance and risk management are significant given that there are so many stakeholders involved in the management of NIMS and also given that the specific roles and responsibilities are not clearly identified. Senior management within the HSE require information on performance in terms of the process of the collection and use of NIMs data. This involves using KPIs to measure and report on performance, undertaking regular audits to assess practice in terms of compliance with the IMF and data quality validation, as well as having a comprehensive risk management framework in place. HIQA was not provided with evidence based on these three measures of performance that senior management can be assured of good practice.

Transparency

Statement of Purpose

- At the time of the review, the HSE did not have a Statement of Purpose published for NIMS. This document is a fundamental requirement for a national data collection as it clearly outlines the aims and objectives of the national data collection, and helps to build a culture of transparency. Although the details of a Statement of Purpose are contained within the NIMS terms and conditions, it is good practice to develop and publish a document such as this.

Data Sharing Agreements

- It is essential that robust governance structures are in place to allow appropriate data sharing to occur. These include having oversight, assurance and transparency for all data entering and leaving the organisation. Although data sharing arrangements are indicated in some of the governance documentation for NIMS, there are no specific data sharing agreements in place at any level to clearly support the appropriate sharing of data from the HSE to the SCA, or back to the HSE in terms of the national database.

3.6 Recommendations — Governance, Leadership and Management

Governance, leadership and management	
1.	**Joint governance arrangements for NIMS**
	HSE QAV and the SCA should enhance the current governance arrangements in place for NIMS. This is to ensure that NIMS is fit for purpose as the single system for incident management, reporting and learning within the HSE and HSE-funded services and will support the implementation of the Incident Management Framework. The enhanced arrangements should: ▪ define clear and distinct responsibilities in relation to governance, leadership and management for HSE QAV and the SCA in relation to all aspects of information management for NIMS in the HSE. ▪ provide clarity on the responsibilities of the SCA as service provider for the NIMS platform, software and IT support; in addition, appropriate arrangements should be put in place to provide assurance to the HSE that NIMS is being effectively managed and supported within these arrangements, through audit schedules, access control and identification of key risks. ▪ review and clearly outline the terms of reference of each of the current joint governance groups in place: NIMS Sponsorship Group; NIMS Steering Committee; NIMS Project Team and working groups. ▪ provide clarity in relation to the strategic direction of NIMS through the development of clear project plans for the next phases of NIMS implementation and identification of specific roles and responsibilities for both organisations.
2.	**Governance, leadership and management of NIMS within the HSE**
	An enhanced governance, leadership and management model needs to be put in place internally by the HSE to support the efficient and effective collection and use of NIMS data within the HSE and HSE-funded services. The National Director of QAV, in association with Acute and Community Operations, should ensure that the structures of governance, leadership and management for NIMS in the HSE are

	fit for purpose, and support the implementation of the HSE's Incident Management Framework. Current arrangements should be enhanced to: ▪ provide a detailed scheme of delegation showing clearly defined roles and responsibilities for HSE QAV, HSE Acute and Community Operations, and the Senior and Local Accountable Officer (SAO/LAO) roles at local service level, in relation to information management for NIMS within the HSE. ▪ work to align HSE QAV with HSE Acute and Community Operations and provide clarity on specific responsibilities in relation to NIMS within the HSE and to ensure that all HSE-funded services including Section 39 agencies, have access to the NIMS system for incident reporting, management and learning.
3.	**Strategy for information management**
	HSE QAV, in collaboration with the SCA, and HSE Acute and Community Operations, and other key stakeholders, should lead on the development of an organisation-wide strategy for NIMS within the HSE that addresses: ▪ the advancement of NIMS to ensure it is fully implemented as the single incident management system used by all HSE and HSE-funded services ▪ a long-term vision for the collection, use and sharing of NIMS data. This should include the phased introduction of electronic point of entry reporting across the HSE and HSE-funded services, where this option is feasible and necessary ▪ data quality and assurance ▪ risk management ▪ stakeholder engagement/system evaluation in relation to meeting the needs of users ▪ the development of guidance in key areas of information management such as information governance and data quality ▪ effective use of NIMS data and information.
4.	**Performance assurance framework**
	HSE QAV in collaboration with HSE Acute and Community Operations should develop a performance assurance framework for NIMS within the HSE that builds on current KPI practice and addresses: ▪ national oversight for KPIs and quality assurance across HSE services

	▪ the addition of KPIs beyond those related to SREs and Category 1 incidents that focus on all five dimensions of data quality; relevance, accuracy and reliability, timeliness and punctuality, coherence and comparability and accessibility and clarity the need for a formal schedule of audits specifically for NIMS within the HSE covering all aspects of information management including data security, data quality, accessibility and use of information ▪ as part of current Performance Agreements, clear pathways and mechanisms for escalation of local issues and risks in respect of information management of NIMS.
5.	**Risk management framework**
	As part of the joint governance arrangements for NIMS, HSE QAV in collaboration with the SCA should implement a NIMS Risk Management Framework, including the development of a joint NIMS Risk Register, to ensure that all risks relating to the system's use within the HSE are identified, monitored and controlled. The framework should address: ▪ specific roles and responsibilities in relation to risk management ▪ the need for a forum to discuss risk within the reviewed joint governance groups.
6.	**Statement of purpose**
	HSE QAV, in collaboration with the SCA and HSE Acute and Community Operations, should develop and publish a statement of purpose that accurately describes the aims and objectives of NIMS within the HSE.
7.	**Data sharing agreement**
	As part of the joint governance arrangements for NIMS, HSE QAV and the SCA should develop a detailed data sharing agreement that clearly outlines the appropriate sharing of NIMS between the HSE and the SCA.

4. Use of information

Health information is a valuable resource – wherever possible, it should be collected once and used many times – provided the appropriate protections and safeguards are in place. It is now widely recognised that the appropriate sharing and effective use of information can bring enormous benefits.[41, 42] In the healthcare sector, effectively using information is the key to driving quality improvements, leading to safer, more integrated care and greater prevention of ill health. Timely access to good quality information benefits a range of stakeholders by enabling individuals to make informed choices about their health; professionals to make better and safer decisions; managers to effectively deliver a high-quality service; policy-makers to strategically plan services; and researchers to establish best practice. In essence, there is a growing expectation that the information held by national data collections will be shared and used optimally for the benefit of the service user and public health.[41, 42]

For organisations that aim to maximise the use of information, there are two important considerations: the underlying data must be of good quality so that all stakeholders can confidently use the information to inform decisions and the data should be aligned with health information standards and nationally agreed definitions to enable comparability and support interoperability.

NIMS is a very rich source of data which should be used to improve the quality and safety of services provided across health and social care, through monitoring incident data and using this data to manage associated risks. It is used by Quality and Patient Safety (QPS) staff in many national HSE and HSE-funded services, including Acute and Community Operations and QAV. It is also used by the SCA for the purpose of patient safety and risk management and to handle litigation and claims. Reports are produced from the data locally and at Hospital Group and CHO level. National reports are also produced and disseminated to QPS leads and HSE senior management. Reports are used locally to manage incidents and reduce patient safety risks within services.

The HIQA review team assessed the theme 'Use of Information' for NIMS against Standards 5, 6 and 7 of the Information Management Standards.

The findings of 'Use of Information' will be presented in following sections:

- Data quality
- Accessibility and dissemination of information
- Use of health information standards and terminologies.

4.1 Findings — Data quality

Data quality is a key component of information management. It is essential that data are accurate, valid, reliable, timely, relevant, legible and complete.[43] NIMS is an extremely valuable national repository of health information and, therefore, it is important that there is confidence in the quality of the data it collects and processes. Data quality needs to be assured at all levels to meet the needs of users locally and nationally. This is essential to allow users to observe patterns in incidents and put measures in place to reduce risk to patients and support patient safety.

4.1.1 Data quality responsibilities

NIMS is a shared system and as previously outlined, there are a number of key stakeholders involved, including QAV, Acute Operations and Community Operations within the HSE, and the SCA. This section will examine what arrangements are in place at both a local and national level within the HSE and from the perspective of the SCA to ensure data quality. While there are aspects of data quality improvement initiatives and activities in relation to data quality underway across the system, HIQA did not identify any individual with overall responsibility for data quality at a national level within the HSE. This is significant given the importance of NIMS as the end-to-end incident management and learning system for the HSE. Overall, HIQA identified that there was a lack of clarity and coordination in relation to how data quality for NIMS was managed. Further details in relation to data quality responsibilities for some of the key stakeholders are outlined below and in Table 4.

Firstly, with regard to the HSE, HIQA was informed through interview that the QAV team do not have specific responsibilities in relation to data quality for NIMS. Although QAV do observe issues with the quality of NIMS data, including timeliness, completeness and accuracy of NIMS reporting, their role is to oversee the implementation of NIMS within the HSE, in their capacity as project lead rather than to specifically provide oversight for data quality. However, through interview, HIQA identified evidence of some collaborative work in relation to data quality that QAV carry out with the SCA and with all services across the HSE. This will be discussed in section 4.1.2.1.

HIQA was informed that Acute Operations and similarly, Community Operations, have a role in relation to data quality within acute hospital settings and community settings respectively through their QPS and risk management staff. This includes monitoring incidents reported onto NIMS, particularly SREs and Category 1 incidents, in relation to the accuracy and completeness of this data. HSE Acute Operations are also responsible for generating incident overview reports from NIMS, which are shared with the Head of Acute Operations and Hospital Group CEOs. HSE Community Operations also generate reports from NIMS and share them within their

governance structures (Chief Officer, Heads of Service and Service Managers etc.). In addition, quarterly reports are provided to HIQA.

At a service level within HSE and HSE-funded agencies, HIQA was informed that the line of overall accountability for data quality management and reporting within a service is at the level of the SAO for that service as laid out in the HSE Incident Management Framework (see section 2.1.2.4 for further details on the role of SAO) . HIQA notes as positive that these responsibilities in relation to data quality at a local service level are clearly laid out within this framework. However, this does not address the issue regarding oversight of data quality for NIMS at a national level.

In respect of the SCA, data quality is a component of this organisation's function relating to risk management and claims management across DSAs under the NTMA Act. Under this function, the SCA provide risk management advisory services to the HSE. This work involves collaboration with risk managers and other relevant personnel in healthcare organisations and, among other topics, addresses issues regarding the quality of incident data relating to claims.

Given the importance of high-quality data for the HSE and the SCA, and given the complexity of governance structures in place within the joint governance model, it would be good practice to implement an overarching Data Quality Framework for NIMS in the HSE. A Data Quality Framework would provide clarity on responsibilities for data quality at both a national and local level in respect of NIMS. It would also demonstrate how the joint governing organisations would address all of the five key dimensions of data and information quality[**]. The implementation of a Data Quality Framework could be overseen by a joint governance forum. Evidence of the strategy's efficacy should be reviewed through KPIs, audit and monitoring. Where issues in relation to data quality were identified, it would be expected that quality improvement initiatives would be put in place.

[**] Five dimensions of data and information quality: relevance; accessibility and clarity; coherence and comparability; timeliness and punctuality; and accuracy and reliability.

Table 4. Data quality responsibilities for key stakeholders in relation to NIMS within the HSE.

Organisation/team/ responsible person	NIMS Data quality responsibilities
State Claims Agency	The SCA has responsibilities in relation to: ▪ Standardising the approach and language around end-to-end incident management across the State ▪ Data quality analysis of NIMS data relating to claims.
HSE - Quality Assurance and Verification team	QAV do not have a direct role in relation to data quality of NIMS nationally. They provide a support role in relation to: ▪ Making improvements to the incident entry process and the data fields on the system based on user requests ▪ Leading on system developments, such as electronic point of entry ▪ Providing support to NIMS users, as required ▪ Providing guidance and training material for users ▪ Producing reports ▪ Managing user access and location hierarchy of NIMS ▪ Maintaining and managing a list of all service users and ensuring appropriateness of use ▪ Engagement with QPS and other managers across the HSE.
HSE - Senior Accountable Officer (SAO)	Under the HSE Incident Management Framework, the SAO has overall accountability and responsibility for incident management. This includes some aspects of data quality and use of information responsibilities:(5) ▪ Reducing the risk of incidents occurring by ensuring that robust structures and processes are in place to both proactively and retrospectively enhance quality and safety systems throughout their organisation or service. ▪ Having in place resources required to ensure incidents reported are logged on NIMS within required timeframes. ▪ Receiving an annual report in relation to incident reporting and management within their area of responsibility.

	▪ Receiving monitoring reports in relation to the progress of reviews and to take necessary corrective action where a review is experiencing delays.
HSE – Acute and Community Operations Quality and Patient Safety (QPS) Managers	Within local acute and community services, the QPS managers have a day-to-day role in relation to: ▪ Providing support and guidance to staff so as to facilitate the reporting and logging of incidents on NIMS.

4.1.2 Data quality arrangements

4.1.2.1 Data quality arrangements at national level (QAV, Acute Operations, Community Operations and SCA)

In the absence of a strategic focus on data quality arrangements for NIMS, HIQA identified, during the course of the review, some examples of data quality activities and initiatives underway involving both the HSE and the SCA. Some of these examples are provided here.

Firstly, in relation to joint arrangements for data quality, a process is in place for de-duplication of incidents on NIMS, which is coordinated by the QAV and SCA. This is in addition to KPIs in place relating to timeliness for reporting incidents on NIMS, which are monitored by HSE Acute Operations, Community Operations and QAV, as well as other National Services such as National Human Resources. Furthermore, HIQA was informed of ongoing work pertaining to the standardisation of data reported within the NIRF, for example, naming conventions and location of occurrence of an incident, to support the collection and reporting of coherence and comparable incident data. This work is overseen by QAV supported by the SCA. In addition to the aforementioned activities, HIQA was informed of a further positive data quality initiative regarding standardising incident reporting for pressure ulcers nationally, guided by the HSE (this will be addressed in further detail under Use of Information Section 4.2.1.1).

In relation to specific data quality activities undertaken by the SCA, the review team were informed that the SCA has been undertaking a programme of work to review the quality of data on extreme and major incidents, in particular the categorisation of severity level of these incidents. Where issues with data quality are identified, it was confirmed to HIQA that the SCA teams engage with local QPS Managers/local NIMS leads in relation to issues with NIMS data; examples include missing data and issues with incidents not being closed out, as depicted through the incident review screen. In the situation where some data quality issues remain unresolved, the SCA

informed HIQA that they escalate such issues to the SAO and upward to the Joint SCA/QAV forum or for final escalation to the Board of the HSE, if so required. HIQA was also informed that the SCA team meets fortnightly to discuss issues in relation to the quality of data relating to claims.

As previously noted, under the NTMA Act, DSAs are obliged to report all incidents to the SCA. While there are various reasons why a claim may not have previously been reported as an incident, the SCA informed HIQA that in many cases they should have been. In this regard, the SCA noted that they have an advisory role in relation to addressing under-reporting of incidents to NIMS. This under-reporting has been identified mainly through the submission of claims, for which there are no corresponding incidents recorded on NIMS, by indicating the data on 'Claims previously reported as Incidents' (CPRI). The difference between the actual CPRI for an organisation and the expected CPRI (as determined by the SCA) is a measure of the level of incident reporting by an organisation. The SCA report this indicator to each service representing the numbers of CPRI as a percentage of the total number of claims received in a period. This enables the SCA to analyse levels of incident reporting in respect of claims, however, this is also an important indicator for the quality of NIMS reporting from services.

HIQA was informed that the SCA have recently initiated a process of removing fraudulent claims/non-claims from NIMS. Furthermore, the SCA generate reports in relation to the number of completed reviews, which they share with the relevant sites, with a view to driving data quality for NIMS (full details on published reports can be found in section 4.2.2).

HIQA was informed through interview that the QPS lead and risk and incident officer in HSE Acute Operations work with hospital groups to improve the accuracy and completeness of incident data on NIMS, and where data quality issues are identified, Acute Operations address this directly with each specific site, to ensure issues are addressed. Data quality reports are sent to all Hospital CEOs and QPS leads, outlining where the gaps are in relation to timeliness and completeness of data. This work is being done with a view to improving the overall quality of monthly incident reports, to give a more accurate picture of what is happening on the ground in relation to incidents. HIQA was informed that this focus on data quality has promoted improvements in the reporting of incidents. However, its main focus is on SREs and Category 1 incidents. While HIQA was not provided with evidence of policies or procedures in place, specifically addressing data quality of NIMS, the review team did receive a number of documents which address aspects of data quality, including:

- the NIMS training manual which provides clarity and guidance to NIMS users on how to report an incident on NIMS, contact the helpdesk or process a NIMS change request
- a document containing NIMS data field definitions
- guidance for generating NIMS reports and analysing incidents using the NIMS Dashboard module.

HIQA acknowledges as good practice, the availability of this guidance for NIMS which can help to improve data quality. However, a more strategic approach to data quality to assess what is working and what policies and procedures are needed to address any gaps would be beneficial. This could be achieved through the development of a Data Quality Framework.

4.1.2.2 Data quality arrangements at a local level (Acute hospitals and Community Healthcare Organisations)

Through interview, HIQA was informed that although data quality practices are not standardised at a local level, a number of data quality activities have been rolled out by local QPS Managers at acute and community service operations level, including the development of training following identification of data quality issues and the establishment of local forums for sharing of learning from management of incidents. Furthermore, QPS Leads within the acute setting and CHOs have responsibility for data quality as part of their role. Although it is positive that QPS leads are responsible for data quality, there is still a need to capture and implement good practice in a more strategic and coordinated way through a Data Quality Framework to ensure a more standardised approach to data quality practices.

Other examples of local data quality activities underway at Acute and CHO service level include the work that QPS Managers and CNMs are undertaking in relation to ensuring that staff complete incident forms accurately, and in a timely manner. HIQA was provided with evidence of daily or weekly meetings of QPS teams, whereby, at a minimum, all SREs and Category 1 incidents are reviewed, and issues regarding the quality of data recorded on NIRFs is discussed. HIQA also acknowledges the positive work of QPS Area Leads across acute and community services, who are addressing data quality for incident reporting as part of their role. This includes following up directly with QPS Managers, regarding incomplete NIRFs, reviewing and standardising the categorisation and severity rating of incidents and amending inaccuracies, ensuring that incidents are recorded on NIMS in line with national KPIs, and working with staff to ensure that forms are completed in a standardised manner across their area.

The QPS Leads at local service level also have a role in following up with staff, in order to ensure a NIRF is completed accurately and within the given timelines. In general, these practices tend to be led and developed locally as HIQA was not

provided with any specific national guidance documents outlining the responsibilities for information governance or data quality at a local level. QPS managers can face challenges in carrying out their work due to the issue of backlogs in incident reporting caused, in some instances, by poor connectivity to NIMS due to local IT issues and also by different models of incident data capture and processing. This can have a negative impact on a QPS lead's capacity to deal with data quality issues. The priority for QPS managers is to review all NIRFs as they are received and to ensure that SREs and Category 1 incidents are dealt with as an immediate priority. However, over-reliance on an individual QPS Manager within an incident reporting system which is overburdened with paper highlights a significant risk for the potential for SREs to be not dealt with in a timely manner.

Despite examples of some positive activities underway, HIQA noted that data quality practices vary considerably across services and there is no clearly defined strategy to guide data quality activity. Lack of coordination of data quality activities at a national level reinforces the need for leadership from the HSE, supported by the SCA, on a coordinated strategic approach, backed by clearly defined procedures and roles and responsibilities, across stakeholder organisations including QAV, HSE Acute and Community Operations, national services such as NAS, Screening, and the SCA.

4.1.2.3. National Key Performance Indicators (KPIs) for data quality in NIMS

In terms of HSE KPIs to monitor data quality across the dimensions, HIQA was informed that a number of national KPIs exist in relation to NIMS. Some of these are described in Table 5 (please see Appendix 8 for a full list).

Table 5: Example of National KPIs for NIMS

National KPIs	Detail of National KPIs
Serious incidents	▪ % of serious incidents being notified within 24 hours of occurrence to the senior accountable officer ▪ % of serious incidents requiring review completed within 125 calendar days from notification to the SAO.
Incident reporting	▪ % reported incidents entered onto NIMS within 30 days of occurrence by CHO/Hospital Group/NAS ▪ Extreme and major incidents as a % of all incidents reported as occurring.

The HSE's Performance Assurance Reports provide an overview of performance across service areas, such as Acute, Mental Health, Social Care, Primary Care, Health and Wellbeing, as well as Finance and HR. The activity data reported is based on Performance Activity and KPIs outlined in the National Service Plan. The report is collated by the Planning and Business Information Unit. These reports are published quarterly. Please see Appendix 9 for a sample report of KPIs for quality and patient safety incidents within HSE acute and community services from July to September 2019.

HIQA recognises the value of identifying, collecting and reporting KPIs in relation to incidents in the HSE across the areas of acute hospitals and community healthcare services.

Through interview, HIQA was informed that HSE Acute Operations monitor KPIs for timeliness of reporting incidents on NIMS, with a view to improving this aspect of data quality. Evidence from interviews with QAV, Acute Operations and staff in other acute and CHO settings, reiterated the importance of the KPIs in relation to reporting of serious incidents within 24 hours of occurrence, with all stakeholders reporting that they place priority on monitoring, reporting and managing SREs. However, HIQA was provided with a report in relation to KPIs for reporting to NIMS, which demonstrates that national (acute hospitals and community healthcare) compliance with reporting of serious incidents within 24 hours of occurrence of the incident, was notably less than half of the minimum recommended compliance level of 80%, as seen in Appendix 9[††].

[††] Of note, in interview HIQA was informed that the figures for CHOs in these reports are not a true reflection of actual numbers due to the majority of Section 39 services not having access to NIMS to input the data.

HIQA was informed that many services are not meeting the 30 day KPI for reporting of all incidents on NIMS, which is a result of many services experiencing significant backlogs in terms of uploading NIRFs to NIMS for all other categories of incidents. While this does not necessarily mean that incidents are not being managed appropriately at a local level, issues with timeliness of reporting onto NIMS leads to inaccuracies and misrepresentations of the true national picture for incidents. Such backlogs also highlight a potential risk that trends in incidents may go unnoticed for prolonged periods of time, due to the lack of availability of real-time data at local and national level. Overall, it was evident to the review team that both compliance with, and awareness of KPIs pertaining to timeliness of reporting incidents to NIMS varies significantly across the acute and community sectors.

Compliance with these KPIs is essential in providing the most up-to-date national picture of incident data, as incomplete or delayed reporting of incidents onto NIMS leads to the generation of incomplete reports, thus providing an unrepresentative picture of incidents across services. Significant improvements are required in levels of compliance with national KPIs. Although SAOs and Acute and Community Operations have a role in reviewing and helping to improve the timeliness and accuracy of incident reporting within their respective services, it is the NPOG chaired by the Chief Operations Officer that has overall responsibility for oversight of KPIs nationally across the HSE and funded agencies. In order for compliance with KPI targets to notably improve, a clear and strategic national approach is required across HSE Acute and Community Operations and QAV with support from the SCA.

HIQA note the good work being done in driving improvements in data quality from the perspective of timeliness of reporting. However, a more comprehensive set of KPIs to assess all five dimensions[‡‡] of data quality should be introduced and implemented locally, which feed into national KPIs. This would help to drive improvements in the quality of NIMS data.

4.1.3 Data quality - training and education

All NIMS users must complete NIMS training in order to gain access to the system. NIMS training for HSE staff is coordinated by the QAV team and hence responsibility for training lies with QAV. This training is available in the form of two HSELanD modules, 'NIMS Training for Incident Entry'; and 'Entering Incident Reviews in NIMS'. Within the HSELanD training modules, there are a number of guidance documents to support NIMS users in navigating the system and utilising it to its potential.

[‡‡] Relevance; accessibility and clarity; coherence and comparability; timeliness and punctuality; and accuracy and reliability.

A NIMS Training Manual is available for all NIMS users. The purpose of this manual is to provide clarity and guidance to NIMS users on how to report an incident on NIMS, taking users through each of the steps that they will encounter within the online NIRF. It guides NIMS users through each stage of the incident lifecycle, outlining the key steps of reporting an incident through to closure of the incident. The manual also provides details of the NIMS Helpdesk and NIMS change request process, should users need to avail of these services.

The SCA also delivers additional tailored training on NIMS Dashboards and reporting, as requested from the HSE. These training requests are processed via NIMS@HSE.ie. The review team received examples of these training presentations delivered by the SCA to NIMS users. These were an overview of the NIMS system and a session on reporting on NIMS which included a live demonstration. These sessions are delivered as requested; hence a formal training schedule is not in place.

In relation to evaluation of NIMS training, HIQA was informed of one example of a Hospital Groups Training Needs Analysis undertaken by QPS Acute Operations in conjunction with QAV in October 2019. HIQA was not provided with other evidence in relation to formal evaluations in place to assess the efficacy of training delivered by either the SCA or the HSE to NIMS users.

The review team was also informed of a number of training initiatives led by local QPS Managers. There was a strong focus on the provision of training for reporting of incidents in line with the HSE Incident Management Framework, and completion of the NIRF, across all services as part of induction for new staff members. Some sites reported having regular refresher training sessions on incident reporting, with a focus on data quality. Furthermore, it was reported that risk management training was being delivered by some QPS Managers, to emphasise the importance of complying with the KPI for reporting all incidents on NIMS within 30 days of the incident occurring. As HIQA identified in relation to other data quality activities, apart from the mandatory training delivered on HSELanD, the type of training, and how often it is delivered, varies across services. Through interview, the team were informed that training at a local level has improved compliance with incident reporting requirements. HIQA's attention was also drawn to initiatives including the presentation of incident case studies by clinical staff to their peers to promote appropriate reporting and management of incidents and a further initiative, whereby a learning hub has been set up at regional level to support improvements in incident reporting and management.

While it was clear to HIQA that there are many positive training initiatives taking place locally, and while a number of guidance documents are available within NIMS itself, NIMS users were unanimous in their views that training could be enhanced, and that additional NIMS training is required, particularly on generating reports from

NIMS. It should be noted that evidence gathered throughout the review pointed to a lack of understanding of the capabilities of NIMS reporting and the Dashboard function, which is potentially contributing to NIMS not being utilised to its maximum potential. This further indicates a need for HSE to engage with all NIMS users in respect of training requirements. The need for engagement in relation to this will be discussed in more detail in the next section.

In addition, ongoing evaluation and formalised NIMS training needs analysis, would benefit the QAV and Acute and Community Operations in understanding the challenges faced by NIMS users and inform them of what training is required, in order for NIMS to be used to its maximum potential and to ensure that the NIMS data are of the highest possible quality. The publication of an overarching NIMS training strategy would also benefit all NIMS HSE users.

4.1.4 Functionality of NIMS and its impact on data quality

NIMS has undergone a number of enhancements since its introduction in 2015 and is currently at Phase 3 of implementation. NIMS has a number of inbuilt modules as displayed in the Incident Life Cycle, including for data entry, incident review, task management and generation of reports (see Figure 2 in section 2.4.2) There is also a claims management module which is accessed and used by the SCA.

Through this review, HIQA was informed that the review screen of the Incident Investigation Module provides valuable information for the HSE and the SCA and is used by QAV in particular. This module enables QAV to track the level of completion of each incident reported on NIMS, enabling them to follow up where data are incomplete. HIQA was informed that these modules are where some of the most detailed data can be obtained. This data will already have been scrutinised at a local level in order to understand the root cause of the incident which has been reported and how the incident was managed. This data in relation to incident review provides a valuable source of learning, which can be used to inform the management of similar incidents in the future and also to reduce the risk of occurrence of similar incidents, therefore the quality of such data is crucial. However, in interview with QAV, HIQA was informed that to date, there has been poor compliance with entering critical data relating to incident reviews on these review screens. This is a symptom of a lack of clarity in relation to the current governance arrangements where it was unclear to HIQA who was responsible for addressing this issue in relation to completeness and data quality at a national level.

In interviews with NIMS users across acute and community services, HIQA identified a number of key challenges users were experiencing in relation to the current functionality of the system. These include challenges relating to:

- Data entry
  NIMS users reported that the use of paper-based/editable PDF NIRF model generates significant volumes of paper and can cause inffeciencies due to having to enter data on to the hard copy or PDF NIRF and then again onto NIMS. Some users also found there was a difference between the layout of the hard copy NIRF and NIMS Incident Entry Screens which caused inefficiencies when entering data. HIQA was informed by the SCA that this could be due to services using alternative forms to the most up-to-date NIRF which is aligned with the NIMS Incident Entry Screens.

- Report generation
  NIMS users felt that the capability of the NIMS Report Module was limited. It requires users to export data to Excel resulting in duplication of effort and concerns about data security. Users also reported that it prevented them from generating the types of reports required to assist in the effective management of incidents locally. However, HIQA was informed by the SCA that as well as recent improvements to the reporting function, such as the generation of realtime reports and graphs, the NIMS report module has significant functionality and that the HSE and SCA can support any user in the development of bespoke reports and eliminate the need for exporting data to Excel.

- The use of an alternative local system
  In cases where services have an alternative local system in place as well as NIMS, users reported that they have to print incidents from a local system and manually input the data on to NIMS. This is a resource intensive process with the potential to cause errors when inputting data. In services that try to avoid printing, there is a requirement to have two screens side by side (one for NIMS and one for the alternative system). This again is resource intensive and increases the potential for error when transferring data between the two systems. It should be noted that these issues only occur where services are not using NIMS as the single and primary system for incident reporting in HSE and HSE-funded services.

HIQA found that it is unclear where responsibility for addressing these issues lies within the joint governance structure. These issues again point to a lack of engagement with NIMS users to understand the difficulties they are experiencing with the system and to communicate the full breadth of the system's functionalities and capabilities.

In relation to paper-based/pdf NIRF models, a rollout of a pilot ePOE model scheduled for April/May 2020 was postponed due to COVID-19. However more

recently, HIQA has been informed that a pilot of the ePOE model was undertaken in a children's hospital in Quarter 3 of 2020.

As discussed in section 3.1.5.3, HIQA was informed that ePOE has been implemented in 25 locations to date with a further 30 scheduled to go live in April 2021. If rolled out across services, it is expected that ePOE will help to alleviate the significant burden on resources that currently exists, by creating efficiencies in the way incident data are gathered and recorded on NIMS. Through correspondence, HIQA was also informed that although the HSE recommend ePOE as the preferred solution for data collection they have, for practical purposes, had to elect to support a number of solutions to best meet the needs of each location. Each location is consulted and decides what process suits their current culture, infrastructure and resources to best meet the primary requirement of compliance with the Incident Management Framework (see section 2.1.2.1 for more information on the IMF).

In relation to the generation of reports, HIQA was informed by QAV that support is provided to NIMS users to assist them in getting the most from the reports that they generate on NIMS. HIQA was also informed by the SCA that many NIMS users are unaware of the capabilities of the NIMS Reports module and that NIMS can actually generate many of the reports about which its users place queries with the NIMS Helpdesk.

Finally, in relation to the challenge regarding the use of alternative local systems, the review team was informed that electronic linkage of local systems to NIMS had been raised by NIMS users and has been discussed at a national level. However, users were informed that such a solution would not be possible. This was reiterated to HIQA by both the HSE and the SCA who emphasised the importance of all services using NIMS given that it is the mandated single system for incident management and was providing a standardised dataset that allows for comparisons, benchmarking and learning across locations.

HIQA acknowledges that Phase 3 implementation plans for NIMS focus on further developments of the system, including increasing usability of the system. It also acknowledges that the HSE with support from the SCA has previously engaged with NIMS users to understand their requirements. However, the challenges faced by NIMS users as outlined above, indicate that a detailed review of the usability and usefulness of the system for NIMS users is required in advance of further developing its functionalities. In addition, a strategic and coordinated approach to improving NIMS functionality and data quality for the end user is required.

4.1.5 NIMS user support to inform data quality

Engaging with and supporting NIMS users is vital given the complexity of NIMS as a partnership model between the SCA and the HSE. Effective engagement would

ensure that all parties involved in NIMS benefit from the availability and use of good quality data. Nationally, QAV, the SCA, HSE Acute and Community Operations, national services and national HR each have a role in communicating with stakeholders in relation to NIMS. This section will describe current activities in relation to NIMS stakeholder engagement. There are two groups in place nationally that provide a forum for engagement and discussion between the relevant stakeholders in relation to operational aspects of NIMS between the partner organisations:

- NIMS Community Healthcare Organisation Working Group
- NIMS Hospital Group Working Group.

HIQA was informed that issues affecting the implementation of NIMS from the perspective of acute hospitals/CHOs can be escalated from these groups to the NIMS Project Team.

4.1.5.1 NIMS Helpdesk and communicating changes to NIMS users

There are two helpdesks for NIMS; the HSE NIMS Helpdesk (nims@hse.ie) and the helpdesk managed by the SCA (NIMShelpdesk@NTMA.ie). QAV recognise that over time at HSE corporate and service level, requirements will be identified by NIMS users to change and enhance the functionality of the system.[27] QAV, via the HSE Helpdesk, handles queries from NIMS users regarding access to the system, resolution of ICT connectivity issues, requests for changes to location structure, enhancement/change requests, requests regarding functionality changes to NIMS and account de-registration. It also manages requests for training on NIMS dashboards. Regarding ICT connectivity issues, NIMS users first contact their local HSE ICT service who log the fault locally. In instances where the HSE NIMS helpdesk is notified that the connectivity issue has not been resolved, they escalate it to the project manager. If the issue persists, it will then be highlighted to the SCA via the SCA helpdesk. Queries for the helpdesk can be logged by email or by phone and there are a number of forms to support the various types of requests. Processes are in place for dealing with user requests to make changes to the existing NIMS system (location structure) and for users to suggest changes for improving the system.

HIQA was informed that QAV works alongside the SCA in relation to changes to location structure, requests for functionality changes to NIMS, and ICT issues that cannot be resolved locally within the HSE. HIQA was informed that a good working relationship exists between QAV and the SCA and there is regular ongoing communication between the two teams in order to ensure that NIMS queries are answered as efficiently and effectively as possible. However, HIQA did not receive evidence of any formal evaluation of this function for NIMS within the HSE.

HIQA was also informed of the work that QAV and the SCA have done in supporting NIMS users, through communicating with them in relation to any changes to the NIMS system. However, from interview, it was evident that this communication is not received by all users, with some reporting that the first time they become aware of changes to the online NIRF is when they log onto the system and view it for themselves. However, HIQA was informed through a number of interviews that any changes are communicated to all registered NIMS users via email. Furthermore, HIQA identified through the document request that 'My NIMS Account' contains a page where all announcements are communicated in relation to, for example, new reporting tools. It does appear, however, that this information is not being accessed by all individuals and this warrants further action by QAV and the SCA, to ensure that communication is received by all stakeholders as efficiently as possible.

4.1.5.2 Acute Operations- User Support

The HSE Acute Operations Quality and Patient Safety team communicated to HIQA that they act as a link between acute services and the HSE senior leadership team and DoH. Acute Operations provide feedback to acute services regarding monitoring and performance for incident reporting, with a view to driving improvements and ensuring that the reports generated from NIMS are accurate for incidents in the acute setting. QPS are available to support the hospital group if they require assistance in relation to SREs or any incident. Acute operations QPS staff also work with the hospital groups and engage at that level with many stakeholders, such as clinical directors.

HIQA was informed that Acute Operations have recently begun issuing reports on SREs to all hospital CEOs and QPS Leads to provide a regular summary of such incidents and they also use this as an opportunity to outline gaps in data. It was reported to HIQA that these measures have led to a significant improvement in the quality of NIMS data over the past nine months since the initiative began.

Furthermore, where incident notifications are not received, Acute Operations contact the respective services to follow up. An important aspect of their role also includes their work with clinical directors in relation to incidents and risks. If Acute Operations have been notified of an SRE, they liaise with the relevant point of contact within that service and support them in working through the SRE. HIQA was also informed that Acute Operations have a role in relation to education regarding the best use of NIMS data locally, and encourage greater use of NIMS dashboards, to support better management of incidents locally, as previously discussed.

4.1.5.3 SCA - User Support

Through interview, HIQA was informed that SCA staff engage with NIMS users on an ongoing basis by providing assistance in resolving technical issues with NIMS,

educating them on the functionality of NIMS and working with HSE services in a support role to increase usage of NIMS. The SCA clinical leads play a role in assisting NIMS users where they are experiencing issues with the system. The SCA Risk Management team also plays a role where users have queries in relation to the system including reporting guidance. However, this support appeared to be provided at the request of NIMS users, more so than through a need identified by the SCA or the HSE. The SCA reported to HIQA that the engagement undertaken by the joint HSE/SCA project team in recent years has led to improvements in NIMS, with feedback received from NIMS users resulting in improvements in the configuration and usability of NIMS, to make it more fit for purpose for local needs.

HIQA was also informed that the SCA also holds an annual conference in relation to Quality, Risk and Patient Safety organised by the SCA's Clinical Risk Unit. This brings together national and international healthcare professionals, with the aim of improving quality and patient safety and reducing risk. The SCA also holds an Enterprise Risk Network (ERN) twice per year. This provides a forum where personnel within State Authorities (including the HSE) who have responsibility for managing risk can collaborate and share their knowledge. In addition, the SCA holds ERN Recognition Awards that promote engagement with NIMS.

4.1.5.4 Local User Support Activities

HIQA was informed through interviews that a number of stakeholder engagement activities are taking place at a local level in relation to NIMS. From the interviews conducted by HIQA, it was apparent that there are effective lines of communication in place between QPS Managers and QPS Leads at group level in relation to challenges faced by them in using NIMS. It was evident from these interviews that QPS Leads are providing invaluable support to QPS Managers in responding to queries about the system. Furthermore, HIQA was informed that QPS meetings take place locally on a regular basis, to discuss learning from incident management. Any issues communicated by QPS Managers and their staff about NIMS are brought to these meetings for discussion, and subsequently reported upwards via the Group Lead to QAV or the HSE Quality Improvement Team. It was reported to HIQA that these lines of communication work well in practice.

While HIQA acknowledges the positive steps taken by QAV, Acute and Community Operations, national services and national HR and by local QPS personnel in relation to stakeholder engagement and NIMS user support, it would be expected that this work would be carried out in a more coordinated way at a national level. Although as outlined in 4.1.5, forums for discussing issues are in place, HIQA has evidence from meeting with NIMS users that not all issues are being adequately addressed. Also, HIQA noted that a comprehensive survey of all NIMS users to assess the usefulness and usability of the system had not taken place. Conducting an in-depth

stakeholder engagement survey, driven in coordination by QAV, HSE Acute Operations and HSE Community Operations and supported by the SCA, would be an effective means of systematically engaging with all users and gaining an understanding of their needs. This information would also prove beneficial in helping to develop an overarching data quality strategy for NIMS at a national level, and would help to reduce duplication of effort in relation to improving data quality, by outlining roles and responsibilities for data quality improvement.

4.2 Findings – Accessibility and dissemination of data

The use of routinely collected healthcare data to generate evidence requires firstly, that reliable and accurate quality data are collected, and secondly, that they are made accessible to those who require them to make decisions in a timely manner.[2]

The use of NIMS data to adequately manage healthcare-related incidents for both staff and service users requires that the data on NIMS is accurate, timely, reliable and accessible to all stakeholders, as required. At a national level, NIMS data are used by the HSE to monitor the occurrence of incidents in healthcare settings, acting as the core information system for communication of incidents between frontline services and Acute and Community Operations. NIMS data are also used to issue a patient safety communication protocol[44] to the National Patient Safety Office in the DoH, where a major/significant patient safety issue or incident arises that has the potential to cause harm. In addition, NIMS data are used to inform the planning of services where deficiencies are identified from trends in incident data. Furthermore, the SCA have access to NIMS data for claims and risk management purposes, as defined by their legislative remit. They also use NIMS data to publish national risk reports including research reports, patient safety notifications and risk advisory notices. Some examples of the key users of NIMS data are shown in Figure 7 below.

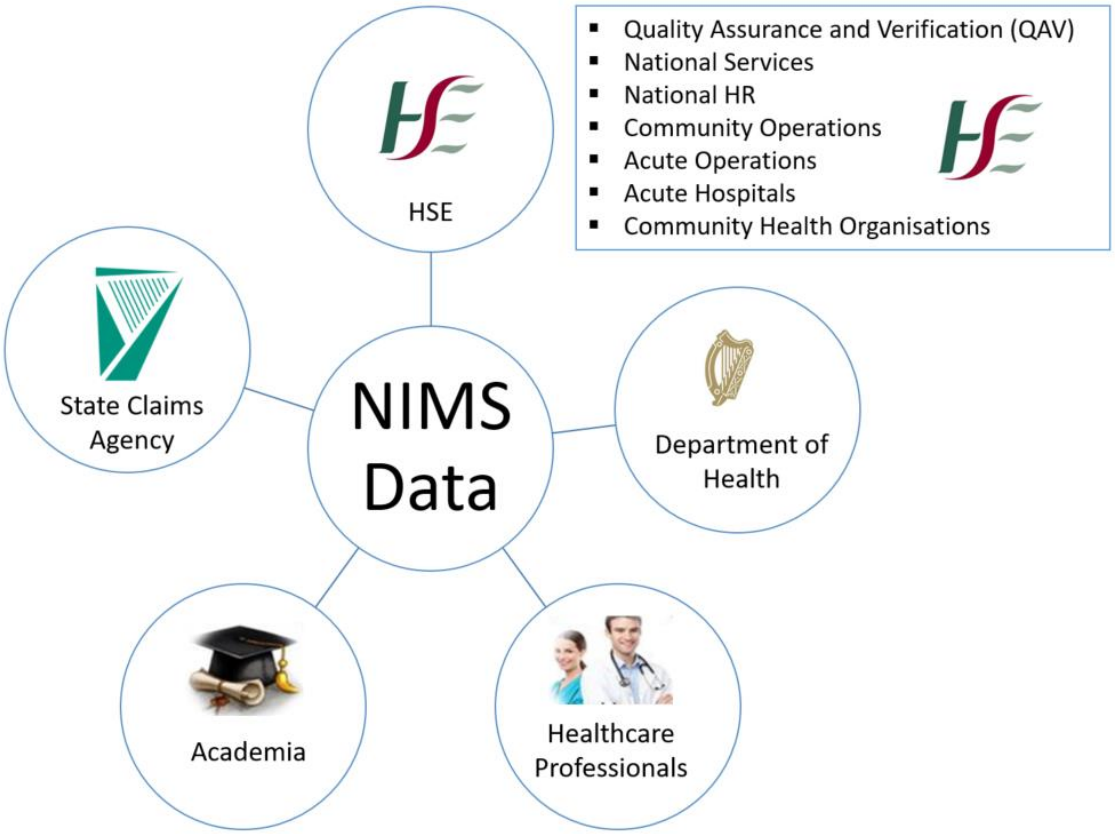


Figure 7: Some of the key users of NIMS data.

In interview, HIQA was informed by HSE Acute Operations that, in general, only Category 1 incidents and data on SREs are reviewed in a routine manner at a national level. It was noted that less focus is typically given to Category 2 and 3 incident data, which may provide a valuable insight into potential patient safety risks and contribute to informing measures that would reduce the opportunity for incidents to occur. This points to the need for a focus on the analysis and use of all categories of incident data locally and nationally.

HSE Acute Operations informed HIQA that a plan was in place at the time of the review for a data analyst to review Category 3 incident data, on a short-term basis. However, in order for incident data to be used to its maximum potential, more permanent arrangements should be in place to ensure that all categories of NIMS data are reviewed and analysed on an ongoing basis.

NIMS facilitates the identification of emerging trends in incidents, raising awareness of patient safety risks locally.[21] It also supports reviews of incidents, as well as recording complaints and monitoring the implementation of recommendations.

However, evidence from this review indicates that NIMS is not being used to its maximum potential by local or national stakeholders.

4.2.1 Dissemination and use of NIMS data

HIQA reviewed examples of approaches to incident reporting in other jurisdictions– see Appendix 7 for a summary of key findings. HIQA noted that a much greater emphasis is placed on the dissemination and use of national incident data in other countries. For example, in the UK, data from the National Reporting and Learning System is available on the NHS website in the format of data workbooks and explorer tools. They also publish Organisation Patient Safety Incident Reports every six months, broken down by NHS trusts, of the incidents reported to the National Reporting and Learning System.[45] In addition, both the NHS National Reporting and Learning System (NRLS) and the British Columbia Patient Safety and Learning System (BC PSLS) follow key data principles to emphasise the purpose and characteristics of incident data, and to promote consistency across all data users.[46] HIQA was informed that there is a Learning from Incidents project underway within the HSE. The project is of high priority to the HSE, but has been delayed due to the HSE COVID-19 response.

4.2.1.1 Use of incident data for learning

In interview with staff in HSE Acute Operations, HIQA was provided with some good examples of targeted initiatives underway to improve patient safety using data from the NIMS system. Please see box below for further details of these initiatives.

Examples of quality improvement initiatives underway to improve patient safety nationally using NIMS data:

- Neonatal Encephalopathy [NE] – review of NIMS data

The HSE established a National Neonatal Encephalopathy (NE) Action Group of which the SCA are members. The purpose of the group is to reduce avoidable instances of NE through the identification of known causes and risk factors and driving initiatives to eliminate or mitigate same. The expected outcome is an improvement of the quality of care with a reduction of avoidable NE cases in the 19 national maternity units/hospitals. The group is reviewing NIMS data in relation to instances of NE, in order to implement strategies to reduce the occurrence of such incidents.

- Analysis of falls data from NIMS

Patient falls are a major cause of inpatient injury and even death, with 26% of all incidents recorded on NIMS relating to falls. The HSE are supporting a quality improvement collaborative aimed at reducing falls. In a partnership with the North/South CAWT (Cooperation and Working Together) Patient Safety Programme. This pilot project saw a 58% reduction in falls over 9 months and

100% improvement in bone health awareness. This improvement collaborative is being extended in 2019 to 31 multidisciplinary teams from around the country (12 CHOs and 19 Hospitals).

- Pressure ulcers incident data

Pressure ulcers represent a major burden of sickness and reduced quality of life for people and their carers. Using data from the NIMS system, the HSE's 'Pressure Ulcers to Zero' (PUTZ) collaborative was the first large scale quality improvement collaborative to take place in Ireland.

HIQA recognises these examples as a positive demonstration of the potential for incident data from the NIMS systems to be analysed and utilised to drive quality improvement and patient safety. However, these initiatives are limited and not strategically driven.[§§] HIQA identified the need for the HSE and the SCA to formalise the governance structures for collaborative work on projects, such as those outlined above, to ensure the NIMS data are used to their maximum potential.

4.2.2 Reports from NIMS

NIMS data are used by both the HSE and the SCA to produce various reports. Those issued by the HSE are, in general, national and regional routine statistical reports. At a local level, some individual services use NIMS data to produce reports according to their own requirements. However, others do not use the NIMS data for reporting purposes. The SCA issues quarterly corporate incident and claims reports, as well as periodical review reports looking at specific types of incidents. The following sections will describe each of the types of reports produced using NIMS.

4.2.2.1 Routine HSE reports

During the review, HIQA was informed that analysis of national NIMS data is disseminated in the form of reports mainly from Acute Operations staff working on NIMS, to the Head of Acute Operations, hospital group CEOs and QPS Leads, as part of an information sharing and quality improvement initiative. The national reports contain non-identifiable, high-level data on SREs and Serious Incidents. Table 6 provides a summary of these reports. HIQA acknowledges as good practice, the dissemination of these reports. However, it is also important that there are clear lines of responsibility regarding national oversight of this data, in order to identify gaps in the areas of incident reporting and drive improvements based on the findings of the reports. HIQA did not see evidence of a coordinated national strategy in place for this.

[§§] HIQA was informed that strategic patient safety initiatives such as patient safety strategy and patient safety programme are to be established in 2021 under the HSE corporate reform programme.

Table 6: Summary of NIMS routine statistical reports

Report	Issued by	Disseminated to	Details
Summary automated daily reports	Acute Operations	Head of Acute Operations, hospital group CEOs and QPS Leads	These reports provide a basic overview of numbers of incidents occurring across the acute hospital sector.
Monthly NIMS reports	Acute Operations	CEOs of each hospital group	These reports contain information on the number of SREs and Serious Incidents, detailing the incident/hazard category, the sub-hazard type, the classification and type of the injury that occurred and detail regarding whether a review is required and if so, if one is being conducted. Those in receipt of the report can clearly see any issues with data quality, including any gaps in data submitted as part of an incident.
HSE Corporate Incident and Claims Report (Quarterly)	State Claims Agency	Members of the HSE Executive Management Team. Local level reports are sent to the Group CEOs/Hospital Managers or Chief Officers/QPS Leads of each CHO and National Leads.	These reports detail safety incidents in acute hospitals and community services and include data on the type and severity of incidents recorded on NIMS. These data are presented by reporting levels for hospital group, acute hospitals, CHO area and service user. Data are also provided in relation to analysis of active claims. The report also includes data on key KPIs including 'number of days to report' an incident, enabling HSE senior management to determine where there may be issues with timeliness of reporting across the system.

4.2.2.2 Periodical SCA clinical review reports

The SCA produces periodical review reports, analysing NIMS data in relation to clinical incidents and claims. Some of these review reports are listed below.

- SCA Risk Research Report 02: Needle stick and Sharps - A 10-year review of incidents and claims across the health and social care sector (2010-2019)
- Medication Incidents Report: A review of medication incidents reported by Irish acute hospitals (2017-2018)

- Risk Research Report 01: Slips, Trips and Falls - A 5-year review of incidents and claims across the State sector (2014-2018)
- Clinical Incidents and Claims Report - Maternity and Gynaecology Services – a five year review: 2010-2014.

These reports demonstrate how NIMS data can be used to inform health and social care services about trends in relation to particular areas of risk and to help to identify ways in which risks can be mitigated. They also highlight the importance of the availability of high-quality data in order to ensure that accurate analyses can be performed.

4.2.2.3 Local reports re NIMS data

In relation to local use of NIMS data, HIQA observed that, at a local level, the use of NIMS data varies considerably. As previously discussed in Section 4.2.2.2, while some services are heavily reliant on the NIMS reporting module to generate incident reports, others simply enter data onto NIMS but do not generate reports. The remainder of services that HIQA engaged with communicated that they cannot obtain the level of detail that they require from NIMS to sufficiently manage incidents locally, so have resorted to more tailored systems which give them the detailed reports they require.

While HIQA acknowledges that NIMS holds a vast amount of data, it is clear from evidence gathered throughout this review, that these data are not being analysed or used to their maximum potential. The reasons for this are multifaceted, some of which are outlined here.

- Firstly, while data are being used to generate reports, and while these reports may be meeting the needs of some stakeholders at a national level, in providing high-level overview of incidents, it must be acknowledged that the data within these reports are often incomplete and therefore are not representative of the true measure of incidents within healthcare settings. Poor quality data results in low levels of assurance for national stakeholders including the HSE and SCA, regarding the levels of occurrence and effective management of healthcare-related incidents.

- While it was reported to HIQA that these reports are beneficial in providing hospital CEOs with an overview of incidents within their relevant services, some QPS Leads and QPS Managers reported that NIMS does not enable them to capture the more detailed data that they require in order to generate meaningful reports to support incident management at a local level. However, HIQA has been informed by the SCA that NIMS is as flexible and capable of capturing the granular data required by services as any of alternative systems

currently being used. This points to a significant issue in relation to the need for additional engagement and training with all NIMS users.

- Some services reported to HIQA that categories on the NIMS NIRF currently do not offer the level of detail that is required by health and social care services locally.

As noted in Chapter 2, a policy decision was made by the DoH that NIMS should be the national system for reporting of all healthcare-related incidents in Ireland. It should be acknowledged that having a single source of national incident data is beneficial for a number of reasons, not least for national oversight of the occurrence and management of incidents, as well as for policy and service planning. However, in order to ensure that the services currently using alternative incident management systems adopt NIMS as their sole incident management system, the full capabilities of NIMS must be effectively communicated to all HSE and HSE-funded sites. Its use at both a local and national level must be promoted and fully facilitated by the HSE with support from the SCA through a national strategy.

Given the feedback HIQA received from acute and community services, an information management strategy must acknowledge the need to review and enhance the current NIRF, which is currently not fully meeting end-user needs in a healthcare context for reporting and managing healthcare incidents locally. Moreover, while HIQA has been informed that NIMS has the capacity to deliver the requirements of all users, the evidence gathered throughout this review points to the need for the QAV, Acute and Community Operations and the SCA to work in collaboration, to communicate and engage with users about the full capability and potential of the software in order for it to be used to its maximum potential. A robust, long-term strategic approach for NIMS within the HSE is required to support this.

4.2.3 Formal data requests

The review team were informed that external requests for access to data from NIMS are submitted via email to the SCA. HIQA was advised that a procedure is in place for dealing with data requests and that each request is reviewed on an individual basis. The majority of requests for data are received from medical researchers and students and only aggregate, non-identifiable data are shared as part of a formal data request. Furthermore, HIQA was informed by the SCA, that they are exempt under legislation from providing patients with any data relating to their incident from NIMS. Requests from patients are referred back to the source of the incident, that is the healthcare setting with which the patient engaged, to be dealt with at that level.

Overall, in respect of sharing of NIMS data, an open data approach to NIMS data has not been adopted. Aggregated data are not shared on Ireland's Open Portal and web-based tools for data users to analyse and manipulate incident data are not available publicly. Although data are available within HSE reports, which are published on the HSE website, these data are often incomplete and quite high level. Further opportunities for better sharing and use of data should be explored as part of an overarching information management strategy for NIMS.

4.3 Findings - Use of health information standards and terminologies

In relation to classification systems, HIQA was informed that a "pick list" — aligned to the World Health Organisation's (2009) International Classification for Patient Safety (ICPS) is currently in place. 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). Details in relation to NIMS terminologies are contained within the NIMS training manual.

HIQA was also informed that work is underway by the HSE supported by the SCA at the level of the NIMS Steering Committee in relation to proposing the use of the ICD-10 classification system for NIMS. In addition, HIQA was informed that work has not advanced to date in relation to development of a data dictionary for NIMS.

4.4 Significance of findings — Use of information

Data quality governance arrangements

- In reviewing data quality practices, HIQA identified there is a high level of awareness of the importance of data quality for NIMS, with a number of data quality activities being undertaken by the QAV, Acute and Community Operations in the HSE, and the SCA. However, through interviews and site visits, HIQA identified examples of key challenges directly affecting the data quality of NIMS.

- Currently, there is no identified individual or HSE department with overall responsibility for data quality for NIMS within the HSE. HIQA identified a number of individuals whose remit addressed some aspects of data quality within their respective roles. However, such arrangements appeared to be informal and uncoordinated. Furthermore, it was reported to HIQA that responsibility for data quality for NIMS should lie at a local level. Although there are a number of groups or forums where aspects of data quality are addressed as part of their wider remit, HIQA identified that there is no overall forum within the HSE with specific oversight for data quality for NIMS. This is essential for the HSE to ensure NIMS data is of the highest quality and fit for purpose.

Data quality strategy

- HIQA identified that there is currently no data quality strategy in place for NIMS, nor an overall data quality framework for NIMS at a national level. Without such arrangements in place the roles and responsibilities for how data quality activities are coordinated for NIMS, between HSE QAV, HSE Acute & Community Operations and the SCA are unclear. A lack of such arrangements also means that the quality of the incident data captured in NIMS cannot be adequately monitored and evaluated. A data quality strategy would help to guide data quality activities and enhance compliance with KPIs for NIMS, providing greater reassurance of the quality of NIMS data for all stakeholders.

- Although HIQA was informed that the HSE Acute Operations and SCA undertake evaluations of subsets of NIMS data, it did not find evidence of any formal evaluations undertaken by the HSE to address the five key dimensions*** of data and information quality in respect of NIMS. Without this,

*** Relevance, accuracy and reliability, timeliness and punctuality, coherence and comparability, and, accessibility and clarity

it is difficult to create a benchmark for improving data quality and for informing a data quality strategy.

Data quality arrangements

- HIQA observed that while the NIMS system has developed since it was first rolled out, there it is a perception among users that it does not currently sufficiently support the information needs of all NIMS users, and thus does not adequately support the effective management of incidents locally.

- Local services within the Acute and Community setting are responsible for the quality of data uploaded to NIMS. However, such local data quality arrangements lack national guidance to ensure that data quality activities and processes happen in a strategic manner across all local services, at the same time. This can have an impact on the standardisation of validation across all services.

- A significant issue identified throughout this review was the recording of incident data on two systems, NIMS and an alternative system. The use of a secondary system alongside NIMS generates inefficiencies, not only in creating backlogs and duplication of data input, but can also lead to a reduction in the quality of data reported on NIMS.

HIQA also concluded that the current NIRF is not adequately meeting the needs of users in a health and social care context with some services reporting inability to report data that is necessary for effective local incident management. This can lead to incomplete data and ultimately have an impact on data quality.

Support for NIMS users to drive improvements in data quality

- HIQA acknowledges the work that the HSE, supported by the SCA, have undertaken to date in engaging with users of NIMS. The NIMS Helpdesk, which is a partnership model between the HSE, QAV and the SCA, appears to be working well in practice, in terms of addressing issues with technical aspects of NIMS, as well as issues with access and general queries. However, while users reported that support has been provided to them in relation to reporting and use of Dashboards on NIMS, such engagement has been ad-hoc and has not taken place in a coordinated manner. Although forums for discussing issues are in place, HIQA has evidence from meetings held with NIMS users that not all issues are being adequately addressed.

- HIQA did not find evidence of a mapping exercise having been undertaken by the HSE to understand the current levels of engagement with NIMS users. In addition, there is no strategy in place to guide stakeholder engagement. Without a strategic approach to this area, it is difficult to fully understand the needs of those using NIMS and to ensure that all users are made aware of the capabilities of NIMS and thus are better able to use the system at a local level. Without fully understanding the needs of NIMS users it is also difficult to develop a data quality framework and strategy for NIMS.

Training

- While HIQA was informed of a number of training modules available through HSELanD, as well as the availability of detailed training guides to support users in entering data onto NIMS, generating reports and utilising the NIMS dashboard, it was apparent from interviews that current training does not meet the needs of NIMS users who felt they would benefit from additional and or refresher training, particularly in generating reports from NIMS.

- Furthermore, HIQA did not find evidence of a training needs analysis having taken place for NIMS. While HIQA is aware of the existence of the NIMS Helpdesk, which NIMS users can contact if they have any issues with the system, a survey may help to formally identify training requirements.

Accessibility and dissemination of data

- HIQA identified that there is no accessibility and dissemination plan in place for NIMS. Such a plan within a data quality strategy would help the HSE to strategically focus on how the potential of NIMS data can best be realised and made more accessible for all stakeholders to inform the effective management of incidents within healthcare.

- While HIQA recognises that NIMS data are disseminated to key stakeholders, through a number of reports, it must also be acknowledged that the use of these NIMS data could be significantly improved, both at a national and local level. HIQA observed that, at a local level within acute and community services, the use of NIMS data varies considerably. HIQA found that while some services are heavily reliant on the NIMS reporting module to generate incident reports, others simply enter data onto NIMS but do not generate reports.

- At a national level, NIMS is an extremely important source of patient safety intelligence. While HIQA was provided with some good examples of targeted initiatives underway to improve patient safety using data from the NIMS system, HIQA concluded that overall, the approach lacked strategic focus and coordination. Examples highlighted within the international review from other jurisdictions including Canada (British Columbia province), the UK, Denmark and New Zealand demonstrate a much stronger focus within these jurisdictions in relation to disseminating and using incident and patient safety learning data to maximise its use for all key stakeholders.

4.5 Recommendations — Use of information

Use of information	
8.	**Data quality framework and arrangements**
	HSE QAV should develop and implement a data and information quality framework for NIMS to systematically address and improve data quality of NIMS across all HSE and HSE-funded services. This framework should include an accessibility and dissemination plan to optimise the use of NIMS as a key source of patient safety intelligence. This would ensure that the benefits of incident and patient safety and learning data is maximised for all stakeholders. Additional data quality arrangements to complement the framework should be implemented by HSE QAV in collaboration with HSE Acute and Community operations to include: ▪ assigning an individual with overall responsibility for data quality in relation to NIMS within the HSE ▪ clearly outlining responsibilities for data quality at every level through a scheme of delegation for the HSE in line with the HSE's Incident Management Framework ▪ developing a stakeholder engagement plan in collaboration with HSE Acute and Community Operations to address the needs of all NIMS users. This should include a survey of NIMS users to assess the usefulness and usability of the system and their requirements of the system. ▪ a review of current National Incident Report Forms (NIRF) to ensure that they are fit for purpose for health and social care services ▪ a formal Training Needs Analysis to be carried out across acute and community services to identify training needs and a more coordinated approach to training to ensure all NIMS users who require training are receiving it.

5. Information Governance

National health data collections, such as NIMS, are repositories for large volumes of important health information. Health information is considered to be the most sensitive form of information and, therefore, extra precautions need to be taken to protect privacy. The process of collecting, using, storing and disclosing personal health information can present a risk to privacy and confidentiality of service users. National data collections have an obligation, under legislation, to protect personal health information. Information governance provides a means of bringing together all the relevant legislation, guidance and evidence-based practices that apply to the handling of information.

Robust information governance arrangements focus on the following areas: the maintenance of privacy and confidentiality of individuals; the protection of information security; the generation of high-quality data; and the implementation of appropriate safeguards for the secondary use of information. In Chapter 4, the use of information and the generation of high-quality data were discussed in detail due to the significance of enhancing the appropriate use of good quality data for a wide range of stakeholders. However, data quality will be further considered in this chapter in the context of developing good information governance practices.

Good information governance enables personal health information to be handled legally, securely, efficiently and effectively in order to deliver the best possible service. The main aim of information governance is to create a balance between effectively using information and meeting the needs of the service user while also respecting an individual's privacy. To develop good information governance practices, it is necessary for an organisation to have the structures and processes in place to provide clear direction to staff:

- Responsibility and accountability for information governance must be clearly defined, and the appropriate governance and management structures should be outlined. These arrangements should align to and integrate with the organisation's overall governance structure. Formalised arrangements are essential to ensure that there are clear lines of accountability for information governance. All staff should be aware of their responsibilities for information governance, and management should assign specific tasks to named staff members.

- A culture of information governance is embedded within the organisation through the development of policies and procedures to help all staff to comply with legislation and information governance requirements, as well as identifying training requirements on a routine basis. Employees should be

promoted and supported by management to engage in good information governance practices as part of their routine working schedule.

- Organisations need to perform information governance assessments to identify good practice and to highlight areas that need improvements. Self-assessments, in the form of internal and external audits, monitoring of key performance indicators (KPIs) and assessing risk, are necessary to examine compliance with policies and procedures, to identify specific training needs of employees and to ultimately identify and implement improvements to information governance practices based on the findings.

The HIQA review team assessed the information governance and person-centred arrangements for NIMS in the HSE against Standards 1 and 8 of the Information Management Standards.

The findings will be presented in following sections:

- Information governance structures in NIMS within the HSE and the SCA
- Effective arrangements to assess and manage information governance.

5.1 Findings — Information governance structures for NIMS

Information governance is a key component of information management as it is essential to maintain the privacy and confidentiality of individuals, to protect information security, to generate high-quality data and to implement the appropriate safeguards for the secondary use of information.

5.1.1 Information governance (IG) structures for NIMS within the HSE

As previously described in Chapter 3, there is a joint governance model in place between the HSE and the SCA in relation to NIMS. Under this arrangement, it was acknowledged in interviews that both organisations recognise that they have individual responsibilities in respect of Information Governance within this model. However, HIQA identified that there is a lack of clarity regarding who has overall responsibility and accountability for information governance for NIMS within the HSE. While there is a Statement of Partnership in place between the HSE and SCA, HIQA identified that this does not address the specific delegation of functions in relation to information governance responsibilities, including information security, data quality, data protection and the secondary use of information. It was noted in interview that while there is an implicit arrangement that both organisations in this

partnership have respective roles and responsibilities regarding information governance, and that each has a duty to embed a culture of good information governance practices to staff working within the services, these roles and responsibilities are not well defined or clearly documented.

HIQA has noted that there are references to some roles and responsibilities outlined within the 'NIMS Terms and Condition's and 'NIMS Access and Control Policy' documents. However, in light of the joint governance model in place, such as the current arrangements for NIMS within the HSE, one would expect to see the detailed roles and responsibilities of each data controller specifically outlined within a Data Sharing Agreement. Such documentation would clearly outline the roles and responsibilities of the data controller and data processor, and sub-processors, as is required under GDPR.

5.1.2 Information governance arrangements within HSE

In interview, HIQA was informed that the QAV National Director, as the designated 'Information Owner' for NIMS in the HSE, has responsibility for arranging and controlling access to NIMS for staff within the HSE and HSE-funded services. However, HIQA identified that there is no one with overall responsibility for all aspects of information governance for NIMS within the HSE. In addition, although there is a Data Protection Officer (DPO) and regional deputy DPOs in place within the HSE, in light of the large scale processing of sensitive health and social care-related incident data, it would be good practice to assign specific responsibility for information governance of NIMS to a named individual within the HSE. This would ensure efficiency in terms of responding to data protection issues and improve communication and oversight in relation to wider information governance issues.

In reviewing the roles and responsibilities of the different joint governance groups for NIMS as outlined in Chapter 3, Table 3, HIQA identified that none of these teams has a specific responsibility for information governance. In addition, information governance is not a standing item on the agendas of any of the senior governance team meetings, nor does it appear to be discussed in a strategic manner at this level. HIQA was therefore not able to ascertain what processes the HSE has in place to be assured in relation to information governance aspects of data held on NIMS. While there are governance committees in place at the level of SCA, there does not appear to be an information governance committee in place within the HSE, nor a joint committee between the HSE and the SCA to use as a forum to discuss aspects of information governance, such as information security, data quality and data protection.

In relation to information governance activities undertaken by QAV, HIQA was informed in interview that the QAV team is primarily responsible for arranging and

controlling role-based access to NIMS for HSE staff. The team also manages requests for changes and enhancements to NIMS. Details of the process for these activities are set out in a policy document entitled '*HSE Guidance for NIMS to include Access and Control*'. This work is coordinated through a NIMS administrator, who also manages setting up locations for users within NIMS. In addition, there is a resource within QAV which promotes the effective use of NIMS data through supporting the better use of NIMS Dashboards and daily updates on incidents to specific managers of services within the HSE. However, HIQA identified that currently the QAV does not have any specific role linked to coordinating a national approach to improving aspects of information governance within the HSE, such as improving data quality, information security, or ensuring privacy and confidentiality of data.

During the review, HIQA were informed of some of the current information governance challenges that exist in the HSE in relation to NIMS. These included:

- NIMS being a decentralised system, meaning extensive data being processed from different locations using multiple platforms
- local IT issues within the acute/community sector, such as bandwidth, equipment, internet access, firewalls
- no dedicated NIMS IT system support within the HSE
- local IT systems that are out of support and not upgraded with the latest security.

This results in large amounts of sensitive data being held on these systems, creating potential challenges in relation to security, scalability, sustainability and back-up for local IT systems. In addition, NIMS is not listed as a key information system in the HSE's list of ICT systems because it is hosted outside of the organisation. This creates a challenge under the current joint governance model; NIMS is not seen as a HSE system because it is hosted by the SCA, yet the SCA do not have any responsibilities for ICT in the HSE and therefore cannot fully address the IT issues that arise. A more effective arrangement in relation to information governance for NIMS within the HSE is therefore required to address some of the challenges as identified above.

5.1.3 Information governance arrangements within acute and CHO settings

The process regarding the management of incidents and the roles and responsibilities at a service level within acute and CHO settings are clearly detailed in the HSE's Incident Management Framework (see Chapter 2 for further details on the IMF). As NIMS is a decentralised system, the management of incidents in the HSE

and HSE-funded services is the responsibility of the SAO for each service. The collection, use and sharing of incident data that is input onto NIMS at a local level is managed differently, depending on the process in place for uploading of incident data to NIMS, for example, paper-based/pdf model or use of an alternative incident management system (as outlined in Section 2.1.2). However, all activity is subject to the HSE-wide ICT codes of practice, policies and procedures that relate to information governance (Appendix 10). HIQA was also informed that in some hospitals there is an Information Governance Committee in place that reviews any NIMS-related issues for that particular service. HIQA identified through site visits that while there were examples of good practice, many of these local information governance arrangements appear to be uncoordinated and are not undertaken in a standardised way across all services.

5.1.3.1 Culture of information governance

Through site visits to a number of hospitals and CHOs, HIQA identified that staff have a good understanding of the steps involved in the management of an incident, and the levels at which incidents need to be reported and signed-off, as well as who is responsible for escalating an issue, if necessary. HIQA also observed that there is a clear understanding of the information governance principles at a local level within each service and the associated issues. This understanding was illustrated by staff concerns about data security and quality. For example, in interviews with healthcare staff, concerns were raised to HIQA regarding: the risk of paper NIRF forms being lost or misplaced compromising the privacy and confidentiality of the subject; concerns in relation to quality and patient safety; the duplication of work and significant issues with backlogs impacting on data quality; concern as to how the information governance model would work if those using a paper-based model moved to an ePOE model; and the lack of transparency regarding the level of access to the data for each stakeholder once data are submitted to NIMS, which in turn has an impact on building trust in the system. This understanding of the importance of information governance among staff was seen as positive by the review team. However, the issues highlighted at service level again point to the need for a role that can provide oversight of information governance across services specifically in relation to NIMS within the HSE. They also point to the importance of education and guidance at a local and national level to provide full transparency to NIMS users about what happens to data once it is entered onto the NIMS system.

5.1.4 Information governance structures for NIMS within the SCA

The person with overall responsibility for NIMS within the SCA is the Deputy Director. The team were informed in interview that there are no specific information governance roles within the SCA, but that the following roles are in place at the level of the NTMA:

- Data Protection Officer
- GDPR compliance lead (responsibility for data protection operational issues included in remit)
- IT Security Committee that forms part of the Risk Governance Structure of the NTMA
- Head of IT Security (audits of NIMS included in remit)
- Head of Compliance
- Risk Manager
- Information Manager
- Head of Data Services (responsibility for Data Quality included in remit).

The NIMS System operates on software, computer programmes, databases and interfaces which are licensed to the SCA by a third party system provider, who provide the technical infrastructure to operate the NIMS system which is hosted on a dedicated private cloud environment within the EEA.

The relationship between the SCA and the system vendor is governed by a contract under which the system vendor acts as a data processor on behalf of the SCA as the data controller. Contracts are in place between the NTMA and system vendor which include data processing clauses, and reflect the data processing contractual requirements under the GDPR. The SCA also provided HIQA with a statement of work amendment setting out updated terms of work between the NTMA and the third party system provider.

In relation to committees in place within the SCA/NTMA addressing the area of information governance, HIQA was informed of the following being in place:

- NTMA IT security committee
- SCA/System vendor operational, communication and oversight meetings, including:
    - weekly review meetings with key system vendor personnel from both UK and US; monthly reviews to track and progress stewardship meeting actions;
    - quarterly stewardship meetings with Director level employees of system vendor;
    - yearly site visits encompassing meetings between executives from the third party system provider and SCA and ICT senior management, including the Director for SCA
    - escalation process to the system vendor's Executive Management Team, where required.

HIQA was also informed that the SCA have a number of the system vendor's information security policies and procedures in place in relation to NIMS which include:

- IT Change Control;
- Data Classification and Control;
- Data Retention and Disposal;
- Backup Policy;
- Encryption Policy
- Incident Response Plan and Procedures.

In addition, the HIQA review team received the SCA's personal data processing inventory for May 2020[†††]. This document contains information on data processing activities of the SCA in relation to ten processes including the General Indemnity Scheme Claims Management, the Clinical Indemnity Scheme Claims Management and Enterprise Risk Management. The SCA is listed as data controller for each data processing description. NIMS is listed as one of the systems used for data processing under each of the processes. The evidence provided by the SCA to HIQA demonstrated good information governance practices in relation to NIMS on the part of the SCA and the third party system provider.

In summary, HIQA reviewed the arrangements within the SCA and the HSE which are used to assess and manage information governance. Through interview, the team observed that there was good overall awareness of the importance of information governance among those overseeing the use of NIMS in the HSE and HSE staff. However, this understanding did not translate into clear information governance structures and strategies for NIMS within the HSE. There is no committee in place that specifically addresses information governance for NIMS within the HSE, nor is there an identified individual with overall responsibility for this area. HIQA therefore identified that a gap remains in the current structures, and there is a need for clarity regarding oversight of information governance as part of the NIMS joint governance model between the HSE and the SCA.

[†††] Note, HIQA was informed that the data processing inventory was updated again in quarter 1 of 2021

5.2 Effective arrangements to assess and manage information governance

5.2.1 Legislation, policies and procedures

5.2.1.1 Compliance with legislation for information governance

The work of the SCA and the HSE, as statutory bodies, is governed by a number of key pieces of legislation including: the General Data Protection Regulation 2018 (GDPR)[47]; the Data Protection Act 2018 (DPA)[48]; the Freedom of Information Act 2014[49]; and National Treasury Management Agency (Amendment) Act 2000.[50] As previously noted, Section 11 of the NTMA Act provides a statutory basis for the collection and disclosure of personal data by DSAs, to the SCA through NIMS. Furthermore, where deemed appropriate, further data on incidents and reviews may be required to be provided on NIMS in order for the DSA to fulfil their mandated requirements.

5.2.1.2 General Data Protection Regulation, 2018

The General Data Protection Regulation (GDPR) took effect from 25 May 2018 and imposes a statutory obligation on both data controllers and data processors to ensure that personal data are used appropriately and the rights of individuals are safeguarded. There are also obligations in respect of sub-processors, or agents used by data processors in providing services. Under the complex governance model in place between the SCA and the HSE, HIQA was informed both of the organisations currently have dual roles of data controller and data processor. These roles are explored in more detail below.

5.2.1.3 NIMS - Data Controller Arrangements

In interview with the SCA, HIQA was informed that for the purposes of the SCA's statutory functions under the NTMA (Amendment) Act, the SCA acts as the data controller of personal data processed through NIMS, while all delegated State authorities (including the HSE) also act as the controller of such personal data on NIMS for the purposes relating to their own administration. Appendix 11 provides detail of the processes the SCA have in place for the Data Protection Principles in relation to NIMS as stated in their DPIA.

HIQA was informed that the HSE does not have a DPIA in place addressing data protection aspects of NIMS within the HSE. Although the roles of the SCA and the HSE as controllers are outlined in documents received by the review team[‡‡‡], in interview the review team noted the ambiguity, and the lack of clarity regarding specific responsibilities in relation to this joint data controller model. As previously

[‡‡‡] Contract between the system vendor and the SCA; the NIMS 'Terms and Conditions of Use'; SCA Personal Data Inventory.

noted, having a Data Sharing Agreement in place would ensure that there are named individuals who are responsible for specific information governance aspects of NIMS, such as responding effectively to potential data breaches or complaints, and safeguarding the data protection rights of individuals.

HIQA also did not receive evidence of a specific Privacy Statement or 'Statement of Information Practices' in place for NIMS. These should clearly outline what information is collected, how it is used, with whom it is shared and for what purpose, the safeguards in place to protect it, and how people can access information held about them. In line with this finding, HIQA learned through site visits to hospitals and community organisations, that many health and social care staff were uncertain about what data in relation to incidents was being shared and used by the SCA and in what format. This lack of transparency has led to an element of mistrust, with some questioning whether the SCA were holding data beyond what was required to fulfill their claims and risk management function. This was highlighted in interviews with senior HSE staff and NIMS users within local HSE acute and community services. As previously outlined, this lack of transparency, was seen to affect local practices in relation to the effective use of NIMS as an end-to-end risk management system to support local user needs and learning from reviews. These findings indicate that there is a lack of clarity in relation to the use of the data provided to the SCA, and held by the third party system provider.

In relation to some international examples of best practice reviewed by the HIQA team, the Scottish Government have developed an Information Sharing Toolkit which outlines the elements that should be in place to accommodate informed decision-making for the sharing of information across organisations (Figure 8).[51] This outlines that it is good practice to have an overarching memorandum of understanding, specific information sharing agreements, agreed instructions, policies, procedures, SOPs, as well as a DPIA. While the Statement of Partnership between the HSE and SCA could act as an MOU (the first element of the toolkit outlined in Figure 8), the joint governance model lacks the Information Sharing Agreement(s) recommended in the toolkit. There is also a lack of clarity on the policies and procedures governing the joint model specifically in relation to NIMS.

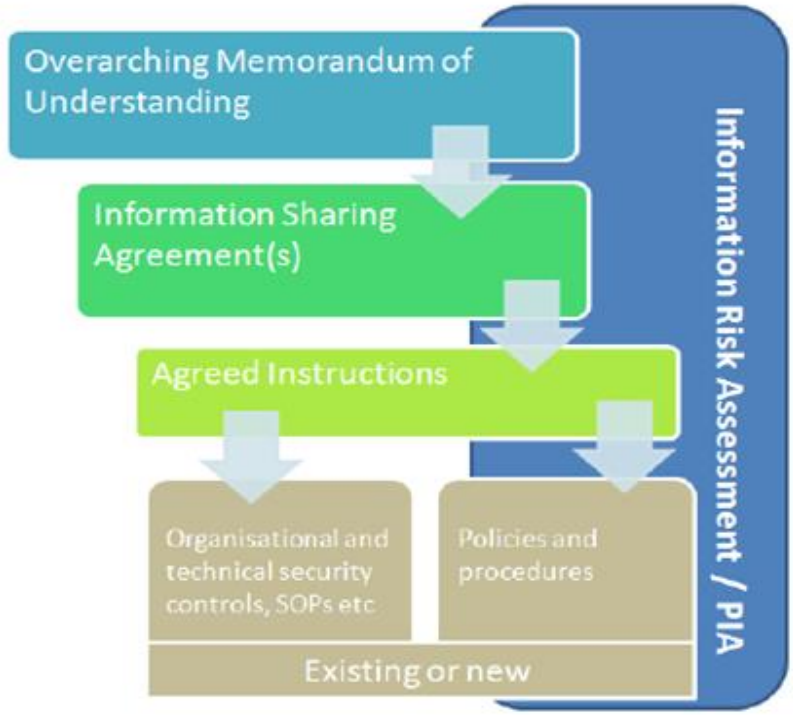


Figure 8: Framework for informed decision-making for sharing of information

5.2.1.4 NIMS - Data processor arrangements

Under the NIMS joint governance model, the SCA have a role as data processors for data received from the HSE on NIMS; and HSE are data processors for data uploaded to NIMS through its services. Under the GDPR, data processors still have several direct legal obligations under this legislation and are subject to regulation by the Data Protection Commission (DPC).

HIQA reviewed some of the main obligations of data processors and examined how these are being met in respect of NIMS in Table 7.

Table 7: Main obligations of data processors and how they are being met

Data Processor Obligations under GDPR	Arrangements in place for NIMS
Controller's instructions: data processors can only process personal data on instructions from a controller (unless otherwise required by law). This is often outlined in a contract between the two agencies.	HIQA identified that a '*NIMS Terms and Conditions of Use*' document sets out the contractual undertaking confirming that each user is: ▪ authorised to access and use the NIMS System; ▪ will only access and use the NIMS System in the performance of their statutory functions; ▪ access and use the NIMS system in the performance of their own statutory obligations; and ▪ has accepted the terms of the system vendor's licence agreement, the NIMS System terms of use, the NIMS System privacy statement and the SCA Guidance document on use of NIMS system.
Processor contracts: data processors must enter into a binding contract with the controller. This must contain a number of compulsory provisions, and data processors must comply with the obligations imposed on the processor under the contract.	HIQA identified that a contract is in place for the third party system provider as processors outlining the controller's (SCA) instructions and there are Terms and Conditions of Use in place between the SCA and the HSE (DSA). However, HIQA also noted that there is a lack of documentation in place in relation to the HSE's role as data processor for NIMS data. It also noted that although details of data sharing arrangements are contained within the the Terms and Conditions document, there is no specific Data Sharing Agreement in place between the HSE and the SCA.
Security: the data processor must implement appropriate technical and organisational measures to ensure the security of personal data, including protecting against accidental or unlawful destruction or loss, alteration, unauthorised disclosure or access.	HIQA identified organisational measures in place including: HSE policy in place regarding access and control to NIMS; SCA NIMS access policy in place; access rights to NIMS are controlled through a central point in the HSE under the governance of the QAV; compulsory system training for NIMS users is provided before a user accesses the system. In addition, technical measures include: Different user account types that enable different functions that is, imputing rights, editing rights, reporting rights, searching rights; data is encrypted at rest

	and transit; security "defence in depth" approach and firewalls in place; backup, disaster recovery and business continuity process; vulnerability and penetration testing completed regularly on NIMS.
Notification of personal data breaches: if a processor becomes aware of a personal data breach, it must notify the relevant controller without undue delay.	HIQA noted that the HSE has a Data Protection Breach Management Policy in place. The SCA also has the system vendor's Breach Response Plan in place.
Accountability obligations: a processor must comply with certain GDPR accountability obligations, such as maintaining records and appointing a DPO (where the processor is a public body).	HIQA noted that the SCA has a DPO in place at NTMA level and has a data processing inventory in place. The HSE has a DPO in place at a national level, however no data processing inventory for NIMS was received.

In summary, HIQA identified that there is evidence of good practice regarding data processing for NIMS, however, HIQA identified gaps in relation to the HSE and its role and duties as data processor. As there is a joint governance model in place for NIMS, clearly outlining responsibilities for the different aspects of IG is particularly important from the HSE's perspective.

5.2.2 Security measures for NIMS

5.2.2.1 Access controls for NIMS in the HSE

Under GDPR there is a specific duty to limit access to personal data on a 'need to know' basis and sensitive data should have greater access limitations or controls in place. Users need appropriate access to perform their duties.

HIQA was informed in interview that, for NIMS users, there are a number of types of user accounts which enable different functions, including inputting rights, editing rights, reporting rights and searching rights.

At the level of data collection and management at the local level within hospitals and CHOs, the HSE have developed a *'HSE Guidance for NIMS to include access and control'*. This policy sets out the arrangements for specified and appropriate access to NIMS in order to meet the HSE's governance requirements and ensure that all confidentiality and data protection requirements for a national information management system are adhered to. Its purpose is to outline the processes for arranging and controlling access to NIMS by HSE staff and funded agencies (including Section 38 and 39 agencies) and for managing requests for changes and

enhancements to NIMS, for example, functionality changes and/or changes to location structures maintained on NIMS. HIQA recognises as good practice having a policy such as this in place, as it ensures good governance in the area of data security.

HIQA also identified as good practice additional security measures for NIMS in place which are outlined in Table 8.

Table 8: Additional security measures for NIMS

Security measure	Detail
De-registration of user accounts	User accounts are automatically disabled after 3 months of inactivity. Requests to de-register NIMS accounts are to be made to the Systems Administrator either via a telephone call or an email.
Automatic log out	Users are automatically logged out after 30 minutes of inactivity.
Compulsory training	Users must undergo training before being able to gain login detail through eLearning Modules and/or directly by SCA.
Data protection and confidentiality	Only HSE employees with access privileges may access NIMS. Staff with access to NIMS must only be allocated the necessary levels of access in order to fulfil the responsibilities of their role and function.

5.2.2.2 Access controls for NIMS in the SCA

HIQA were informed that there is an access policy for NIMS in place in the SCA. The team was also informed that additional security measures for NIMS in the SCA include:

- Data encrypted at rest and transit.
- Security "defence in depth" approach and firewalls in place.
- Backup, disaster recovery and business continuity process.
- Vulnerability and penetration testing completed regularly.
- Role-based[§§§] and secure access processes.

5.2.2.3 Record collection and retention policies

At a local level, within both acute hospitals and CHOs, paper-based forms are stored for one to two years before being transferred to an archiving service for long-term storage in line with the HSE's retention policy. Regarding the level of detail collected for each record, this is variable at local level and there seems to be little guidance at a national level regarding this. For example, HIQA was informed in interview that the description of an incident can often yield personal information, which poses an ongoing risk even if a decision is made to anonymise data by restricting viewing rights to personal data fields.

[§§§] In a training presentation provided by the SCA entitled "SCA Systems Overview" the specific screens viewed by specific units within the SCA were listed: Risk Units- Risk Review Screens; Claims Units- Claim Management Dashboards and Financial Dashboards; Litigation Units- Litigation Dashboards and Financial Dashboards; Legal Costs- Legal Cost Screens; Data Services Unit- Incident/Claim Entry and Tasks; Accounts Unit- Financial Dashboards and Tasks

At a national level, HIQA was informed that once data is entered onto NIMS, there is no limit to the retention period of data. However, the SCA notes in the NIMS DPIA that prolonged retention of personal data is a risk. It states that a range of options are being considered to mitigate the risk of data being retained for unduly long periods. These include: partially anonymising certain datasets; and introducing various additional access controls within the NIMS System.

HIQA has concluded that the area of data retention and destruction requires clarity and transparency to ensure both organisations and data subjects are aware of how this is being managed. This is of particular importance to the HSE in terms of assurance in relation to how NIMS data is protected and managed.

5.2.2.4 Data breach management

The HSE has a Data Protection Breach Management Policy which all services are obliged to follow. HIQA was informed by the QAV that they have never had a data breach reported to them in relation to NIMS. However, evidence gathered through interviews indicated some examples of potential data breaches including aggregated data being sent to the wrong hospital or an incorrect email address. HIQA noted that a guidance document addressing information governance for NIMS within the HSE would be beneficial to services locally to provide clarity in respect of some of these practices.

The SCA provided HIQA with an Incident Response Plan from the system vendor which includes a Data Breach Response Plan. The various stages for responding to a breach are detailed in the plan and include:

- Data Breach Actions
- Data Breach Analysis and Assessment
- Data Breach Mitigation
- Data Breach Prevention
- Restore Affected System
- Documentation (including data breach logs)
- Evidence and Document Preservation
- Assess Damage and Cost
- Review Response and Update Policies
- Further Notifications.

The review team was also informed in interview with the SCA that there had never been a data breach in terms of personal data or a breach of the system. The review team were also informed that most reported data from NIMS is in aggregated format. No personal data from NIMS is analysed for the purposes of producing routine reports except in instances where a personal data report is required for lawful purposes.

HIQA were satisfied that data breach procedures are in place in both organisations. This would be expected in organisations of this size to ensure appropriate actions are taken in the event of a breach. To ensure full understanding of what a data breach is, however minor, and the process to follow in order to report a suspected breach, training (including refresher training) for all staff in this area would be beneficial.

5.3 Information governance practices

5.3.1 Data Protection Impact Assessment (DPIA)

HIQA was informed in interview and document request, that the SCA conducted a DPIA of the NIMS system in May 2018, which was subsequently updated in July 2018 and June 2019. HIQA acknowledges the completion of a DPIA and identification of risk as good practice by the SCA as data controller. The DPIA is an overarching document assessing high-level data protection and privacy risks from the perspective of the SCA and the operation of the NIMS system across all DSAs in Ireland.

However, given the scale of implementation of NIMS within the HSE and HSE-funded bodies, and the sensitive nature and volume of health and social care-related incidents, HIQA has concluded that the current DPIA is not fully comprehensive to cover all issues that currently exist across the joint governance model. It would be useful for the HSE to develop its own DPIA to cover the entire flow of NIMS data, particularly from the perspective of the HSE and HSE-funded bodies. This would ensure that any risks regarding data processing for NIMS within the HSE are identified and that specific controls are put in place, where necessary, to mitigate these risks.

5.3.2 Information governance risk management

HIQA was informed in interview with the QAV that there are currently no risks on the HSE risk register in relation to information governance for NIMS, and, as previously outlined in Chapter 3, there is also no joint risk register in place between the HSE and SCA for NIMS.

In relation to information governance issues identified during this review, HIQA was informed throughout site visits to hospitals and CHOs in one region, that those working on NIMS have experienced significant local IT infrastructural issues in relation to connectivity to the NIMS system. For example, HIQA was informed that in one HSE region, access to NIMS was disrupted for up to three months as a result of local IT issues, resulting in significant backlogs for data inputters. Also, HIQA was informed that the local IT issues cause the system to regularly lose connectivity which often results in a form having to be input to the system twice. In interview,

QAV and the SCA acknowledged that this was an issue and that they had been working with the third party system provider to identify the problem. However, the lack of IT resources for NIMS in the HSE was also identified as a barrier to effective resolution of this issue.

In addition, as previously outlined, during site visits to hospitals and CHOs, the HIQA team noted that an over-reliance on large volumes of paper records in many settings presented a potential information governance risk, given the potential for loss of such files or potential for them to be viewed by unauthorised personnel. In order to adequately address and manage such issues, they first need to be identified and documented as risks and a plan for controls to be put in place to mitigate these. This highlights the value of the HSE conducting a DPIA specifically for NIMS within the HSE.

The SCA provided the review team with a risk register for NIMS, covering all DSAs, which included some information governance-related risks along with controls in place to mitigate same. Risks included: data being accessed by unauthorised personnel including through loss of a paper file; system being breached or compromised; poor connectivity to system for users. HIQA noted that it was not clear from the document who was the owner of each of the risks and controls, and also how often the risk register is reviewed and updated. However, HIQA was informed by the SCA that it is reviewed at least annually.

HIQA has concluded that an up-to-date joint risk register for the joint governing organisations, SCA and HSE, would help to identify and mitigate information governance risks specific to NIMS within the HSE. This would be valuable to ensure that all potential risks for NIMS are identified and dealt with appropriately in a timely manner.

5.3.3 Statement of information practices

HIQA found that neither the HSE nor the SCA publish information to describe how NIMS data are used. A method employed by organisations to comply with the principle of transparency, is to publish a statement of information practices which outlines what information the service collects, how it is used, with whom it is shared and for what purpose, the safeguards that are in place to protect it, and how people can assess information held about them.

While a privacy policy is available for the HSE, this is a generic document and not specific to NIMS. It does not provide any detail about the transfer of incident data to the SCA or in relation to the system being hosted by the third party system provider, an external agency. The detail needs to be extended to provide specific information regarding NIMS, including the collection, use and sharing of information generated and held by the HSE and the SCA. As required under GDPR, a comprehensive

privacy statement or statement of information practices should be developed by the HSE to enhance a patient centred and transparent approach to the processing of health information.

5.3.4 Data subject requests/Data Requests

The GDPR gives individuals the right to request a copy of any of their personal data which is being processed by controllers, as well as other relevant information. HIQA was not provided with documents outlining the process by which data subjects can request access to their data.

The review team were informed in interview that the SCA are exempt within legislation from providing data subjects with access to their personal information. As a result, they direct any such requests they receive back to the relevant HSE service.

In relation to external data requests, the team was informed in interview that these requests go through the SCA. The SCA have a data request form in place and provided evidence to the team of an internal process that must be followed before sign-off is given.

HIQA has concluded that a clear procedure outlining the terms and conditions for data requests should be in place to provide assurance that both organisations are meeting their obligations under the GDPR in this regard.

5.4 Information governance audits

Although no formal schedule of regular audits was received from the SCA, HIQA was informed through correspondence that they have controls in place in relation to monitoring of the NIMS system vendor and data security and integrity. These include:

- Annual NTMA Third Party Monitoring and Review Report for NIMS in line with NTMA Third Party Risk Policy.
- External SOC1 and SOC2 accreditation[52] (in relation to security, availability, processing integrity, confidentiality, and privacy for a service organisation) for data centres in Europe where NIMS data is held.
- External audit - Completion of Web Application Security Assessment in 2018.
- Annual web application security assessment completed by Sirius on behalf of the vendor to provide assurance to SCA.
- An IT Cloud Security Assessment carried out prior to going to cloud and is repeated when there are significant changes to infrastructure.

No formal schedule of audits in relation to information governance for NIMS was received from the HSE. However, QAV informed the review team through interview, that a recent audit of user access was completed to identify accounts that still

required access and to ensure that the correct level of access was being granted. This is seen as good practice on the part of the HSE. However, it would be beneficial for the joint governing organisations to develop a formalised schedule of NIMS information governance audits that include information security and data quality, with effective action taken where necessary to address areas needing improvement.

5.5 Information governance training

Although HIQA identified evidence through interview that there is a good awareness of information governance issues among staff, no evidence of a formalised schedule for information governance training for NIMS users was received. However, in the NIMS Terms and Conditions of Use, training in relation to authorised uses of, and access to, the NIMS system is noted as a requirement to being granted access to the NIMS system. Generic information governance training is also provided at induction to all newly recruited HSE staff through an online information governance module on HSELanD.

A more formalised approach to providing and keeping records of information governance training for NIMS users would provide assurance that they have the adequate level of knowledge of information governance for their specific roles. In addition, it would be beneficial to have specific guidance documents in place outlining the responsibilities for information governance for NIMS within the HSE to ensure that all aspects of information governance across the joint governance model are adequately addressed.

5.6 Significance of findings- information governance

Information governance arrangements

Information governance roles and responsibilities

- While both the SCA and the HSE recognise that they have individual responsibilities in respect of information governance within the joint governance model in place for NIMS, HIQA identified that it was not clear who has overall responsibility and accountability for information governance for NIMS data collected within the HSE.

- HIQA also noted that the specific roles and responsibilities of each agency in relation to the different aspects of information governance, such as data security, data quality, data protection and the secondary use of information were not clearly documented. At a minimum, when a joint governance model is in place, one would expect to see these responsibilities clearly outlined within a Data Sharing Agreement. Such documentation should clearly outline the roles and responsibilities of the data controller, data processor, and sub-processers. Without clear documentation in place, it is challenging for an organisation to respond effectively to information governance issues, such as data quality, breaches, complaints or the need to safeguard the data protection rights of individuals.

Arrangements within QAV

- HIQA identified that within QAV there is no one with overall responsibility for information governance of NIMS within the HSE and none of the governance teams currently in place for NIMS have a specific responsibility for information governance. This can make it difficult to systematically address issues that arise in relation to information governance for NIMS and identify potential risks.

- HIQA noted that although QAV acts as the designated '*NIMS Information Owner*' and, is in effect, the main point of contact within the HSE for NIMS, in practice it has limited responsibility in respect of information governance. While it has a role in the area of access control for NIMS, it does not have a role in coordinating a national approach to information governance for NIMS within the HSE. This can have an impact on areas of information governance, such as improving aspects of data quality, data security or ensuring privacy and confidentiality of data in respect of NIMS.

Arrangements within acute and CHO settings

- The process regarding the management of incidents and the roles and responsibilities at a service level are clearly detailed in the Incident Management Framework (2020). HIQA identified that HSE staff had a good understanding of the steps involved in the management of an incident, and the levels at which the incidents need to be reported and signed-off as well as who was responsible for escalating an issue, if necessary. HIQA also observed that there was a clear understanding of the information governance principles at a local level within each service and the associated issues. However, HIQA identified gaps in knowledge in relation to how information governance would be managed if an ePOE model were adopted. This highlights a need for comprehensive education and guidance at a local and national level as how to each service would develop a fit for purpose information governance model to suit their requirements.

- HIQA also found that in general, information governance practices tend to be developed and implemented locally within acute and community services. There was no evidence that a coordinated approach was being implemented at a national level and there was an absence of specific guidance documents in place outlining the responsibilities for information governance at a local level for NIMS within the HSE.

Legislation – information governance (GDPR)

- As part of the complexity of the joint governance model in place between the SCA and the HSE, HIQA was informed that both of the organisations currently have dual roles of data controller and data processor for the data collected on NIMS. However, HIQA concluded that there was a lack of clarity in relation to this.

- This lack of clarity was also evidenced by the fact that some key documentation in line with the principle of accountability were not in place, namely, a data sharing agreement between the HSE/SCA, or a NIMS privacy statement or statement of information practices for NIMS.

Information governance practices

- Data Protection Impact Assessment (DPIA)
  HIQA acknowledges the completion of a DPIA of the overall NIMS system by the SCA. However, given the scale of implementation of NIMS with the HSE and HSE-funded bodies, it would be good practice for a DPIA to be undertaken in respect of NIMS within the HSE. This would ensure that any data protection issues and risks pertaining to NIMS within the HSE are addressed and also to consider additional issues that currently exist across the joint governance model.

- Risk management
  HIQA was informed in interview with the QAV that there are currently no risks on the HSE risk register in relation to information governance for NIMS, and there is also no joint risk register in place between the HSE and SCA for NIMS. This is surprising despite a number of key information governance risks having been identified by the review team through site visits to acute and community settings, such as connectivity, data quality issues and risk of unauthorised access to paper-based records.

- Statement of information practices
  HIQA noted as a significant gap that neither the SCA nor HSE publishes information to describe how NIMS data is used. While a privacy policy is available for the HSE, this is a generic document and not specific to NIMS. It does not provide any detail about the transfer of incident data to the SCA or in relation to the system being hosted by a third party system provider, an external agency. The detail needs to be extended to provide specific information regarding NIMS, including the collection, use and sharing of information generated and held by the HSE and the SCA and the different levels of access to this information.

Information security and access control

- HIQA recognises as good practice the security measures in place in the SCA in respect of the NIMS system. In relation to the HSE, HIQA acknowledges that the HSE has developed a detailed guidance document in relation to access control entitled 'HSE Guidance for NIMS to include access and control'. In interview, HIQA was informed that the access rights to NIMS were controlled through a central point in the HSE under the governance of the QAV. A clear

process is therefore in place for controlling access to NIMS within the HSE. However, the issue of over-reliance on large volumes of paper records in many settings presented a potential information governance risk, given the potential for loss of such files or potential for them to be viewed by unauthorised personnel. This again points to the importance of a joint risk register where risks such as these can be mitigated and managed.

- Additional information governance measures for NIMS within the HSE include: deregistration of user accounts after three months of inactivity; automatic log out after 30 minutes of inactivity; compulsory training for users before being able to gain login; data protection and confidentiality as only those HSE employees with access privileges may access NIMS in order to fulfil the responsibilities of their role and function.

NIMS record retention and destruction policies

- At a local level within acute hospitals and CHOs, paper-based forms are stored for one-to-two years before being transferred to off-site archiving for long-term storage in line with the HSE's retention policy. At a national level, HIQA was informed that once data are entered onto NIMS, there is no limit to retention of data. The rationale for this is for learning purposes through trending patterns overtime and also for claims management purposes.

- HIQA has concluded that the area of data retention and destruction requires clarity and transparency to ensure both SCA/HSE and importantly, all data subjects, are aware of how this is being managed.

Information governance audit

- HIQA did not receive any formal schedule of audits in relation to information governance for NIMS within the HSE. It would be beneficial for the joint governing organisations to develop a formalised schedule of NIMS information governance audits that include information security, data protection and data quality with effective action taken, where necessary, to address areas identified as needing improvement.

Information governance training

- Although HIQA identified evidence through interview that there is a good awareness of information governance issues among HSE staff, no evidence of a formalised schedule for information governance training for NIMS users was received. Without a formalised schedule in place it is difficult to provide assurance that NIMS users have the adequate level of knowledge of information governance for their specific roles.

5.7 Recommendations - information governance

Information governance	
9.	**Effective arrangements for information governance**
	As part of a strategy for NIMS within the HSE, HSE QAV in collaboration with HSE Acute and Community operations, should lead on the establishment of more effective arrangements for information governance that include: ▪ assigning an individual within the HSE overall responsibility for information governance who can take a national approach to key aspects of this area, such as data quality, data security, and ensuring privacy and confidentiality of data in respect of NIMS ▪ ensuring responsibility for information governance is assigned to one of the NIMS governance groups ▪ clearly defining roles and responsibilities for information governance for NIMS from local to national level across the HSE ▪ addressing specific aspects of information governance in services where an electronic Point of Entry model has been implemented ▪ the assessment and management of information governance risks through the joint risk register ▪ audits in relation to information governance that form part of an overall schedule of audits for NIMS ▪ a formalised approach to providing and keeping records of information governance training.
10.	**Compliance with legislation and privacy risk assessment**
	HSE QAV should develop a Data Protection Impact Assessment (DPIA) for NIMS within the HSE to: ▪ cover the entire flow of NIMS data from the perspective of the HSE and HSE-funded bodies to ensure HSE-specific data protection and privacy risks can be identified and mitigated ▪ provide clarity in relation to data retention and destruction. HSE QAV, in collaboration with HSE Acute and Community Operations, should also develop a Privacy Statement or Statement of Information Practices specifically for NIMS within the HSE.

6. Conclusion

The aim of this this review was to assess the compliance of the National Incident Management System (NIMS) within the HSE with the Information Management Standards. Ultimately, the overall review programme of national data collections in Ireland aims to drive improvements by identifying areas of good practice and areas where improvements are necessary across national data collections. It is essential that health information is managed in the most effective way possible in order to protect public health. The Sláintecare report, published in 2017, outlines the priorities for the health services over the next ten years, and particularly emphasises the importance of quality health data and information to drive improvements in the future of healthcare in Ireland.[53]

In healthcare, incident management plays a vital role in patient safety surveillance and learning. The publication of an Incident Management Framework (IMF) by the HSE, updated in 2020, outlines the key principles, governance requirements, roles and responsibilities and processes to be applied for the management of incidents in all HSE service areas. NIMS is the nationally mandated information system that is in place to support the implementation of the IMF. Its importance has been emphasised by the decision by the DoH to use NIMS as the single national information system for incident management and patient safety and learning within the HSE and HSE-funded services.

The importance of the NIMS system is further emphasised in light of the forthcoming enactment of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.[6] This legislation specifies that health service providers must report notifiable incidents through the National Treasury Management Agency's (NTMA) incident management system. Furthermore, it is expected that the new National Patient Safety Surveillance System being developed within the National Patient Safety Office in the DoH will incorporate NIMS as a key source of patient safety intelligence. With these significant developments underway, it becomes ever more important that NIMS is fully fit for purpose and functional as the single incident report and learning system across all HSE and HSE-funded health and social care services in Ireland.

Effective information management for NIMS is essential, as NIMS is a key national repository of data and information that can be used to improve the quality and safety of services through the monitoring of incident data and using this data to manage associated risks. It is used for the purpose of patient safety by the HSE and also to handle risk management, litigation and claims by the SCA. Good information management practices instil confidence in the public, healthcare professionals and all other stakeholders that high-quality information is securely held and shared effectively to inform decisions about patient care and protection of the health of the public. Furthermore, good information management promotes assurances and puts

in place the necessary precautions to maintain individuals' privacy and confidentiality, facilitates greater empowerment and involvement by communicating effectively with the public and, ultimately, it creates a culture in which information will be used more effectively.

HIQA recognises the achievements of the HSE to date in the implementation of NIMS. While HIQA also acknowledges that the HSE and SCA have demonstrated good practices in relation to some aspects of information management of NIMS within the HSE, there are also areas highlighted in the report that need to be addressed to ensure the long-term success of NIMS as the single system for incident management within the HSE and HSE-funded services. HIQA have recommended improvements in a number of areas within this review. The ten recommendations outlined in this report should be considered in conjunction with the findings of this review in order to improve information management practices for NIMS.

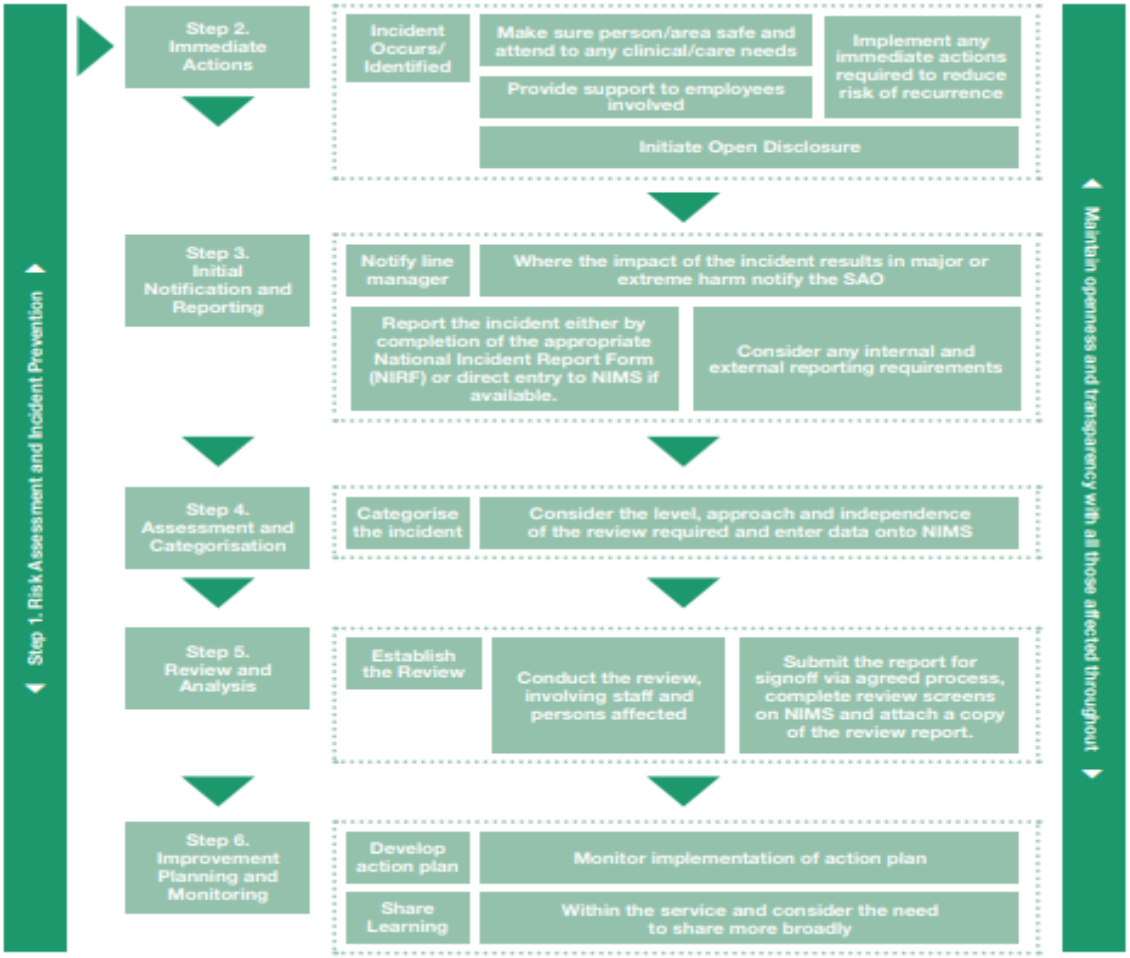
HSE QAV, with support from the SCA, is responsible for preparing and implementing quality improvement plans to ensure that the areas for improvement are prioritised and implemented in order to comply with the Information Management Standards. The HSE should continue to assess adherence to the Information Management Standards in between reviews by HIQA to ensure that they are meeting all requirements.

Appendices

Appendix 1 - Key publications by HIQA in relation to national health and social care data collections

- A catalogue of all national health and social care data collections in Ireland was first published in 2010 and was most recently updated in 2017 — *Catalogue of National Health and Social Care Data Collections in Ireland.* The current catalogue features 120 data collections.
- In 2013, HIQA published *Guiding Principles for National Health and Social Care Data Collections,* which provide current and new national health and social care data collections with advice and guidance on best practice.
- In 2014, HIQA published and submitted to the Minister for Health *Recommendations on a More Integrated Approach for National Health and Social Care Data Collections.* These recommendations emphasise the need for a strategic framework to inform policy development in this area. The implementation of these recommendations has the potential to reduce fragmentation and duplication and ensure a more consistent approach to improving the quality of data collected.
- HIQA has published a number of detailed guidance documents on best practice for information management:
    - *What you should know about information governance: a guide for health and social care staff*
    - *Guidance on information governance for health and social care services in Ireland*
    - *What you should know about data quality - a guide for health and social care staff*
    - *Five quality improvement tools for national data collections*
    - *Guidance on privacy impact assessment (PIA) in health and social care*
    - *Privacy impact assessment (PIA) toolkit for health and social care*
    - *Guidance on a data quality framework for health and social care.*

Appendix 2 – Overview of incident management process from the IMF (2020)[5]



Appendix 3 – The purpose of the NIMS system (Source: SCA DPIA for NIMS)[11]

Purpose of NIMS	
1	capture of incidents (including Serious Reportable Events) involving staff members, patients (clinical and general), members of the public, property, dangerous occurrences and complaints
2	management of investigations
3	recording of investigation conclusions
4	recording of recommendations
5	tracking recommendations to closure
6	management of the claims and litigation processes
7	multiple reporting and analytical tools which could be pointed at all captured data
8	facilitation of reporting and analysis of patient safety, staff safety, members of public, property damage, dangerous occurrences and complaints
9	facilitation of reporting and analysis of investigative conclusions and contributory factors
10	facilitation of reporting and analysis of key performance indicators (KPIs) as set out in the HSE National Service Plan
11	facilitation of the analysis of safety performance to inform risk initiatives.

Appendix 4 – Details of Phase 1 and Phase 2 Implementation

Phase 1 NIMS implementation

In June 2014, under Phase 1 of the National Incident Management System (NIMS) Implementation Project, NAEMS was rebranded as NIMS to take into account a broader range of incidents in line with the World Health Organization's definition of an incident and the HSE Safety Incident Management Policy at the time. The scope of Phase 1 of the NIMS Implementation Project was to ensure that all existing STARSweb/NAEMS user sites and users would have access to and training on using the NIMS data entry module. The scope also facilitated access to NIMS for some new users who had not used STARSweb/NAEMS previously.(54) Over the course of Phase 1, 882 users were identified and provided with access and training to use NIMS.

Phase 2 NIMS Implementation

In April 2016, the Phase 2 Project Initiation Document outlines the core scope of Phase 2; to increase incident reporting levels, provide transparency in relation to safety incidents and embed new functionality. Phase 2 of the project formally closed in February 2018. The close out of phase 2 involved the delivery of the following:(23)

- Rollout of incident review functionality.
- Development and implementation of incident review screens.
- Decommissioning of the Incident Information Management System (IIMS)****. The IIMS is closed to the input of new incidents. As of 1 January 2018, new incidents are no longer entered on IIMS, instead they are entered on NIMS.
- Incident reports: The development of periodic incident reports for the Leadership Team members, as well as the management teams of Hospital Groups and Community Healthcare Organisations, is an ongoing deliverable of this Phase.
- Complaints Management System - Module one: a unified, standardised national database management system developed in partnership with the State Claims Agency. The rollout of this complaints module 1 was carried out by QAV's National Complaints Team with the support of the NIMS project team. A detailed project plan was developed and the module went live for all users on the 1 Jan 2018.

Actions remaining are managed by the NIMS project team and were incorporated into Phase 3 deliverables, where necessary. The benefits of the rollout of NIMS

**** The Incident Information Management System (IIMS) was an internal HSE system that recorded and collated relevant information regarding serious incidents that were communicated to the Divisional Quality and Patient Safety Lead and, where necessary, escalated to the then QAV National Incident Management and Learning Team.

within the HSE are detailed in the Phase 3 Project Initiation Document, some of which include:

- Increased effectiveness and timeliness of incident reporting across the organisation (HSE Corporate Goal 2)
- Easy generation of comprehensive reports, providing transparent and detailed views of incident occurrences (HSE Corporate Goal 3, 5)
- Reduction in the duplication of work, as NIMS is a single, common incident and complaints management system rolled out across the HSE (HSE Corporate Goal 3, 5).

Appendix 5 – Plans outlined for (current) Phase 3 implementation of NIMS[23]

Area of work	Actions
Reporting and Data Analysis	▪ development of NIMS dashboards and their utilisation to meet user reporting requirements ▪ rollout of local level reports across hospital groups ▪ support of the National Patient Safety Programme by providing intelligence from NIMS in support of the Programme ▪ developing an approach to enable the capture and analysis of staff health and safety incidents.
System Maintenance	▪ review of the severity rating algorithm relating to the classification of staff incidents ▪ review of 'Clinical' and 'Birth Specific' procedures classification and utilisation ▪ facilitation of onward incident notification to other agencies for example, HSA, HPRA, HIQA ▪ delivery of ongoing maintenance & support activities by the HSE project team in conjunction with the SCA ▪ examination of potential linking of NIMS with electronic health record ▪ review of NIMS user terms and conditions and access control procedures against GDPR requirements.
openSystem Utilisation	▪ increasing NIMS user competency relating to the interpretation of data ▪ examination of the potential expansion of point of occurrence NIMS reporting ▪ promoting the use of NIMS as the primary system for the capture and management of incidents in accordance with HSE national policies ▪ review of the complaints module operation and the identification of improvements ▪ an agreement of consent by Section 38 hospitals to the sharing of incident information ▪ identifying and challenging all those areas that are non-compliant, in conjunction with the SCA ▪ rollout of other initiatives which may be deemed appropriate by the sponsorship group.

Appendix 6 – Summary details of the national and regional incident reporting systems included in this review

Country	Name	Scope	Governance
England* (NRLS)[55]	National Reporting and Learning System	To identify hazards, risks and opportunities to continuously improve the safety of patient care	Hosted and managed by NHS
Denmark (DPSD)[56]	Danish Patient Safety Database	To promote patient safety by gathering, analysing and communicating knowledge about unintended incidents, hence creating a systematic learning system	Hosted and managed by DPSA
British Columbia (BC PSLS)[57]	The British Colombia Patient Safety and Learning System	To make healthcare safer through shared learning and continuous improvement	Hosted and managed by BC PSLS Central Office
Australia[58]	Australian Sentinel Reporting System	To ensure public accountability and transparency and drive national improvements in patient safety	Hosted and managed by the Australian Commission on Safety and Quality in Health Care
New Zealand[59]	Central Repository hosted by Health Quality and Safety Commission	To contribute to improved quality, safety and experience of health and disability services.	Hosted and managed by Health Quality and Safety Commission

*A new national NHS patient safety incident management system (PSIMS) is in the final stages of development.

Appendix 7 - Summary of key findings of an international review of national patient reporting systems

Area	Recommended Approach
Reportable Incidents	▪ Prioritise which incidents to report to the national reporting system including 'never events', device failures, hospital acquired infections and medication incidents.
Report Form	▪ Collect detailed data for each individual incident to inform learning.

Report Review	▪ Have a process that anonymises all incoming reports and removes personally identifiable information
	▪ Have a process to ensure the quality of data in incoming reports, including correct classification
	▪ Prioritise incoming reports for review using algorithms to extract incidents more likely to need a national response – within these prioritise those associated with serious harm
	▪ Review process should, at a minimum:
	  ▪ Identify hazards in the healthcare system and prioritise them for further evaluation
	  ▪ Be expert – evaluated by experts who understand the clinical circumstances and who are trained to recognise underlying system causes
	  ▪ Be credible – involve independent and content experts
	  ▪ Be timely – review reports without delay and share recommendations promptly
	  ▪ Result in preventative recommendations.

Data transfer from local to national systems	▪ Provide for automatic online dataflow between local and national systems using a Cloud platform or integration between national and local system ▪ Avoid batched transfer of data ▪ Ensure data security when transporting, storing, sharing and archiving data ▪ Store basic data from different sources of reports to allow for integrated analysis.
Care settings	▪ Cover all care settings (hospitals, laboratories, imaging services, rehabilitation institutions, outpatient clinics, primary care, pharmacies, substance abuse treatment centres, ambulance services, home care agencies, social care services) ▪ Involve both public and private organisations.
Other Data Sources	▪ Patient safety reporting systems do not provide a complete picture of risks, hazards and system vulnerabilities. Use other sources of information for example, patient file reviews, incidents detected from

	administrative data, complaints, health and safety incidents, inquests, claims, clinical audits, patient and family perspectives. Introduce mechanisms at national level to collect this information and share the lessons learned. ▪ Link automatically with pharmacovigilance and other similar systems to avoid duplication of reporting.
Shared Learning	▪ Methods of learning from reports include alerts about new hazards, sharing lessons from incident investigation, analysing multiple reports to gain insights into underlying system failures and develop best practice recommendations ▪ Share preventive measures through existing channels ▪ Include changes in relevant existing policies ▪ Consider providing central support for implementing change, resource that support.

Appendix 8– National KPIs collected for the HSE National Scorecard

National Scorecard		
Scorecard quadrant	**Priority area**	**KPI**
Quality and Safety	Serious Incidents	▪ % of serious incidents requiring review completed within 125 calendar days of occurrence of the incident
Access and Integration	Ambulance Response Times	▪ % of Clinical Status 1 ECHO incidents responded to by a patient-carrying vehicle in 18 minutes and 59 seconds or less ▪ % of Clinical Status 1 DELTA incidents responded to by a patient-carrying vehicle in 18 minutes and 59 seconds or less.

National KPIs collected for the HSE National Performance Indicator Suite

National Performance Indicator Suite				
System wide Indicator	**Reporting period**	**NPS2018 target**	**Projected outturn**	**Target 2019**
Serious Incidents % of serious incidents being notified within 24 hours of occurrence to the senior accountable officer	M	99%	21%	80%
Serious Incidents % of serious incidents requiring review completed within 125 calendar days of occurrence of the incident	M	90%	1%	80%
Incident Reporting % of reported incidents entered onto NIMS within 30 days of occurrence by CHO/Hospital Group/NAS	Q	90%	50%	90%
Incident Reporting	Q	<1%	0.1	<1%

Extreme and major incidents as a % of all incidents reported as occurring				
Medication Safety Rate of medication incidents as reported to NIMS per 1,000 beds	M	New PI NSP2019	New PI NSP2019	2.4 per 1,000 bed days
Emergency Response Times % of clinical status 1 ECHO incidents responded to by a patient carrying vehicle in 18 minutes and 59 seconds or less	M	80%	80%	80%
Emergency Response Times % of clinical status 1 DELTA incidents responded to by a patient-carrying vehicle in 18 minutes and 59 seconds or less	M	80%	58%	80%

Appendix 9 – Example of HSE Performance Profile report (July to September 2019)

Quality and Patient Safety

Performance area	Reporting Level	Target/ Expected Activity	Freq	Current Period YTD	Current (-2)	Current (-1)	Current
Serious Incidents – Number of incidents reported as occurring	National			**663**	**62**	**67**	**62**
	Acute Hospitals (incl NAS, NSS & NCCP)			382	35	39	33
	Community Healthcare			281	27	28	29
Serious Incidents – Incidents notified within 24 hours of occurrence	National	80%	M	**33%**	**32%**	**37%**	**24%**
	Acute Hospitals (incl NAS, NSS & NCCP)	80%	M	40%	37%	41%	21%
	Community Healthcare	80%	M	29%	26%	32%	28%
Serious Incidents – Review completed within 125 calendar days*	National	80%	M	**16%**	**12%**	**9%**	**16%**
	Acute Hospitals (incl NAS, NSS & NCCP)	80%	M	22%	15%	11%	22%
	Community Healthcare	80%	M	3%	4%	3%	3%

* Current - reflecting compliance YTD May 2019 (-1 YTD April 2019), (-2 YTD March 2019)

KPI - % of serious incidents being notified within 24 hours of occurrence to the senior accountable officer was introduced in 2018 and is defined as any incident that results in a rating of major or extreme severity. Data is reported from the National Incident Management System, the primary reporting system across the HSE and HSE funded agencies. The report is run by date of occurrence and figures are subject to change. The system has been aligned to complement the new Incident Management Framework (IMF), **While the IMF was being rolled out across the system and workshops on-going during Q1 2018, reporting on compliance commenced in Q2 2018.**

Serious Reportable Events

48 SREs were reported on the National Incident Management System (NIMS) as occurring during September 2019.

Division	Total SRE Occurrence
Acute Hospitals (inc. Ambulance Service)	**32**
Community Services	**16**
Grand Total	**48**

23 SREs reported as patient falls and 15 as Stage 3 or Stage 4 pressure ulcers.
The remaining 10 SREs reported comprised 5 SRE categories.

Appendix 10 – Information governance codes of practice, policies and procedures

HSE ICT codes of practice, policies and procedures
HSE policy documents in relation to information security, computer systems, data management etc. including the following list of policies.
HSE Information Technology Acceptable Use Policy.
HSE Electronic Communications Policy.
HSE Password Standards Policy.
HSE Encryption Policy.
HSE Access Control Policy.
HSE Remote Access Policy.
HSE Mobile Phone Device Policy.
HSE Data Classification & Handling Policy.
HSE Data Protection Breach Management Policy.
HSE Internet Content Filter Standard.
HSE Service Provider Confidentiality Agreement.
HSE Third Party Network Access Agreement.
HSE Risk Management Policy and Procedures.
HSE Annual Controls Assurance Process.

Appendix 11– NTMA Processes in place for NIMS in the context of the General Data Protection Regulation (as per current DPIA)

Principle	Definition	NIMS
Lawfulness, fairness and transparency	Making sure there is a "legal basis" for the processing; for example, the data subject has consented or the use of the data is necessary the performance of a task in the public interest or exercise of official authority by a public body	Section 8, Section 9 and Section 11 of the 2000 Act provide sufficient legislative support for the current data processing through the NIMS System.
Purpose limitation	Only using data for a specified purpose	Personal data to be processed only in accordance with the statutory purposes set down in sections 8, 9 and 11 of the 2000 Act. Users accept the terms and conditions which require that they only process personal data in accordance with their statutory functions.
Data minimisation	Only using what is actually necessary and no more	Users are trained to ensure that only "relevant" information is logged in the NIMS System. The NIMS System only requests that relevant information fields be populated.
Accuracy	Making sure the data is accurate and up to date	Data can be corrected to ensure its accuracy and there is an audit trail to trace when and who amended records to ensure the integrity of the data. A data quality scorecard initiative is underway to incentivise high standards of accuracy.
Storage limitation	Keeping data for only as long as necessary	Long retention periods of personal data can be justified by reference to the important statutory functions for which such data is retained. Data needs to be retained over a sufficiently long period, such that statistical analysis can be undertaken and trends identified by reference to an appropriate reference period.
Integrity and confidentiality	Keeping data secure and managing data breaches	Required to implement appropriate technical and organisational measures to ensure a level of security appropriate to the level of risk: - Personal data is critical to the performance of the risk and claims functions both within the SCA and externally to facilitate the appropriate management of same, the

		accurate identification of incident records by users for updates, reviews, and the identification of trends. Anonymised or dummy data is used on the development and training platform. - Data is encrypted at rest and transit. - Security "defence in depth" approach and firewalls in place. Annual review by independent third party. - Backup, disaster recovery and business continuity process in place - Vulnerability and penetration testing completed regularly. - Role-based and secure access processes in place. Further security measures include: ▪ users are automatically logged out after 30 minutes of inactivity; ▪ users must undergo training before being able to gain login detail through eLearning Modules and/or directly by SCA and, in certain cases, supplemented by the delegated State authorities; ▪ user accounts are automatically disabled after 3 months of inactivity ▪ user access rights on the NIMS System are restricted by to relevant field and certain access rights are limited based on necessity to certain grades of employee.
Accountability	Demonstrating compliance by having policies and procedures in place	Maintain written records of data processing activities.

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Published by the Health Information and Quality Authority (HIQA).

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