Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Draft recommendations

on a model for health information standards to support the delivery of health and social care services in Ireland

June 2022

About the Health Information and Quality Authority

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

Healthcare 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. Therefore, it is imperative 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 medication, a nurse needs to be sure that they are administering the appropriate dose of the correct medicine to the right patient and that the patient is not allergic to it. Similarly, a 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 a key 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)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the 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 drive 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 Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevents the safe, effective, transfer of information. This results in people using the service being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation quality varies, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions.

Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, 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, the general public, patients and service users, health professionals and policy makers 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.

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Glossary of Terms

Certification of Clincal Systems	Certification procedures to verify vendor's compliance with national health information standards.
Clinical terminologies	A structured collection of descriptive terms for use in clinical practice.
Conformance Testing	Assessing conformance against a national health information standard. Conformance testing is a way to determine directly or indirectly that all relevant requirements in a standard have been implemented correctly. The implementation is tested (via conformance testing) against the requirements in the specification to determine if all requirements are met.
Compliance	Regulatory compliance against national standards when the standard is in use and is implemented in an eHealth service such as an identifiers service, eRefferals, eDischarge. This function is conducted by an Inspectorate.
Data	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed.
Database	A collection of data that is organised so that its contents can easily be accessed, managed, and updated.
Dataset	Data is collected by the information collections is usually presented in tabular form.
Data dictionary	A descriptive list of names (also called representations or displays), definitions, and attributes of data elements to be collected in an information system or database. The purpose of the data dictionary is to standardise definitions and therefore have consistency in the collection of data.
Data quality	Data that are complete, valid, accurate, reliable, relevant, legible and available in a timely manner.

eHealth	The combined use of electronic communication and information technology in the healthcare sector. The use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health.
entity	An entity is something about which an organisation needs to keep data on and can be a single thing, person, place, or object.
General practitioner	A doctor who has completed a recognised training programme in general practice and provides personal and continuing care to individuals and to families in the community.
Governance	In healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for service users.
Health information	Health information is defined as information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present or future, physical or mental health or social care of an individual or group of individuals (also referred to as a cohort). Health information also includes information relating to the management of the health and social care system.
Healthcare	Services received by individuals or communities to promote, maintain, monitor or restore health.
Information	Information is data that have been processed or analysed to produce something useful.

Information and communication technology (ICT)	The tools and resources used to communicate, create, disseminate, store, and manage information electronically.
Information governance	The arrangements that are in place to manage information to support national health and social care data collections' immediate and future regulatory, legal, risk, environmental and operational requirements.
Interoperability	The ability of health information systems to work together within and across organisational boundaries in order to advance the effective delivery of healthcare for individuals and communities.
Key performance indicator (KPI)	Specific and measurable elements of practice that can be used to assess quality and safety of care.
Metadata	Can be defined as 'data to explain data'. Metadata provides summary information in a structured way about the content of a resource such as a report, a book or a dataset.
Minimum dataset	A minimum dataset is the least agreed number of data elements collected for reporting purposes.
Semantic Interoperability	The ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards. Many systems can achieve technical interoperability but the real challenge is when different electronic health record (EHR) systems attempt to share clinically meaningful information. Semantic interoperability can only be achieved when a reference model, data structures and terminologies or clinical classifications work together harmoniously and not as separate entities. (Global Digital Health Partnership).

Integrated National Health Information System	An integrated health information system means that all different types of health information from health and social care, community, public health, private healthcare can flow to where it is needed, when needed and are fit for use. In the context of the health system, this means enabling secure data exchange across the numerous silos and requiring technical and semantic interoperability standards.

Executive Summary

Since the publication of the eHealth Strategy for Ireland (2013),(1) the strategic policy framework for eHealth in Ireland has evolved, with the Department of Health publishing the Sláintecare Implementation Plan in 2018(2) and the more recent Sláintecare Implementation Strategy and Action Plan (2021 – 2023).(3) Under the Sláintecare implementation plan (2018), which sets out how to implement the 10-year, cross-party vision for healthcare in Ireland, a key action is to 'identify improved information architecture, including standards, information and identity to underpin the delivery of integrated care'. This is further strengthened by the recent announcement that the Department of Health received Cabinet approval to develop the general scheme of a Health Information Bill.(4) This Bill will aim of ensuring that Ireland has a fit-for-purpose national health information system.(4)

Standardisation is a crucial enabler for an integrated national health information system[1] making it a key strategic priority. There is a need to drive adoption of standards through policy, legislation, agreements, co-development and education. Ireland has much to learn from the experience of other countries who have taken a strategic approach to both developing and implementing health information standards. A best practice review (2021) undertaken by HIQA in this area included countries Australia, Canada, Denmark, England and New Zealand.(5) Each country emphasised the need for strong strategic leadership and governance mechanisms for the purpose of delivering their overarching national health IT agenda. They have established dedicated organisations with appropriate governance structures in place including: the Australian Digital Health Agency (ADHA),(6) Danish Health Data Authority in Denmark,(7) NHS Transformation Directorate in England,(8) the Ministry of Health in New Zealand(9) and Health Infoway in Canada.(10) Such organisations have a broad remit, tasked with leading the development of national health IT strategy and play a role in delivering on that strategy by implementing, delivering and supporting national health IT systems. As part of their remit, some organisations are also responsible for developing and implementing health information standards.

Where organisations have a wider remit, it makes it more achievable to undertake all stages of standards development which involves developing, testing and piloting, technical conformance and certification, implementation and maintenance of

[1] An integrated national health information system means that all different types of health information from health and social care, community, public health, private healthcare can flow to where it is needed, when needed and are fit for use. In the context of the health system, this means enabling secure data exchange across the numerous silos requiring technical and semantic interoperability standards.

standards. Broadly, health information standards setting organisations perform a number of functions including:

- co-ordination and system-wide oversight of standards
- developing a roadmap to underpin standards development
- governance of the national standards development model
- developing standardisation policies
- resourcing for standards development
- establishing stakeholder engagement
- evaluation of health interoperability standards.

When reviewing other countries and their standards setting functions some key findings were identified. All countries leverage work from standards development organisations and they develop standards which work together to enable interoperability including:

- **Data standards** for clinical content which define the scope (who it applies to, what the purpose is), what data or information content are required for various use cases, to ensure consistency of meaning between systems.
- **Terminology and classification standards** which are structured vocabularies or codes that represent clinical ideas or concepts – SNOMED CT, LOINC, ICD.
- **Data exchange standards** describing the data structures and formatting of messages needed for exchange between systems – HL7 technical standards and specifications specify how information is to be made available technically.
- **Data security and information governance standards** set out rules that organisations should use for handling information in a safe and secure way, and also which information may be legally processed and covers information rules that implement privacy, security and identity management.[11]

Having analysed the standards development process for technical standards in three countries of comparable population size to Ireland – Denmark,[12] Scotland[13] and New Zealand[14] — and a Canadian province with almost three times the population — Ontario,[15,16,17] it can be deduced that the lifecylce involves eight main stages, is iterative and it is vital that each of the stages involved are allocated responsibility. Each stage is summarised as follows:

- **Stage 1-3** is about **identifying the requirements** for a standard, prioritizing requests, and importantly developing the draft standards in consultation with stakeholders.
- **Stage 4 –** is around **testing and piloting**. Versions of the draft standard are tested and should be fit-for-purpose prior to deployment and then piloted.

- **Stage 5 –** is on **providing support for implementation** – through education and training and raising awareness around standards. Support is provided in the form of tools, guidelines and advice.
- **Stage 6 –** is where the standards are **approved, published and then deployed in a live setting.**
- **Stage 7 – conformance and certification** is a stage where the system is checked against the standard to make sure it has been properly implemented and any lessons learned are fed back into subsequent revisions of the standard. Certification of systems can occur before vendor systems are allowed to be deployed into live environments.
- **Stage 8 –** And finally **maintenance and support** as Standards require ongoing maintenance and need to be updated if there are any changes to requirements.

All countries reviewed, have included conformance assessment and testing and certification of a system as an important feature of their standards development process. In this report, we make the distinction between 'conformance testing' and 'compliance' of Standards (see glossary) whereby 'conformance testing' is conducted as part of developing and implementing standards and 'compliance' refers to assessing compliance against the standard when it has been adopted and are in use in an eHealth service such as electronic referrals' or the identifiers service. The compliance role is typically undertaken outside of the standards setting development organisation. Internationally, experience with assessing compliance against eHealth services is limited. Where compliance is starting to be considered, in Sweden and the Netherlands, it is usually conducted by organisations at a higher level and a broader level remit on patient safety i.e. the regulator or inspectorate carry out this function.[18] Regarding the certification of systems, a recent OECD survey (2021) on digital health, reported that 16 of 25 OECD member countries and the Russian Federation (Russia) have a certification process for vendors of electronic health record system software that requires vendors to conform to electronic messaging standards. Thirteen respondents reported a certification process that requires adherence to national standards for clinical terminology.[19]

Engaging stakeholders is fundamental to the development and adoption of health information standards. In all countries reviewed, standards setting bodies collaborate with government, industry, academia and healthcare providers and all countries reviewed are well represented on international standards development organisations.[5]

In Ireland, while there are pockets of good practice for standards development overall there is a fragmented approach and health information standards are not

implemented at the scale that is required to support an integrated healthcare system. There are three separate organisations with different remits and roles in health information standards.

- HIQA has a legislative remit under the Health Act 2007, as amended, to develop recommendations, standards and assess compliance with those standards, and develop guidance in health information and have developed numerous national health information standards.[20]
- The HSE implement standards through national messaging broker system, HealthLink, host the National SNOMED CT release centre and have developed infrastructure for OpenNCP (an EU project for cross-border sharing of electronic prescription and electronic patient summaries) and include standards in their requirements documentation when procuring national systems.[21]
- National Standards Authority of Ireland (NSAI) has a remit to develop ISO and CEN standards, including those on health information.[22]

In relation to a compliance function, under section 8(1)(j) of the Health Act 2007,[23] HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available. HIQA will commence an eHealth Services review programme to assess compliance of major eHealth services such as the individual health identifiers, electronic referrals, National Information Medical Imaging System (NIMIS) against national standards. HIQA's current remit is limited to assessing compliance of health information standards within the HSE and does not assess services provided by private health and social care providers. As international evidence suggests, some countries are building or developing a compliance function and where this function is in place, it is carried out by the Insepctorate rather than the standards setting body.[18,24]

Through Sláintecare, and as outlined in various health information strategies and the most recent eHealth strategy (2013), there has been a commitment to adopt a standards-based approach in Ireland. However, there are a number of challenges as there is currently no single organisation that has a mandate to develop, implement and promote adoption of health information standards in order to fulfil the whole of lifecycle processes needed to proliferate the adoption of standards. In Ireland parts of the lifecycle for standards development are the responsibility of HIQA, HSE and furthermore some parts of this lifecycle are absent. There has been an under-investment in standards development and implementation and fragmentation of resources, experience and expertise which are spread across multiple agencies.

In April 2022, the Department of Health announced it had received Government approval to develop the general scheme of a Health Information Bill, with the aim of ensuring that Ireland has a fit-for-purpose national health information system. The proposal will also support the introduction of a National Health Information Agency with clearly specified functions and governance rules in relation to the collection and processing of health information for population health purposes and research and innovation that leads to better outcomes for patients i.e. a health information agency for secondary use data.[4] From international experience, many OECD countries who have separate organisations responsible for national health data (or secondary use data) and for national electronic health record systems (primary use data), have proven problematic. Specifically, this occurred where there were no formal structures requiring separate organisations to work together toward a common goal of enabling the primary and secondary use of health data.[19] Given this new development from the Department of Health, which is welcome, it is now timely to review how we in Ireland will progress the health information standards agenda and should include legislation to ensure the adoption of nationally agreed standards by mandating standards to be implemented throughout the national health information system across public and private healthcare.

Recommendations

Strengthening how health information standards are developed and ensuring they are implementable is critical and at a national level requires strong leadership, a dedicated organisation with clear governance structures, stakeholder engagement, a skilled workforce and adequate resourcing.

As highlighted in the Position Paper on National Health Information System Reform (2021),[25] recommendations were made on standards and interoperability calling for: (a) a clear policy decision needs to be made on where the health information standards function will reside and (b) the function for assessing compliance with health information standards needs to be supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE.

From the perspective of developing and implementing national health information standards, this requires orchestration, co-ordination and system-wide oversight of national standards.

Options to provide strategic oversight and governance needed for standards setting and adoption across health and social care in Ireland.

To inform the recommendations on a model for health information standards, HIQA propose the following three options for an organisation to govern and manage the end-to-end lifecycle of technical standards development, implementation and adoption. They include the following and are outlined in detail in section 3.1:

1. Maintain the current status quo — no change
2. The HSE, HIQA and NSAI to establish formal shared governance arrangements for the development and implementation of health information standards.
3. The Department of Health — as it develops new policy — could consider the need to consolidate standards development to include creating a new strategic independent entity which has a broad remit for co-ordinating national efforts in health information, with one of its roles to orchestrate the end-to-end lifecycle of technical standards development and implementation.

Preferred option

To inform the model on health information standards, HIQA considered the arguments for and against options (1-3) which are outlined in detail in section 3.1 of this report. HIQA also took on board the strong findings from the international review that organisations have a wider remit than just standards setting - they have a role in setting strategy for digital health and in some cases implementation.

As HIQA recommended in its Position Paper on Health Information Reform (2021),[25] there is a need for a strategic independent entity, as set out in eHealth Strategy (2013),[1] with responsibility for overall governance around eHealth implementation — including funding, legal enabling, public awareness and stakeholder engagement through building the eHealth ecosystem in Ireland — to work in partnership with Government and State agencies.

HIQA believe that the absence of a single entity leads to overall lack of accountability and coordination for health information across the Irish health and social care system including the development, implementation and adoption of health information standards. International best practice has indicated that a dedicated entity with full authority and responsibility for digital health across both public and private healthcare is optimal.

HIQA's Position Paper on Health Information System Reform (2021) also made a recommendation specifically on standards and interoperability which outlined the need for:

- A clear policy decision needs to be made on where the health information standards function will reside.
- A health information standards setting function, and the function for assessing compliance with health information standards needs to be supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE.

HIQA believes the most optimal model to provide strategic oversight and governance for setting, implementing and adoption of health information standards across health and social care in Ireland is the creation of a new strategic independent entity charged with having full ownership, governance, responsibility and accountability for the delivery of Ireland's national health information system, including primary and secondary use data across private and public healthcare. One of its key roles would include orchestrating and having oversight of national efforts to develop, implement and to promote the adoption of national standards and to work with HIQA's

compliance function, whereby health information services are assessed against national standards.

However, in the absence of such a model — and given the significant undertaking involved in establishing and operationalising a new strategic independent — HIQA suggest an appropriate interim solution could be appropriate whereby the HSE, HIQA and the National Standards Authority of Ireland (NSAI) establish formal shared governance arrangements for the development and implementation of health information standards.

Considering that the Department of Health are currently developing policy, strategy and legislation it is timely to consider the propsed models and determine if firstly Ireland are going to continue to build a standards-based approach and secondly where would this function be best placed to operate effectively?

HIQA is making recommendations under three themes:

- Recommendation 1.0: Model for health information standards and governance structures to support it.
- Recommendation 2.0: Standards development process
- Recommendation 3.0: Stakeholder engagement, each are outlined below.

Recommendation 1.0: Model for health information standards and governance structures to support it.	
Number	**Recommendations**
1.1	HIQA believes the most optimal model to provide strategic oversight and governance for setting, implementing and adoption of health information standards across health and social care in Ireland is the creation of a new strategic independent entity charged with having full ownership, governance, responsibility and accountability for the delivery of Ireland's national health information system, including primary and secondary use data across private and public healthcare. One of its key roles would include orchestrating and having oversight of national efforts to develop, implement and to promote the adoption of national standards and to work with HIQA's compliance function, whereby health information services are assessed against national standards. However, in the absence of such a model — and given the significant undertaking involved in establishing and operationalising a new

	strategic independent — HIQA suggest an appropriate interim solution could be appropriate whereby the HSE, HIQA and the National Standards Authority of Ireland (NSAI) establish formal shared governance arrangements for the development and implementation of health information standards.
1.2	A clear policy decision on using a standards-based approach for the development, implementation and adoption of health information standards and the model to support ensuring the allocation of adequate resources. This is timely given forthcoming changes in Ireland's policy and legislation around health information.
1.3	Legislation to mandate compliance of nationally agreed health information standards for sharing health information and to promote adoption of standards between major national health information programmes of work and priority Sláintecare projects, including a shared care record, electronic prescribing and national patient summaries and across public and private health and social care services is needed As outlined in HIQA's positon paper on health information system reform, HIQA's remit for assessing compliance with health information standards needs to be supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE. Legislation is needed to ensure that national health information standards are tested and certified for use in national health information systems across public and private health and social care services.
A standards setting function should be responsible for recommendations 1.4 – 1.9 described below:	
1.4	Ensure an appropriate governance structure is established for a health information standards setting function with accountability and national oversight for the development and implementation of standards across the whole-of-lifecycle from inception through to standards development and their adoption and use. All stages of the standards development process needs to be considered including: ▪ Define business case and requirements analysis ▪ Options analysis

	▪ Develop the standard ▪ Test and pilot ▪ Change management, education and training and ongoing support ▪ Approve, publish and implement the standard ▪ Compliance, conformance, certification and or accreditation ▪ Maintenance and support
1.5	Establish a Programme Board comprised of independent subject matter experts — both clinical and technical — in the area of national health information standards as well as public and patient representatives. Primarily, this Board would be responsible for overseeing and governing the development of national health information standards for use in health information systems in both public and private healthcare across the health and social care system to enable interoperability. Its purpose is to support and promote the development, and use of health information standards across the health and social care service in Ireland including to: ▪ Provide standards-related advice to the Department of Health by proposing national standardisation policies, influencing policy-makers about standards and prepare briefing material for Governments and policy-makers on the importance of making standardisation visible in all strategies that depend on interoperability. ▪ Ensure standards support the future direction of a National Health Information Strategy. ▪ Ensure health information standards are developed in accordance with approved processes for I. **Prioritisation** – to identify and prioritise the projects where health information standards are required, that is to say, new eHealth services, domains or retrofitting existing health information systems. Prioritise the development of national health information standards across a broad range of domains including: II. **Approval** – Approve and endorse standards for publication and gain consensus and agreement with all required stakeholders on health information standards III. **Change management activities** – for governance and maintenance of health information standards incorporating an implementation science approach to ensure standards development incorporates human factors throughout the standards development lifecycle.
1.6	Establish expert working groups needed for domain expertise and specialist knowledge of the topic on which the standard is based on.

	Informed by a prioritisation process, the purpose of the expert working group is to aid the development of specifications based on a quality assured standards development process.
1.7	Developing, implementing and maintaining consistent national standards for data standards (content), terminology (semantics), data exchange (electronic messaging) and harmonisation of data privacy and security policies and practices. More specifically, the scope of health information standards should include: health information modelling, clinical and administrative datasets, messaging standards (ISO, HL7, OpenEHR), information standards for clinical terminologies (Irish editions of SNOMED CT) and classifications (ICD-10-AM) and data security standards.
1.8	Developing a National Interoperability Roadmap to be included as a key priority in an overarching national health information strategy for Ireland. The roadmap should include the requirements for standards for various purposes for specific use cases covering domains such as primary care, acute, and community care settings.
1.9	Building relationships with stakeholders across the health and social care sector to raise awareness and promote adoption of health information standards. National stakeholders could include: policy and legislative organisations, HSE eHealth and disruptive technologies, HSE clinical programmes, national standards organisations including HIQA, National Standards Authority of Ireland (NSAI), professional representative bodies, such as for general practice and pharmacy, patient and public organisations, public and private hospitals, academics and subject matter experts, broader governmental bodies and the health IT vendor community in Ireland.

Recommendation 2.0 Standards development process

Number	Recommendations
2.1	A standards setting function in collaboration with expert working groups should develop specific, fit-for-purpose standards and ensure whole-of-lifecycle maintenance and support using a robust standards

	development process and complete the following recommendations from 2.2 – 2.8 below.
2.2	Develop digital maturity assessments using a consultation process with key stakeholders to identify main gaps in the adoption of national standards and highlight the level of standardisation maturity across Ireland.
2.3	Maintain a standards development framework model to highlight types of standards, that is to say, catalogue of appropriate standards to use depending on the use case and where standards need to be applied in various domains of healthcare. Similar to the NHS Digital which published a draft framework — NHS digital, data and technology standards framework describing their expectations around the use of data, interoperability, and design standards within the NHS.[26]
2.4	Develop standards for specific use cases, to integrate standards from different healthcare domains, and ensure they are fit for purpose. This should incorporate modern standards, such as HL7 FHIR.
2.5	Provide support for implementation through education and training, tooling and guidance documents to assist with implementation for all stakeholders implementing standards.
2.6	Ensure that nationally agreed standards are included in procurement specifications.
2.7	Establish conformance assessment and certification processes to assure that specific products are compliant with standards. Develop certification for vendors of IT solutions and digital tools for compliance with national standards.
2.8	Develop an evaluation framework to continuously improve the standards development process to takes account of lessons learned from the implementation of previous health information standards.

Recommendation 3.0: Stakeholder Engagement

Number	Recommendations
3.1	A standards setting function should establish international and national collaborations and undertake engagement with key stakeholders through functions 3.2-3.7
3.2	Undertake stakeholder engagement and public consultation about national health information standards and their implementation, adoption and use; and provide public transparency through clear communication about health information standards.
3.3	Develop a comprehensive stakeholder engagement plan – for both national and international stakeholders. This should identify all stakeholder groups needed for the development, deployment and maintenance of health information standards. Stakeholders should be engaged with consistently and appropriately as needed through a variety of means, including discussion groups and forums, reference groups and peer networks, and patients and patient representative organisations to share knowledge and best practices.
3.4	Build consensus regarding national health information standards across a broad spectrum of stakeholders, and position the health information standards function to expand its leadership role in healthcare information standards across Ireland.
3.5	At local level, establish a network or forum to support IT departments and software developers, and for people responsible for managing and delivering health and social care services at a service provision level. The aim of this network should be to assist and guide in developing consistent standards and guidance for implementing health information standards, and enhancing upskilling and training people delivering services within health and social care services.
3.6	Establish relationships and participation in leading International Standards Development HL7, Organisations such as OpenEHR, and continued participating in ISO, SNOMED International.
3.7	Establish HL7 Ireland to support and collaborate with the health IT community in Ireland and to contribute to national and international standards development.

Introduction

A recent position paper published by HIQA on *The need to reform Ireland's national Health Information System to support the delivery of health and social care services*, (referred to in this report as HIQA's position paper on health information reform), called for the reform of Ireland's national health information system. The report makes recommendations in six areas to move towards a well-functioning national health information system: strategy, strategic leadership and governance, legislation, workforce, health information standards and interoperability, and health information infrastructure and security.[(25)]

In particular, the paper explicitly calls for three fundamental enablers to realise the vision of what a well-designed national health information system would look like:

- Strategy – A clear national health information strategy is needed, outlining a sound legal framework, a viable workforce and appropriate funding mechanisms, Ministerial approved standards, and a robust and secure health IT infrastructure.
- Strategic leadership and governance – A strategic entity (eHealth Ireland) should be established, outside of the HSE, with the legislative remit to provide strategic leadership and governance on eHealth and on the collection, use and sharing of health information in Ireland. In parallel, an operational function, developing and supporting the systems required for the delivery of care, should continue to exist in the HSE. Clear policy on health information is also needed, together with a clear roadmap on how the different agencies within the health and broader governmental organisations are coordinated to deal with health information.
- Legislation – A legislative framework, setting out clearly how information should be collected, used and shared for people interacting with the health and social care system and covering national eHealth priorities, including summary and shared care electronic health records.

The paper identified the need for clear policy direction for national health information standards, for resolution of current fragmentation of governance structures, and for a secure health IT infrastructure, supported by ongoing investment. Public and patient engagement was also held to be critical to the successful workforce, to support health professionals to use digital health solutions in an effective, responsible and ethical way.

As highlighted in HIQA's position paper on health information reform, recommendations made on standards and interoperability are for: (a) a clear policy decision needs to be made on where the health information standards function will

reside and (b) and the function for assessing compliance with health information standards needs to be supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE.

Based on this need, HIQA has developed draft recommendations on a model for health information standards to support the delivery of health and social care services in Ireland.

HIQA believe the development of these draft recommendations is timely given forthcoming changes in Ireland on policy and legislation around health information.

These draft recommendations have been published for public consultation to ensure that members of the public have an opportunity to engage in, feedback on, and inform the final recommendations.

The draft recommendations were developed as per HIQA's legislative remit under the Health Act 2007 and subsequent amendments to the Act. Under the Health Act 2007, HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information. The responsibilities of HIQA in this regard are outlined in the following sections of the Act:

- Section 8(1)(i): to evaluate available information respecting the service and the health and welfare of the population.
- Section 8(1)(j): to provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the information referred to in paragraph (i).

Methodology

The recommendations were developed in line with the methodology outlined in HIQA's *Health Information and Standards Quality Assurance Framework* and include the following stages:

Stage 1: Evidence review - At this initial stage of the development process, HIQA undertook a review of health information modelling to identify examples of best practice internationally, which is available on its website. Experts in each of the five jurisdictions were contacted for interview to ensure the most relevant and up-to-date information was gathered. The five jurisdictions included in the reviews were: Australia, Denmark, England, New Zealand and Ontario (Canada). In addition, an analysis of the current health information standards landscape in Ireland was included in the review. The significance of the key findings from the evidence gathered will be discussed in this document.

Stage 2: Advisory group - An advisory group was convened to provide assistance in developing the recommendations (see Appendix A for list of members). Advice and guidance is sought from the advisory group throughout the recommendations development process.

Stage 3: Public consultation - Based on the findings from the evidence review and engagement with stakeholders, the project team prepared a draft set of recommendations for public consultation. The advisory group reviewed the draft recommendations prior to the public consultation.

Stage 4: Next steps (Approval of draft recommendations) – After the public consultation, the recommendations will be reviewed and amended to reflect the feedback. An advisory group meeting will be reconvened and the updated draft recommendations will then be presented to the advisory group for final considerations. Following analysis and review of the additional feedback, the final recommendations document will be completed and sent for approval to the HIQA Executive Management Team, before final approval by the HIQA Standards Information Research and Technology committee, a sub-committee of its Board, and then the HIQA Board.

Stage 5: Publish the recommendations - After the HIQA Board has approved the recommendations, they will be submitted to the Minister for Health for approval and will also be published on the HIQA website.

Chapter 1 – Health Information Standards

Health information standards are essential to improving Ireland's health and social care services. Health information standards underpin health information systems. Service providers share information according to a set of standards which are agreed-upon requirements for connecting systems together. Agreeing national and international standards greatly increases the potential for having quality health information available when and where needed, leading to quicker and more informed clinical decisions and ultimately, improvements to patient safety and patient outcomes.

Standards are defined, updated, and maintained by international standards development organisations (SDOs) through a collaborative process involving all stakeholders that use the standards. Typically, at a national level, organisations are dedicated to developing national standards, implementation specifications and guidance to support a variety of clinical health information interoperability needs. Assessing compliance against national health information standards that are in use in eHealth services may also be undertaken by a regulatory authority.[27]

Across health information systems, standardisation is required at many levels — data standards, data dictionaries, metadata standards, key performance indicators, messaging standards, classification and terminology standards. Processes are required to ensure that data quality is incorporated into the collection and use of health information, that is to say, some business rules, quality checks are embedded in data exchange, data, and code system standards. For the purpose of these draft recommendations on a model for health information standards development in Ireland, the scope includes standards to support interoperability and should include: health information modelling, clinical and administrative datasets, key performance indicators, messaging standards (ISO, HL7, OpenEHR), information standards for clinical terminologies (Irish editions of SNOMED CT) and classifications (ICD-10-AM), data security standards and a supporting data security and protection toolkit.

1.1 Expected benefits

A range of stakeholders will benefit from the development of health information standards supporting semantic interoperability, including service users, service providers and implementers. The benefits are outlined below:

- Service users benefit from interoperability in a number of ways. By ensuring that all relevant high quality information relating to their care is available in a timely fashion, the risk of an adverse event is reduced, quality is improved,

and the unnecessary duplication of tests and investigations is eliminated. Specifically, patients will benefit from safer and timelier care.

- Service providers manage large volumes of health information to carry out a multitude of clinical tasks. Structured information enables better communication and transfer of knowledge between healthcare professionals. Service providers can reduce implementation costs, accelerate integration projects, and take advantage of common tooling by making an effort to use standards whenever possible.
- Implementers - when implementing computer systems, health interoperability standards can help to reduce the time to design a computer system, improving the quality of the solution, and ensuring better integration with other computer systems.

By not working towards implementing semantic interoperability across the health and social care sector and not applying a standards-based approach to healthcare, it will negatively impact patient safety, reduce efficiency, hinder continuity of care, diminish clinical decision making, decrease patient engagement and it increases costs.

The most effective health information systems are fully interoperable and interconnected, achieved by using a strategic standards based approach. This makes it fundamental that a standards-based approach is used to define, structure and provide semantics for health information to enable service providers and service users to share health information regardless of the system they are using. In effect, all of the systems involved need to use a common 'language' or standard to communicate. Using a common 'language' in this way is known as semantic interoperability([2]). It ensures a patient's health information can be shared securely, seamlessly and appropriately, and is meaningful for people using the information, which improves the overall coordination and delivery of healthcare.[(28)]

Interoperability depends on widely adopted health information standards being implemented throughout the national health information system. Without interoperability, it is more time consuming and costly to provide patient care. To achieve widespread adoption of agreed standards, adherence to the whole-of-lifecycle for developing and supporting health information standards should be undertaken and typically covers - developing, testing and piloting, implementation,

[2] Interoperability has been defined by the Global Digital Health Partnership as: The ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards. Many systems can achieve technical interoperability but the real challenge is when different EHR systems attempt to share clinically meaningful information. Semantic interoperability can only be achieved when a reference model, data structures and terminologies or clinical classifications work together harmoniously and not as separate entities.

technical conformance and certification and maintenance of health information standards. As evidenced internationally, standards development involves not only developing and publishing standards but also piloting and implementing standards in real world systems. Often, standards developers play an important role in implementation by ensuring conformance and certification of standards in health information systems. Assessing compliance against national health information standards that are in use in eHealth services may also be undertaken.

1.2 How Health Information Standards are developed

Standardisation is achieved not just through developing and publishing standards but through the implementation and adoption of standards across the health and social care system. Standards are not static and they require ongoing management and maintenance. They have lifecycles and they evolve as requirements and technologies evolve, and through evaluation of their performance.

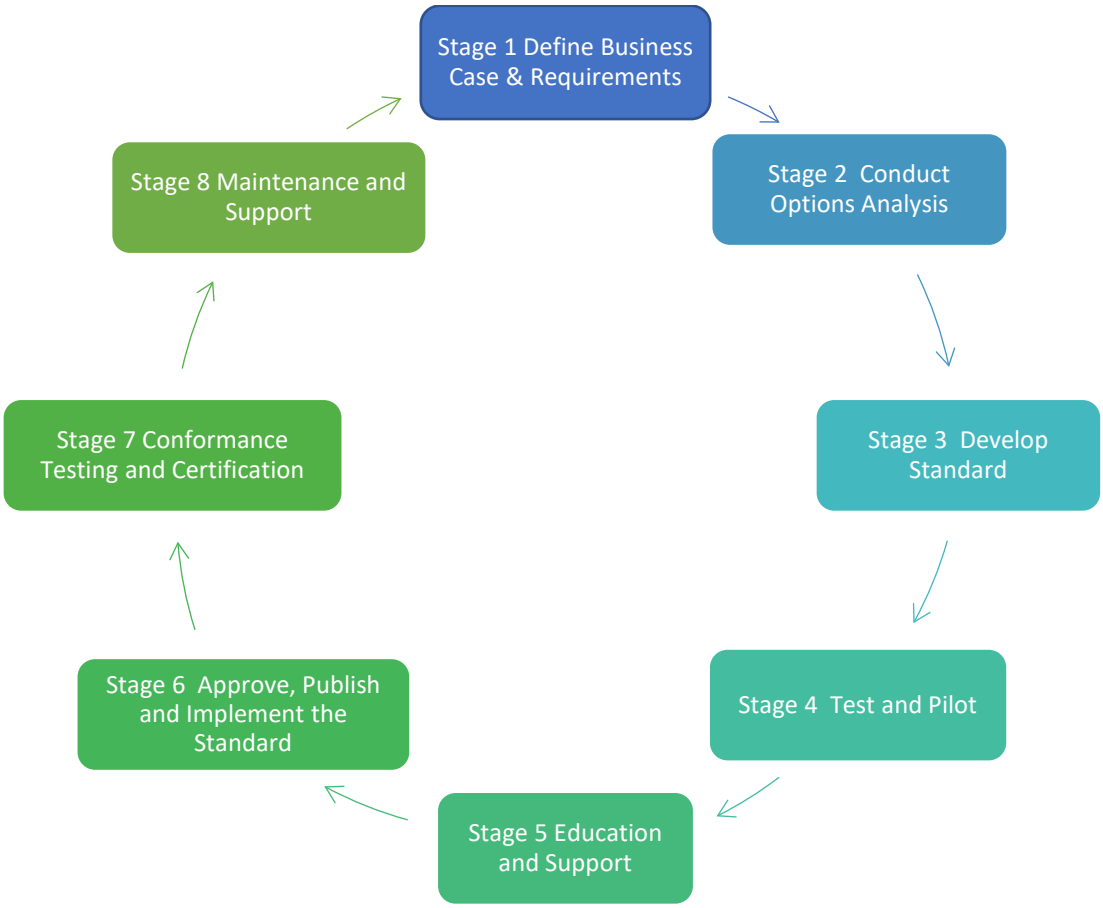
Standards are dependent on other standards and the ability for standards to work together must also be maintained – a change in one may require change in others. A standards framework can be used to gather and present information about standards including the types of standards and where standards are applied in various domains of healthcare. It can also present the standards landscape in a particular country with an overview of standards governance, development, adoption, and implementation. For example, the National Health Service's in England NHS Digital published a framework — NHS digital, data and technology standards framework — which describes their expectations around the use of data, interoperability, and design standards within the NHS.[(26)]

Digital maturity assessments can be developed using a consultation and co-design process with key stakeholders to identify main gaps in the adoption of National Standards and highlight the level of standardisation maturity across a country. Another important consideration is around profiling. Standards need to be tailored for specific contexts reflecting local requirements and workflows to meet specific use cases. Also, additional investment in tooling that allows developers to experiment with and refine their approaches to the adoption of standards, and for standards developers to learn from these processes should be planned.[(27)]

There are various stages to the standards development lifecycle. Having analysed the standards development process for technical standards in three countries of comparable population size to Ireland – Denmark,[(12)], Scotland,[(13)] and New Zealand,[(14)] – and a Canadian province with almost three times the population –

Ontario[15,16,17], Figure 1.0 below depicts the main stages a standards lifecycle. Diagram 1.0 below elaborates on each stage.

Figure 1.0 Eight Stages of the Standards Development Lifecycle



HIQA adhere to the development of standards in consultation with key stakeholders and through public consultation. However, there has been a lack of progress in the standards development area as it has been underdeveloped and under resourced. HIQA's current remit does not allow for the implementation of standards. As a result, key stages of the standards development lifecycle are not conducted including:

- Test and pilot
- Change management, education and training and ongoing support
- Approve, publish and implement the standard
- Conformance and certification

Table 1.0: Stages of standards development and what steps are undertaken in each stage based on international evidence.

Stage of Standards Development	Description of Stage
Stage 1 - Define Business Case and Requirements Analysis	Identify and confirm the need for a standard. This could be through a request for a new standard or a request to change existing standards. Requests are assessed and prioritised.
Stage 2 - Options Analysis	Following a request for a standard, the process for researching and developing the standard begins. An options analysis is conducted to determine if other standards exist that can be re-used, either in whole or in part, adopt or adapt an existing standard or develop a new one.
Stage 3 – Develop the standard	Undertake research and produce the draft standard in consultation with stakeholders and user communities, incorporating comments, workshops, through as many iterations as needed to achieve consensus.
Stage 4 – Test and Pilot	Versions of the draft standard are tested to uncover any design issues and to be deemed fit-for-purpose prior to deployment. At this stage, the draft standard may be piloted.
Stage 5 – Change management, education and training and ongoing support	Education and training, awareness raising, need to be considered support networks may need to be established to assist with implementation. Support is provided in the form of tools, guidelines and advice.
Stage 6 – Approve, Publish and Implement the Standard	Approve, publish and then implement the interim standard. This stage can involve deployment of the proposed standard in live settings. The capture of implementation feedback is also important as input for continuous improvement.
Stage 7 - Compliance, conformance, certification and/or accreditation	Check that standards have been properly implemented and that lessons learned are captured to be fed back into subsequent revisions of the standard.

Stage 8 - Maintenance and Support	Standards require ongoing maintenance to ensure they are accurate in view of changes to requirements, supporting technologies. Different maintenance strategies may need to be defined for specific standards.

Chapter 2 below outlines the organisations internationally who develop health information standards and the governance structures they have in place to support this function. The current Irish landscape regarding health information standards is also described.

Chapter 2 – Model for Health Information Standards Development

2.1 International Evidence

Evidence from countries internationally suggest that there is a single dedicated organisation or function which has responsibility for developing health information standards and in some cases also has a much wider remit including developing strategy and implementation of major health information systems. Internationally these organisations include the Australian Digital Health Agency (ADHA), MedCom in Denmark, NHS Transformation in England, and the Health Information Standards Organisation (HISO) in New Zealand.[6,8,29,30] From the HIQA best practice review on health information modelling,[5], the jursidictions reviewed have different governance structures in place for delivering eHealth, however they all place significant emphasis on the development of health information standards. MedCom in Denmark and NHS England, not only develop health information standards but also play a role in implementation. In November 2021, it was announced that NHS Digital the function that implements standards would be merged with NHSX their standards setting functions and incorporated into NHS England Transformation Directorate.[31]

All countries reviewed, have included conformance assessment and certification as an important feature of a standards development process. MedCom was the first European Competence Centre to follow the ISO9001:2015 standard in the process for testing and certification of healthcare IT-systems, resulting in high-quality and uniform test and approval of systems.[32] In this report, we highlight the distinction between ‘conformance testing’ and ‘compliance’ whereby conformance testing is conducted as part of developing and implementing standards whereas ‘compliance’ refers to assessing compliance against the standard when it has been adopted and are in use in an eHealth service such as electronic referrals' or the identifiers service. This is done outside the standards setting development organisation. Internationally, experience with assessing compliance against eHealth services is limited. Where compliance is starting to be considered, in Sweden and the Netherlands, it is usually done by organisations at a higher level and a broader level remit on patient safety i.e. the regulator or inspectorate carry out this function.

2.1.1 Australia

In Australia, the Australian Digital Health Agency, is tasked with improving health outcomes for Australians through the delivery of digital healthcare systems and leading the development of the National Digital Health Strategy and its implementation framework. The Australian Digital Health Agency has a mandate to

ensure health information standards including interoperability standards are in place and effective. Australia has some world-leading expertise in the area of health information standards and historically a good track record of influencing international standards development.(6)

The Australian Digital Health Agency is currently governed by a 'skills-based' Board comprised of members with skills, knowledge and experience relevant to business leadership as well as the health sector. To assist the Board in carrying out its functions, there are four standing advisory committees including the Clinical and Technical Advisory Committee who provide advice to the Board about the efficient and effective delivery of clinical care using digital health and the architectural integration of digital health systems.(33)

A recent report was commissioned by the Australian Digital Health Agency in 2020 to provide advice on how interoperability standards development, maintenance and management can be improved to meet health sector needs.(27)

For example, it outlines how the Standards Development Function should develop specific, fit-for purpose standards and they should be maintained across the whole-of-lifecycle. The type of competencies needed to carry out this function appropriately is to have:

- Standards development expertise
- Standards implementation expertise
- Awareness of other relevant standards and endeavours
- Health sector knowledge (workflows, data)
- Digital health industry knowledge (standards used and standardisation capabilities)
- Product management expertise
- Negotiation skills

The report outlined the core roles and functions required for a health information standards development function and is summarised in Table 2.0 below. The table identifies the essential roles that an organisation needs to develop national health information standards taking into account that standards require ongoing maintenance throughout the whole of their lifecycle – from funding through to support for standardisation and conformance and certification testing. Each role has corresponding functions associated with them and the core competencies required. (27)

Table 2.0: Roles, functions and competencies required for standards development, maintenance and management. Taken from 'A Health Interoperability Standards Development, Maintenance and Management Model for Australia'.[27]

Role	Function	Competencies
Orchestration of a complex, adaptive standards ecosystem	▪ System-wide oversight of the interoperability standards ▪ Development and communication of agreed architecture and roadmap to underpin standards development ▪ Source of truth[3] regarding standards requirements for various purposes ▪ Ongoing governance of the national Standards Development Model ▪ Development of standardisation policies ▪ Sourcing of resources for sustainable standards development capabilities ▪ Liaison and advocacy with other key players to ensure overall architectural coherence ▪ Evaluation of the value realised through the development and adoption of health interoperability standards.	▪ System governance ▪ Engagement, partnership and collaboration ▪ Strategic and tactical planning ▪ Liaison, negotiation, advocacy ▪ Standardisation expertise (strategic, technical) ▪ Health sector knowledge (policy, structures & frameworks) ▪ Digital health industry knowledge (markets) ▪ Enterprise architecture expertise ▪ Policy development and implementation
Commissioning	▪ Articulation of the cases for and requirements of new standards development nationally ▪ Articulation of purchaser-required standards development protocols (e.g. process requirements) ▪ Sourcing of resources for new standards development ▪ Assurance that developed standards are fit for purpose	▪ Procurement and commissioning expertise ▪ Strong standardisation expertise (technical) ▪ Strong health sector knowledge (workflows, data) ▪ Digital health industry knowledge (standards used and standardisation capabilities)

[3] In information systems design and theory, single source of truth (SSOT) is the practice of structuring information models and associated data schema such that every data element is mastered (or edited) in only one place. Any possible linkages to this data element (possibly in other areas of the relational schema or even in distant federated databases) are by reference only. Because all other locations of the data just refer back to the primary "source of truth" location, updates to the data element in the primary location propagate to the entire system without the possibility of a duplicate value somewhere being forgotten.

Standards development	• Development of specific, fit-for purpose standards and associated artefacts, sourced both internationally and locally • Whole-of-lifecycle maintenance and product management	▪ Standards development expertise ▪ Standards implementation expertise ▪ Awareness of other relevant standards and endeavours ▪ Health sector knowledge (workflows, data) ▪ Digital health industry knowledge (standards used and standardisation capabilities) ▪ Product management expertise ▪ Negotiation skills
SDO accreditation or endorsement	Independent assurance that SDOs meet international and national requirements for standards development	▪ Accreditation expertise ▪ Standards development expertise
Support for standardisation	• Marketing • Consistent and coherent education and training • Dependent on the kind of support concerned • Authoritative technical support • Support for networking amongst developers and implementers • Sandpits, reference sites, etc. • Knowledge translation and preservation	

	• Community-building	
Conformance assessment and certification	Assurance that specific products are standards-compliant	▪ Conformance assessment and certification expertise ▪ Strong standardisation expertise (technical)
Research and development	Ongoing investigation into how standardisation can be best directed to achieve interoperability in a context of exponential growth of the Internet of Things and a data tsunami	▪ Research and development expertise
Funding	Ensuring sufficient funds and other resources flow from all sources, public and private	

2.1.2 Denmark

Denmark has significantly invested in a standards-based approach to health information. Denmark commenced its journey with the establishment in 1994 of MedCom and focused on developing health information standards to enable interoperability that allows the most common electronic messages to pass between various stakeholders in the healthcare system — referrals, discharge summaries, prescriptions. In 2011, it was reported that the system was almost now fully electronic with all frequent documentation being transferred electronically.[29]

In Denmark, a governance structure exists to support parties who are involved in prioritisation and implementation of health information standards. The following section gives an overview of what governance structures are in place including groups and committees and the role they play in the standards lifecycle:

- The **Ministry of Health (MoH)** is the highest authority in the Danish healthcare sector. They have the legal authority to decide on the use of standards.
- The **National Board of eHealth** is the highest authority regarding eHealth. It advises the Minister of Health on the IT-strategies and IT-architecture along with national demands and standards for eHealth. The board also initiates and secures the quality of new approaches regarding cross-sector investments.

- The **Health Data Authority** (SDS): the Danish Health Data Authority is instrumental in providing coherent health data and digital solutions that benefit patients and practitioners as well as research and administrative purposes in the healthcare sector. The Danish Health Data Authority is a part of The Ministry of Health and was established in November 2015. It is made up by an Executive Management, an Executive Secretariat and eight departments with approximately 300 employees.

  It is responsible for the IT architecture and standards framework. They do this in cooperation with the different actors in the health care sector. It is the responsibility of SDS to approve IT standards used within the Danish health care sector and they have a national catalogue of standards. In the catalogue of standards, you find an overview of which demands an IT system in the health care sector has to meet. The catalogue is targeted at organisations who develop requirements and specifications for IT systems, procurers, IT vendors as well as the owners of standards. Before a standard is approved and binding, a public hearing is conducted.
- Sitting within the Health Data Authority (SDS), an **advisory committee** has been established to assess and select standards and assess architecture in healthcare.
- **MedCom** was established in 1994 as a publicly-funded, non-profit co-operation. MedCom facilitates the communication between authorities, organisations and private firms linked to the Danish healthcare sector. MedCom is financed and owned by the Ministry of Health, Danish Regions and Local Government Denmark. One of its key activities is regarding the development of standards and testing and certification — MedCom documents, tests and certifies IT vendors' implementation as well as offering support, consultancy and training courses and are responsible for a number of public IT solutions.[29]

MedCom's Standards development lifecycle is outlined below:

MedCom's role is to develop new health information standards and profiles and update existing standards when required. MedCom is the owner of approximately 194 national standards which are in the national catalogue of standards. When a standard is approved by RUSA - advisory committee for standards and architecture - and published in the catalogue of standards, the vendors are responsible for implementing it in their system and make it available to their users in the healthcare sector. Once they have updated their system, MedCom has a test procedure which becomes a certification when the system passes all tests. MedCom was the first

European Competence Centre to follow the ISO9001:2015 standard in the process for testing and certification of healthcare IT-systems, resulting in high-quality and uniform test and approval of systems.(32) MedCom also helps the regions and municipalities to have the standards implemented in their healthcare organisations. The process includes the following:

- **Identify business need (funding, requirements) -** When a new standard or version is proposed, it is often described in a strategy and/or always agreed between the partners involved. It can be part of the financial agreement between the government and the municipalities and regions which takes place every year. This means that the financial aspect of implementing the new standard is addressed and is binding for all involved parties.
- **Develop the standard in consultation with stakeholders -** A draft standard is produced in consultation with stakeholders and user communities. Once agreed upon, a project is set up and development starts. If MedCom is asked to lead the project, a project group is established with all relevant stakeholders in order to ensure that what is developed is exactly what is requested from the healthcare professionals. The main stakeholders are regions, municipalities, vendors, doctors' associations, and SDS. This ensures that the project is anchored locally, that vendors knows what is expected of them and can provide input on what is technically possible, and that content is correct from a health care professional perspective. MedCom's key role is to bring stakeholders together to develop standards which gives values to the end users. Involvement of key stakeholders in the whole process is key.
- **Test and pilot -** When a standard has been developed, it is piloted and tested in real use in order to gain experiences and collect input which means adjusting the standard before implementing it nationally in all relevant systems. Usually, an agreement is made with some system vendors who implement the new standard in their system for the pilot phase.
- **Conformance and certification –** Vendor systems are tested and certified by MedCom before piloting. The pilot vendors are compensated financially.

When the project is operational/business as usual, official system management is agreed upon. The responsibility of system management can lie with a region, a company or MedCom, for example. MedCom monitors the use of standards.

Also, MedCom is the main provider for maintaining international standards for use in Denmark. It leads working groups where all parties are invited to join in this effort, which involves regions, municipalities, GP organisations, vendors, the Danish Health Data Authority and the GTS institutes that offer knowledge, technology and

consultancy (GTS – Advanced Technology Group is a network consisting of independent Danish research and technology organisations).

2.1.3 England

In England, interoperability standards have been a priority and the NHS's Long Term Plan (2019) underpins the importance of technology in the future NHS committing to: 'Mandate and rigorously enforce technology standards ... to ensure data is interoperable and accessible' and 'requiring every technology supplier to the NHS to comply with published open standards to enable interoperability and continual improvement'.[34]

In 2021, the Health Secretary, announced a re-organisation of how digital functions are structured within the NHS in England, committing to merging both NHSX and NHS Digital into a NHS Transformation Directorate. responsible for driving digital transformation and leading policy, implementation and change in the area of digital health.[8] NHS Transformation directorate is accountable for ensuring there are robust processes and governance models for the development of information standards. The Standards and Interoperability team at NHSX were established to drive this aim forward and establish fit-for-purpose interoperability standards, working closely with NHS Digital including NHS Digital's information standards delivery, assurance, and publication and implementation teams - the wider NHS, the social care sector, standards bodies and the vendor community. Their goal is to deliver tangible benefits to the health and care service by developing and improving the governance, framework and processes to support standards which get widely adopted across the system.[35]

NHSX have identified and are focusing on five key priorities to enhance standards and interoperability. In summary, their priorities are to:

- Develop a new end-to-end process and governance model for standards development to ensure that new standards are fit for purpose and co-developed with key users
- Publish a standards and interoperability strategy outlining a vision and the benefits of adopting standards so they are clearly understood by both clinicians and technical staff.
- Publish an Open source playbook to provide tangible guidance and advice to providers and commissioners for adoption and implementation of open source solutions.
- Outline a long-term roadmap for standards and interoperability with timelines for new standards and prioritising the implementation of existing standards.

- Launch a new service, the standards portal to include a registry of standards used across health and care collating standards by use-case, providing clarity on which standards are applicable to enable vendors, providers and commissioners to select standards for adoption.[36]

Aligned with priority one, the NHSX Standards and Interoperability programme published the 'end-to-end operating model for interoperability Standards core concepts' in early 2022.[11] It was developed in conjunction with a variety of stakeholders and outlines the requirements and core capabilities needed in a model for developing, managing, maintaining and retiring interoperability standards. The intention is to publish a more detailed roadmap on how to establish an operating model for information standards in the longer term.

The model applies to four types of standards for the processing of health information including governance and codes of practice standards, record standards for the collection and use of information, data definitions and terminologies to provide semantics or meaningful information, and technical standards and specifications for data exchange. A capability framework defines the requirements and criteria needed to operate a model and provides the structure for developing and assessing improvements to how standards are developed, managed, maintained and retired. The capabilities are categorised into four groups including:

- **strategic oversight and governance** - relates to managing the overarching strategies, information model and architectures needed for standards setting and adoption across the health and social care sector.

- **standards development lifecycle management** - a set of capabilities to allow programmes to achieve solutions for use-cases and user needs, to develop interoperability and other information standards in an agile way, and develop a lifecycle framework for standards management.

- **interoperability standards ownership and management** - a set of capabilities to allow interoperability standards to be actively managed, owned and updated in line with use-cases.

- **adoption, monitoring and compliance** - a set of capabilities to support transformation programmes with managing the roll out of information standards to the health and social care system, support adoption of standards, and support providers and suppliers with implementation.

In England, NHS Digital play a role in technical conformance and compliance and in order to connect to services such as the electronic prescription (ePrescription) services, vendors are required to have the systems to be certified by NHS Digital and are provided with a spine compliance certificate.[37] In addition, NHS Digital provides the Interoperability Toolkit (ITK) which is a national standard that defines requirements and rules for the creation and transport of electronic health information. The ITK supports interoperability within local organisations and across local health and social care communities. Vendors can self-assess against the toolkit and certificates are awarded following successful submission of test results and supporting evidence. Finally, SNOMED CT has been adopted as the national clinical terminology in England and as of 1 April 2018 SNOMED CT was required to be used across primary care settings.[38,39]

2.1.4 New Zealand

The Health Information Standards Organisation (HISO) was established in June 2003 and is a committee operating under the authority of the Ministry of Health, accountable to the Deputy Director-General of Health, Data and Digital. HISO is the governing body for health information standards in New Zealand.

HISO's overall purpose is to ensure that appropriate standards benefit the public through the best use of information and digital technology. HISO governs the selection, development and adoption of information and digital standards for the health and disability sector. The standards lifecycle can include tracking, evaluating, selecting and adapting international standards, and commissioning new standards, for national use. HISO empahasise the importance of trying to ensure that standards are adopted and used productively in widely implemented solutions. To meet these objectives, HISO is responsible for ensuring that standards are:

- 'aligned internationally and based on best practice evidence
- consistent with the national strategic and architectural direction
- introduced in consultation with the sector
- promoting collaboration and innovation
- published and proactively maintained
- supported by implementation guides and tools
- adopted widely and adding measurable value'.[40]

HISO creates technical working groups to evaluate, develop and review standards and lead their implementation. Working groups develop, review and maintain

standards for a number of years. Standards advisors in the Data and Digital directorate support HISO and its working groups, to perform research, provide advice, help to draft standards, support and monitor adoption and maintain work plans.(41)

Table 3.0 HISO Actors involved in the standards development lifecycle and their responsibilities. (Taken from New Zealand HISO).

Individual	Group Definition	Responsibility
Project / proposer	Identifies the need for a standard to be developed, engages early with the HISO office about the proposed development, and is the driving force in terms of progressing the development work through to the public comment stage.	▪ Collaborating with the HISO office ▪ Establishing (in conjunction with HISO office) and managing the working group ▪ Gathering evidence around standard's fit-for-purpose and implement ability.
HISO office	The operation arm of the HISO committee.	▪ Providing support, advice and expertise on standards development ▪ Working collaboratively with the project/proposer ▪ Assisting with development of the working group to ensure balanced representation. ▪ Providing early advice on what standards may be required. ▪ Ensuring development processes are followed appropriately. ▪ Managing stages of the HISO development process.
HISO committee	Its purpose is to support and promote the development, understanding and use of health information standards across the New	▪ Providing standards related advice to the Ministry of Health. ▪ Ensuring standards support the future direction of the New Zealand Health Strategy.

	Zealand health and disability sector.	▪ Ensuring health information standards are developed in accordance with approved processes. ▪ Approving/endorsing standards for publication.
Working group	Group of individuals selected for their specialist knowledge of the topic on which the standard is based on.	▪ Developing the specification(s). ▪ Working with HISO office through the development. ▪ Reviewing and agreeing actions on comments received during public comment period.

HISO maintains relationships with other national and international organisations in order to deliver standards for the sector. HISO works with health providers and shared services organisations, clinical and consumer groups, software vendors and industry bodies, the academic community, the wider government sector and other standards development organisations. HISO links with the international standards community through the SNOMED International for SNOMED CT, and through HL7 New Zealand for HL7 standards.

New Zealand has also developed an interoperability roadmap which is a key part of the Ministry's digital health strategic framework which will 'accelerate a shift to a fully interoperable digital health ecosystem'. Standards are integral to realising the vision of the roadmap.[42]

2.1.5 Technical conformance and certification

All countries reviewed, have highlighted the need for technical conformance and certification of a standard (product) as an important feature of the standards development process. MedCom in Denmark documents, tests and certifies IT vendors' implementation as well as offering support, consultancy and training courses. Vendor systems are tested and certified by MedCom before piloting. The pilot vendors are compensated financially. MedCom was the first European Competence Centre to follow the ISO9001:2015 standard in the process for testing and certification of healthcare IT-systems, resulting in high-quality and uniform test and approval of systems.[32] Australia's Digital Health Agency promote the adoption of standards by co-producing a conformance, compliance and accreditation framework and provide expert advice to implementers in the development of conformance requirements and standards.[43] Canada Infoway have an 'Infoway Mark of Conformity' to certify products to promote compliance with relevant pan-

Canadian standards.[44] In England, in order to connect to services such as the electronic prescription (ePrescription) services, vendors are required to have systems certified by NHS Digital and are then provided with a compliance certificate.[37]

2.2 Compliance against eHealth services.

Assessing compliance of eHealth services such as electronic referrals, electronic prescriptions or identifier services against health information standards can also be undertaken, verifying through quality checks and reviews that healthcare providers and other actors have achieved interoperability standards and are exchanging useable, high quality data and improving data flow throughout the health and social care system.

In the Netherlands, NICTIZ develops health information standards.[45] The Health and Youth Care Inspectorate (or IGJ), part of the Ministry of Health, Welfare and Sport (VWS) supervise healthcare and youth care services and the international market for medicines and medical devices. The inspectorate covers a wide range of healthcare services and providers, including youth care. Regarding eHealth, there is a focus on safe products and safe use of medical technology and software in the healthcare setting. The inspectorate ensure compliance with the relevant legal and regulatory standards. Foreseen challenges include various new regulations such as the EU NIS-Directive,([4]) on information security, AI and information exchange. The inspectorate uses various tools and methods to conduct oversight. In general, oversight is organised either risk-based (e.g. risks for information security) or incidence-based (e.g. incidents with failing systems, power outages). In addition specific themes, such as e-health, may be selected for specific focus. There is a drive towards more data-driven oversight, this is however in its early stages. For both risk and incidence-based oversight various tools are available, for example:

- Desk inspections;
- Face-to-face inspections/site visits and virtual inspections;
- Legal interventions, including warnings, fines/penalties and orders;
- Aggregated analysis/reporting on a range of inspections, in order to provide an overview of risks/issues within a health care sector.[18]

In Sweden, the Health and Social Care Inspectorate (IVO) is a government agency under the Swedish Government (Ministry of Health and Social Affairs). IVO are responsible for conducting supervision and issuing permits to contribute to health and social care that is safe and high quality. IVO conduct their supervision role through inspections and handling of reports and complaints, analysis and guidance,

[4] The Directive on security of network and information systems (the NIS Directive) provides legal measures to boost the overall level of cybersecurity in the EU

feedback from supervision and guidance for services and through risk-based supervision. In the area of health information, IVO's supervision is in accordance with national law enacted as a consequence of the NIS-Directive, with the aim to achieve a high level of security in network and information systems.(24)

2.3 EU Developments in Health Information Standards

The European Union (EU) continues to invest significantly in the area of health information standards. A new regulation is proposed to establish EU Health Data Space to promote better exchange and access to different types of health data. Three pillars to support the EU Health Data Space are proposed:

1. Developing a health data governance framework for EU member states that provides guidance toward secure and privacy protective primary and secondary uses of health data that foster the accessibility and sharing of data. Such guidance would support greater harmonisation of the implementation of EU GDPR requirements in practice.

2. Data quality and interoperability including technical and semantic (terminology) interoperability between the different infrastructures and IT systems and ensuring health data in Europe are FAIR (Findable, Accessibly, Interoperable and Re-Usable).

3. Technical infrastructure that builds upon and scales up EU infrastructure, including the eHealth Digital Service Infrastructure, the European Reference Networks and the Genomics Project (EC, 2021)(46)

An EU project called X-eHealth, consisting of 47 health actors across Europe, use the three pillars put forward by the EC, to develop the basis for a workable, interoperable, secure and cross border Electronic Health Record exchange format. X-eHealth's purpose is to advance the integration process of eHealth services by developing a common framework for medical imaging, discharge letters, laboratory results and rare diseases.(47)

Other important EU developments in health information standards include the EU Cross Border Directive 2011/24/EU which relates to the introduction of cross-border care through the secure exchange of patient information between participating member states for electronic prescribing and patient summaries. The main standard used to implement the secure exchange of the electronic prescribing and patient summaries is the HL7 Clinical Document Architecture standard and integrating the Health Enterprise profiles were also used.(48) The epSOS project was a pre-cursor to this, ran for six years (2008-2014) and set out to develop, pilot and evaluate cross-

border eHealth services for patient summary information and electronic prescriptions, and to formulate recommendations for future work.[49]

Another example of a successful health information standard is the EU Digital COVID Certificate (DCC) the global standard for digital vaccine certificates whereby 27 EU member states are using it. The DCC meets several key criteria that have been identified as important factors for a digital vaccination certificate is to be effective.[50]

2.4 Stakeholder Engagement

International evidence demonstrates that stakeholder engagement is a critical role in the development of health information standards. Countries invest greatly in collaborative partnerships and relationships by engaging with various stakeholders as part of their standards development process most notably with national digital health agencies, clinical groups and patients, the public, academics, and vendors and also through international collaboration and participation in international standards development organisations.

Canada Health Infoway (Infoway) works with partners to accelerate the development and use of eHealth in Canada. Partners include federal, provincial and territorial governments and various industry stakeholders — technology vendors, provincial eHealth agencies, and healthcare organisations. Infoway works with Canadians, clinicians, the IT community, jurisdictions, and academics. They collaborate with partners through a variety of means, including discussion groups and forums, focus groups and peer networks to share knowledge and best practices. Infoway also work with regulatory bodies and colleges to ensure they meet the needs and address the concerns of physicians, nurses, pharmacists, privacy experts and other digital health professionals.[10,51]

NHS Digital is working on several HL7 fast healthcare interoperability resources (FHIR) projects, including collaboration with the Professional Record Standards Body (PRSB) and an action group called INTEROpen - an action group to provide clinical validation of FHIR profiles for use in the national health and social care services. Leading organisations and individuals comprise INTEROPen, which is an OPEN collaboration of individuals, industry, standards organisations and health and care providers, who have agreed to work together to accelerate the development of open standards for interoperability in the health and social care sector. [26] A standards portal will be developed and include a registry of standards used across health and social care will bring together standards by use-case, what standards can be used, and will enable vendors, providers and commissioners to search for and easily locate mechanisms for implementing a standard. The portal will support the standards

community to enable greater collaboration and sharing around standards development, maintenance and adoption.[11]

2.4.1 Engagement with Health IT Vendors

In Australia, generally vendors play a role in working groups (including HL7, HL7 Australia and Standards Australia) with varying powers. Canada Health Infoway work with technology vendors to accelerate the development and use of eHealth in Canada by engaging vendors through a Standards Collaborative, by demonstrating and promoting innovative health technology at Infoway-sponsored events, maintaining communications with industry through a National Industry Executive and by gaining insights from the vendor community on best practices on interoperability. In Denmark, MedCom involve key stakeholders in the whole process of implementing a new health information standard, which it attributes to their success to date with standards adoption. Denmark host a forum called 4S where software developers and vendors meet to connect to each other's systems and request and read data. 4S is a shared 'ecosystem' consisting of a board, a coordinator, a software group and a number of professional forums. It supports knowledge sharing and provides open tools, platforms, tutorials and guides available. 4S works closely with users like regions, municipalities and companies.[52]

2.4.2 Participation in Standards Development Organisations

Internationally, there has been a significant shift in direction towards the HL7 FHIR standard. New Zealand and England have endorsed it for all future standards development. In Ireland, the most widely used technical standard is HL7 v2.4 with some implementations using HL7 Clinical Document Architecture and pockets of HL7 FHIR implementations. As part of the transition to HL7 FHIR, the Australian Digital Health Agency has introduced a process to develop FHIR profiles in a collaborative, open and transparent process in partnership with standards organisations and industry, such as Standards Australia and HL7 Australia. HL7 Australia supports the health informatics community by

- Developing, coordinating, and championing standards
- Facilitating good practice implementation and use of standards
- Developing skills and knowledge amongst members and the wider informatics community
- Fostering a community of practice[53]

In Canada, there is a dedicated team to liaise with international health-related standards development organisations such as HL7 and Canada are well represented

on HL7 technical committees. There are a number of communities providing an opportunity for people to collaborate, communicate and educate on interoperability topics that are of interest to them and their peers on an ongoing basis. Examples of the type of communities that exist include: HL7 Community, Health Terminologies Community, Integrating the Healthcare Enterprise (IHE) Community, International Organization for Standardization (ISO) Community. The HL7 Community shares lessons learned about new and existing HL7 Standards implemented in Canada, such a version 2, version 3, CDA and FHIR. This community is where requests to make changes to any of the pan-Canadian messages occur and where implementers come for OID[5] requests in Canada or find Canadian OIDs in the HL7 OID Registry. Canada actively participates in HL7 Ballots.(54)

HL7 New Zealand is the New Zealand Affiliate of HL7 International, the global developer of standards for the interoperability of health information technology with members in over 55 countries. HL7 New Zealand is a not for profit incorporated society focused on current and emerging HL7 standards, with strong relationships to all other related healthcare IT standards used in New Zealand. A memorandum of understanding exists between the Health Information Standards Organisation (HISO) and HL7 New Zealand to recognise their respective roles and the ways they can work together to use standards for the purpose of interoperability in the New Zealand health and disability system, and to contribute to the international standards community. The HISO also hosts an expert group entitled the 'SNOMED implementation working group' within the Ministry of Health. Its role includes 'innovation, motivation and communication' in relation to SNOMED CT NZ Edition.(55)

The Danish Health Data Authority is represented in different international standardisation organisations and workgroups. The Danish Health Data Authority participates, among others, in:

- Nordic Council of Ministers — eHealth Network, eHAction
- HL7 Denmark
- ISO working groups in health informatics (TC215, CEN/TC251)
- Personal Connected Health Alliance (PCHA)
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
- World Health Organization (WHO)
- The Nordic Medico-Statistical Committee.

[5] An object identifier (OID) is an extensively used identification mechanism jointly developed by ITU-T and ISO/IEC for naming any type of object, concept or "thing" with a globally unambiguous name which requires a persistent name (long life-time). It is not intended to be used for transient naming. OIDs, once allocated, should not be re-used for a different object/thing.

HL7 Denmark is the Danish affiliate of HL7-International managed by Danish Standards Foundation which participates in work on developing international HL7 standards in health informatics. HL7-Denmark focuses on profiling and application of standards at national level. HL7 Denmark is working towards a shared definition of rules and frameworks, and how standards can be used most appropriately. The main actors involved in HL7 Denmark are regions, MedCom, vendors, GS1, Alexandra Instituttet, Aalborg University and Danish Health Data Authority.[56]

International best practice demonstrates that to develop health information standards more effectively, it is important to develop partnerships with various healthcare organisations at national level and ensure collaboration and participation with international standards development agencies.

2.5 Irish Landscape

In Ireland, the development and implementation of national health information standards is fragmented with no overarching governance arrangements to oversee their development, deployment, certification, testing and compliance. This is evidenced by three separate organisations with different remits and roles in health information standards. HIQA has the legislative remit under the Health Act 2007 to develop national standards and assess compliance with those standards. The HSE through the eHealth and disruptive technologies develop technical specifications for health information and has progressed this through their business function — the Enterprise Architecture and Design Authority, and the NSAI has a remit to develop ISO and CEN standards, including those on health information. There is a need for clear policy and strategic direction regarding standards development if we are to make enable integrated care as health interoperability standards are a pre-requisite for semantic interoperability.

2.5.1 Health Information and Quality Authority (HIQA)

As described in section 1.3 above, the standards development lifestyle is iterative and has various stages across its whole-of-lifecycle, from defining requirements, developing the standard, testing and piloting, compliance and certification through maintenance and support. HIQA has a legislative remit under the Health Act 2007,[23] as amended, to develop recommendations, standards and compliance with those standards, and guidance in health information and has developed numerous national health information standards (see Appendix b).

HIQA adhere to the development of standards and the following stages are completed (See Figure 1.0 above in section 1.3):

- Stage 1 - Define Business Case and Requirements Analysis

- Stage 2 - Options Analysis
- Stage 3 – Develop the standard in consultation with key stakeholders including the establishment of a long-standing eHealth Standards Advisory Committee and through public consultation.
- Stage 8 – Maintenance. HIQA has maintained the GPMS messaging specification which is now on version 4.0, having been first published in 2010.

However, standards development is underdeveloped and underinvested and there are major gaps in how standards are maintained and supported leading to a lack of progress in the area of standards adoption. As a result, the following stages are not conducted:

- Stage 4 - Test and Pilot
- Stage 5 – Change management, education and training and ongoing support
- Stage 6 – Approve, Publish and Implement the Standard
- Stage 7 - Conformance, certification and/or accreditation. The GPIT do coordinate an accreditation programme but this is done on a voluntary basis and certification and accreditation should sit within a national health information standards organisation.

HIQA has a legal remit under the Health Act 2007,[23] to develop national standards and also has a remit to assess compliance with those national standards. HIQA has developed national health information standards which can be divided into groupings – document standards, electronic prescribing standards, messaging standards, clinical information, modelling standards and information governance and management standards (See Appendix b). To date, 13 standards in the area of Health Information have been developed but only three standards have been formally approved by the Minister for Health:

- National Standard on information requirements for a national electronic patient summary (2019),[57]
- National Standard on information requirements for national community-based electronic prescribing (2018),[58]
- and the General Practice Messaging Standard (Version 1.0),[59].

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 the quality and filling in gaps where information is needed but is not currently available. HIQA will commence an eHealth services review programme to assess compliance of major eHealth services such as the individual health identifiers, electronic referrals, National Information Medical Imaging System (NIMIS) against national standards. The focus of HIQA's eHealth services review

programme includes reviewing governance arrangements in relation to eHealth services and assessing compliance of eHealth services with national standards developed by HIQA. The review programme identifies good practice in relation to governance of eHealth services and makes recommendation on where Services need to improve. The lack of Ministerial approval of national standards limits our ability to review eHealth Services against those national standards.

Since 2017 HIQA has sought to drive improvements in the collection and use of health information in Ireland by formally reviewing individual national data collections for compliance against the information management standards for national health and social care data collections. To date, five major national data collections have been reviewed in depth by HIQA with regard to their information management practices, including Breastcheck (National Screening Service),[60] the Hospital In-Patient Enquiry (HIPE),[61] scheme, the Primary Care Reimbursement Service (PCRS),[62] the Computerised Infectious Disease Reporting (CIDR)[62] system, and the National Incident Management System within the HSE.[63]

While the review programme has highlighted a number of examples of good practice in Ireland in relation to national data collections, there are also some significant gaps, silos of information and duplication in the country's health information landscape. HIQA identified a lack of a national strategic direction for national data collection, data quality and analytics and use of data — leading to duplication of resources, even within the HSE — and a lack of adequate assurance within the HSE in relation to the quality of national health information.

HIQA's current remit is limited to assessing compliance of health information standards within the HSE and does not assess services provided by private health and social care providers.

2.5.2 Health Service Executive (HSE)

The HSE's Office of the Chief Information Officer (OCIO) develops technical specifications for health information and has progressed this through their business function — the Enterprise Architecture and Design Authority. It does not have a legal remit for mandating national standards or reviewing compliance against them. The Department of Health funded the HSE to host the National SNOMED CT National release centre – a key health information standard and substantial work is ongoing regarding the European Union (EU) Cross Border Directive

Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is a global terminology for use in clinical information systems, developed to improve the quality of clinical data in patient records in order to help improve the overall quality of care received by patients. The SNOMED CT National Release Centre of Ireland was

established to meet Ireland's responsibilities to administer the national license for SNOMED CT, as outlined by SNOMED International. The National Release Centre has developed an Irish Edition of SNOMED CT, based on input from national stakeholder organisations and in line with guidance from SNOMED International. [64] The National Release Centre currently operates within the HSE's Enterprise Architecture and Design Authority and was originally established within this function to meet a local business requirement – to satisfy requirements of a national eHealth programme the (National Laboratory Information Management System programme).

There is an absence of a strategic roadmap in relation to terminologies and classification overall in Ireland as SNOMED CT operates in the HSE, while the ICD-10 AU classification is the responsibility of the National Healthcare Pricing Office. Although there is a governance structure and a strategy for the SNOMED CT terminology, there is a need for a national policy for the implementation of both terminologies and classification cohesively and this needs to be adequately resourced. Also, internationally, the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) National Release Centre (NRC) is part of a standards setting function – for example, the SNOMED CT NRC sits under the NHS Digital and the Australian Digital Health Authority in Australia, within a function that develops other interoperability standards. This highlights the lack of a strategic approach to standards development and the need to include all stages of the standards development process and highlights the need for a national interoperability roadmap that incorporates all national health information standards that is governed by a dedicated organisation.

The EU Open National Contact Point (Open NCP) initiative supports the development of the national infrastructures to exchange health data safely between EU member states. Ireland has committed to develop the infrastructure to enable transmitting health data to another member state and has developed HL7 FHIR resources, a test harness which is conformant with IHE profiles and associated tooling. The Open NCP framework relies on a core set of clinical codes, including SNOMED CT, which are referred to as the 'Master Value Catalogue'. This aligns with the adoption of SNOMED CT as the national clinical terminology needed for the meaningful sharing of data among member states.

2.5.3 National Standards Authority of Ireland (NSAI)

The National Standards Authority of Ireland (NSAI) is Ireland's official standards body, operating under the National Standards Authority of Ireland Act (1996) representing Irish interests in the work of European and international standards bodies — European Committee for Standardization (CEN) and International Standards Organisation (ISO) — and for the publication and sale of Irish standards.

The development process for ISO standards follows defined stages including: proposal, preparatory, committee, enquiry, approval and publication. The process is undertaken by experts in the specific field. The NSAI collaborates with International ISO and CEN, participating in the work of ISO Technical Committee 215 and CEN Technical Committee 251 for Health Informatics adhering to the standards development lifecycle. At a national level, the National Standards Authority of Ireland (NSAI) hosts a Health Informatics Standards Consultative Committee (HISC) with members from the healthcare industry, academics, regulators, Government, healthcare providers, clinicians, IT experts and healthcare software developers covering topics such as architecture, nursing and health terminology, network management, interoperability, security and safety and pharmacy medical device software. HIQA and the HSE are represented on the HISC. The purpose of the committee is to disseminate standards developed by ISO and CEN and to include a national response when standards are progressing through the approval phase of the development process. Standards developed by the National Standards Authority of Ireland are optional and not mandated for use in Ireland.[65]

2.6 Stakeholder Engagement Irish Landscape

In Ireland, there are some activities that have been undertaken to foster collaborations internationally including work carried out by the National Standards Authority of Ireland (NSAI), HIQA and the HSE's Enterprise Architecture function.

A mentioned, National Standards Authority of Ireland (NSAI) collaborates with International ISO and CEN, participating in the work of ISO Technical Committee 215 and CEN Technical Committee 251 for Health Informatics and hosts a Health Informatics Standards Consultative Committee (HISC).

HIQA works to develop high quality national standards for healthcare interoperability, together with recommendations for the implementation and use of these standards, and guidance on other international standards that should be considered for adoption in Ireland. In line with its remit, the team works collaboratively with key national stakeholders to develop national standards that are informed by international standards and through the early engagement of both national and international stakeholders, through later championing and adoption of the standard by those stakeholders, and through ongoing engagement.

The HSE's Enterprise Architecture and the Design Authority, within the HSE's Office of the Chief Information Officer (OCIO), are responsible for supporting the strategic development of technical architecture, technology and operational capabilities. The Design Authority defines standards, blueprints, and a test and assurance

environment. The function is also responsible for data assurance including data security, information governance and semantic interoperability.(66)

The HSE's Enterprise Architecture and the Design Authority collaborate internationally as Ireland has committed to develop the infrastructure to enable transmitting health data to another member state under the European Union Cross Border Directive 2011/24/EU. This project relates to the introduction of cross-border care through the secure exchange of patient information between participating member states. As mentioned in section 1.0 above, The National Release Centre for SNOMED CT is hosted in the HSE Executive Enterprise Architecture and the Design Authority has developed an Irish Edition of SNOMED CT, based on input from national stakeholder organisations and in line with guidance from SNOMED International.

2.7 Conclusion

Standards development is fragmented in Ireland and needs to be progressed to realise an integrated health and social care system. While some progress has been made in the area of standards development for health information, the area is underdeveloped and there has been under-investment in the necessary resourcing that is needed to develop and maintain health information standards throughout their entire lifecycle. In addition, there is no supporting legislation or regulations in place that require adoption of nationally developed standards. Finally, assessing compliance with standards or certification of health information systems has not been undertaken at a significant level nationally due to the under-investment and underdevelopment of standards development and the lack of appropriate governance arrangements between organisations.

Based on international evidence, the key components of a model for the successful development of national health information standards could include:

Table 4:0 Example of a model for a health information standards organisation to undertake the development of national health information standards for interoperability should include the following roles and functions:

Role	Function
Co-ordination and System-wide oversight of standards	▪ develop a roadmap to underpin standards development ▪ governance of the national standards development model ▪ development of standardisation policies ▪ resourcing for standards development ▪ establish stakeholder engagement

	▪ evaluation through the development and adoption of health interoperability standards.
Business Analysis	Identify and manage requests and requirements of new standards refinement of existing standards.
Standards development	Development of specific, fit-for-purpose standards and ensure whole-of-lifecycle maintenance and product management.
Support for standardisation and implementers	▪ Consistent and coherent education and training ▪ Support for networking amongst developers and implementers ▪ Support for tooling.
Conformance assessment and certification	Assurance that specific products are standards compliant.
Research and development	Ongoing investigation into how standardisation can be best directed to achieve interoperability.

Chapter 3 will outline the options proposed for a suitable model for health information standards, followed by Recommendations including the governance, functions and the roles and responsibilities that an organisation should adopt to ensure that standard are developed, implemented and adopted in the most appropriate way.

Chapter 3.0 Recommendations

In 2021, HIQA's Position Paper on Health Information System Reform (2021) called for the establishment of a strategic independent entity, as previously set out in eHealth Strategy (2013). This entity should be established outside of the HSE, with a legislative remit to provide strategic leadership and governance to support the collection, use and sharing of health information in Ireland. In parallel, an operational function developing and supporting the systems required for the delivery of care should continue to exist in the HSE. HIQA also made a recommendation specifically on Standards and Interoperability which outlined the need for:

- A clear policy decision needs to be made on where the health information standards function will reside.
- A health information standards setting function, and the function for assessing compliance with health information standards needs to be supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE.

Furthermore, in April, 2022 the Department of Health announced it had received Cabinet approval to develop the general scheme of a Health Information Bill, with the aim of ensuring that Ireland has a fit-for-purpose national health information system. The proposal will also support the introduction of a National Health Information Centre with clearly specified functions and governance rules in relation to the collection and processing of health information for population health purposes and research and innovation that leads to better outcomes for patients i.e. a health information centre for secondary use data.[(4)]

To inform the model on health information standards, HIQA considered the arguments for and against options (1-3) which are outlined in detail in section 3.1 below.

3.1 Identifying an optimum model to provide strategic oversight and governance needed for standards setting, implementation and adoption across health and social care in Ireland

There are three options proposed for an entity to govern and manage the end-to-end lifecycle of technical standards development, implementation and adoption. They include the following:

1. Maintain the current status quo – no change

2. The HSE, HIQA and NSAI to establish formal shared governance arrangements to support the development and implementation of health information standards.
4. The Department of Health — as it develops new policy — could consider the need to consolidate standards development to include creating a new strategic independent entity which has a broad remit for co-ordinating national efforts in health information, with one of its roles to orchestrate the end-to-end lifecycle of technical standards development and implementation.

Each option is further described in the following section:

Option One: Maintain the Current Status Quo

In Ireland, the development and implementation of national standards is fragmented and uncoordinated with no overarching governance arrangements to oversee their development, testing and piloting, technical conformance and certification, maintenance and adoption.

There are three separate organisations with different roles and responsibilities for the development and management of national standards:

- HIQA has a legislative remit under the Health Act 2007, as amended, to develop recommendations, standards and compliance with those standards, and guidance in health information. Separate to the development and implementation of national technical standards is a monitoring and compliance function. Currently, HIQA have the legislative remit to assess compliance against eHealth services. This role is conducted when standards are implemented and in use in an eHealth service such as identifiers, electronic referrals and electronic prescriptions.
- The HSE implement technical standards through the Access to Information (A2I)/HIDS service. Through their Enterprise Architecture function, the HSE host the National SNOMED CT Release Centre and have developed infrastructure for OpenNCP (an EU project for cross-border sharing of electronic prescription and electronic patient summaries) using technical standards.
- The National Standards Authority of Ireland (NSAI) is responsible for the development of standards, representing Irish interests in the work of the European and International standards bodies - European Committee for Standardization (CEN) and International Standards Organisation (ISO).

Advantages

- Across the separate organisations, it is evident that expertise and experience in standards development and implementation exists and should be capitalized.

Disadvantages

- There is an absence of a clear policy on how these different organisations are coordinated to deliver on a national integrated health information system. To continue developing national standards in a fragmented way is costly, inefficient and hinders adoption of standards across the healthcare system impeding integration of a national health information system.
- Although progress has been made in developing and implementing national standards, historically, the area of standards development for health information has been under-resourced and there is an urgency for highly skilled resources to be assigned and upskilled in such a specialised area.
- National standards for health information have been developed but there are gaps in the types of standards required to support interoperability.
- There is no supporting legislation or regulations in place that mandate the use and adoption of national standards in health information systems.
- Conformance and certification of health information systems has not been undertaken at a significant level nationally and needs to be prioritised.
- An interoperability roadmap to identify critical actions to help advance nationwide interoperability has not been developed.

Option Two: The HSE, HIQA and NSAI to establish formal shared governance arrangements for the development and implementation of health information standards.

Existing health information standards organisations (HIQA, HSE, and NSAI) to establish formal shared governance of standard setting and implementation roles. This would involve a multi-organisational approach to standards development and implementation potentially through a memorandum of understanding or partnership arrangements. It would require strengthening the remit, function, and competencies of existing agencies. Successful implementation will require good governance, policy, and trust between organisations.

Advantages

- This model builds on substantial work already developed or underway by the HSE, HIQA's standards development work and NSAI work on ISO/CEN standards by strengthening and combining expertise and experience.

- A collaborative approach is not restricted to one partner making it easier to undertake a wider breadth of capabilities.
- Facilitates collaborative cross government, multi-sectoral relationships

Disadvantages

- Given that three separate organisations play a role in standards development — making it fragmented and uncoordinated with no overarching governance arrangements in place — it could be problematic to determine who ultimately has responsible and accountability for ensuring there are robust processes and governance models for the development of interoperability standards.

Option Three: The Department of Health — as it develops new policy — could consider the need to consolidate standards development to include creating a new strategic independent entity which has a broad remit for co-ordinating national efforts in health information, with one of its roles to orchestrate the end-to-end lifecycle of technical standards development and implementation.

One of its key roles would include orchestrating and having oversight of national efforts to develop, implement and to promote the adoption of national standards and to adhere to HIQA's compliance function – whereby health information services are assessed against national standards. This would involve the governance, co-ordination and having oversight of all stages of standards development. The strategic independent entity would have ownership of standards at a strategic level - setting out how standards relate to technical, information and enterprise architecture required for implementation of major health IT solutions. They will ensure that the various processes and functions required to deliver on the whole of standards lifecycle are delivered and remain aligned to broader strategic priorities of the health and social care sector. This entity would have formal links with Government, industry participation and academia. The strategic independent entity could either establish an in-house function to develop and implement national standards or have funding and commissioning power that support creation and adoption of standards. The strategic independent entity is responsible for developing national health information projects, implementing them and when operational, the HSE will take responsibility for them.

Advantages

- International experience suggests this model represents best practice.

- Single dedicated organisation facilitates simplified governance and reporting relationships.
- Experience, expertise, access and maintenance of skilled resources.
- Centrally controlled but can still commission or outsource work where expertise/resources that is difficult to source is needed
- Facilitates collaborative cross government, multi-sectoral relationships.

Disadvantages

- Given the significant undertaking involved in establishing and operationalising a new strategic independent, this could cause a delay in progressing the health information standards agenda and an interim solution in the short term would be required.

Preferred option

To inform the model on health information standards, HIQA considered the arguments for and against options (1-3) which are outlined in detail in section 3.1 of this report. HIQA also took on board the strong findings from the international review that organisations have a wider remit than just standards setting - they have a role in setting strategy for digital health and in some cases implementation.

As HIQA recommended in its Position Paper on Health Information Reform (2021),[25] there is a need for a strategic independent entity, as set out in eHealth Strategy (2013),[1] with responsibility for overall governance around eHealth implementation — including funding, legal enabling, public awareness and stakeholder engagement through building the eHealth ecosystem in Ireland — to work in partnership with Government and state agencies.

HIQA believe that the absence of a single entity leads to overall lack of accountability and coordination for health information across the Irish health and social care system including the development, implementation and adoption of health information standards. International best practice has indicated that a dedicated entity with full authority and responsibility for digital health across both public and private healthcare is optimal.

HIQA's Position Paper on Health Information System Reform (2021) also made a recommendation specifically on Standards and Interoperability which outlined the need for:

- A clear policy decision needs to be made on where the health information standards function will reside.
- A health information standards setting function, and the function for assessing compliance with health information standards needs to be

supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE.

HIQA believes the most optimal model to provide strategic oversight and governance for setting, implementing and adoption of health information standards across health and social care in Ireland is the creation of a new strategic independent entity charged with having full ownership, governance, responsibility and accountability for the delivery of Ireland's national health information system, including primary and secondary use data across private and public healthcare. One of its key roles would include orchestrating and having oversight of national efforts to develop, implement and to promote the adoption of national standards and to work with HIQA's compliance function, whereby health information services are assessed against national standards.

However, in the absence of such a model — and given the significant undertaking involved in establishing and operationalising a new strategic independent — HIQA suggest an appropriate interim solution could be appropriate whereby the HSE, HIQA and the National Standards Authority of Ireland (NSAI) establish formal shared governance arrangements for the development and implementation of health information standards.

Considering that the Department of health are currently developing policy, strategy and legislation it is timely to consider the propsed models and determine if firstly Ireland are going to continue to build a standards-based approach and secondly where would this function be best placed to operate effectively?

HIQA is making recommendations under three themes:

- Recommendation 1.0: Model for health information standards and governance structures to support it.
- Recommendation 2.0: Standards development process
- Recommendation 3.0: Stakeholder engagement, each are outlined below.

Recommendation 1.0: Model for health information standards and governance structures to support it.	
Number	**Recommendations**
1.1	HIQA believes the most optimal model to provide strategic oversight and governance for setting, implementing and adoption of health information standards across health and social care in Ireland is the creation of a new strategic independent entity charged with having full ownership, governance, responsibility and accountability for the

	delivery of Ireland's national health information system, including primary and secondary use data across private and public healthcare. One of its key roles would include orchestrating and having oversight of national efforts to develop, implement and to promote the adoption of national standards and to work with HIQA's compliance function, whereby health information services are assessed against national standards. However, in the absence of such a model — and given the significant undertaking involved in establishing and operationalising a new strategic independent — HIQA suggest an appropriate interim solution could be appropriate whereby the HSE, HIQA and the National Standards Authority of Ireland (NSAI) establish formal shared governance arrangements for the development and implementation of health information standards.
1.2	A clear policy decision on using a standards-based approach for the development, implementation and adoption of health information standards and the model to support ensuring the allocation of adequate resources. This is timely given forthcoming changes in Ireland's policy and legislation around health information.
1.3	Legislation to mandate compliance of nationally agreed health information standards for sharing health information and to promote adoption of standards between major national health information programmes of work and priority Sláintecare projects including a shared care record, electronic prescribing and national patient summaries and across public and private health and social care services is needed As outlined in HIQA's positon paper on health information system reform, HIQA's remit for assessing compliance with health information standards needs to be supported through legislation and resourcing and should include both the public and private health and social care sector, including public sector services outside of the HSE. Legislation is needed to ensure that national health information standards are tested and certified for use in national health information systems across public and private health and social care services.

A standards setting function should be responsible for recommendations 1.4 – 1.9 described below:	
1.4	Ensure an appropriate governance structure is established for a health information standards setting function with accountability and national oversight for the development and implementation of standards across the whole-of-lifecycle from inception through to standards development and their adoption and use. All stages of the standards development process needs to be considered including: ▪ Define business case and requirements analysis ▪ Options analysis ▪ Develop the standard ▪ Test and pilot ▪ Change management, education and training and ongoing support ▪ Approve, publish and implement the standard ▪ Compliance, conformance, certification and or accreditation ▪ Maintenance and support
1.5	Establish a Programme Board comprised of independent subject matter experts — both clinical and technical — in the area of national health information standards as well as public and patient representatives. Primarily, this Board would be responsible for overseeing and governing the development of national health information standards for use in health information systems in both public and private healthcare across the health and social care system to enable interoperability. Its purpose is to support and promote the development, and use of health information standards across the health and social care service in Ireland including to: ▪ Provide standards-related advice to the Department of Health by proposing national standardisation policies, influencing policy-makers about standards and prepare briefing material for Governments and policy-makers on the importance of making standardisation visible in all strategies that depend on interoperability. ▪ Ensure standards support the future direction of a National Health Information Strategy. ▪ Ensure health information standards are developed in accordance with approved processes for IV. **Prioritisation** – to identify and prioritise the projects where health information standards are required, that is to say, new eHealth services, domains or retrofitting existing health information systems. Prioritise the development of national

	health information standards across a broad range of domains including: V. **Approval** – Approve and endorse standards for publication and gain consensus and agreement with all required stakeholders on health information standards VI. **Change management activities** – for governance and maintenance of health information standards incorporating an implementation science approach to ensure standards development incorporates human factors throughout the standards development lifecycle.
1.6	Establish expert working groups needed for domain expertise and specialist knowledge of the topic on which the standard is based on. Informed by a prioritisation process, the purpose of the expert working group is to aid the development of specifications based on a quality assured standards development process.
1.7	Developing, implementing and maintaining consistent national standards for data standards (content), terminology (semantics), data exchange (electronic messaging) and harmonisation of data privacy and security policies and practices. More specifically, the scope of health information standards should include: health information modelling, clinical and administrative datasets, messaging standards (ISO, HL7, OpenEHR), information standards for clinical terminologies (Irish editions of SNOMED CT) and classifications (ICD-10-AM) and data security standards.
1.8	Developing a National Interoperability Roadmap to be included as a key priority in an overarching national health information strategy for Ireland. The roadmap should include the requirements for standards for various purposes for specific use cases covering domains such as primary care, acute, and community care settings.
1.9	Building relationships with stakeholders across the health and social care sector to raise awareness and promote adoption of health information standards. National stakeholders could include: policy and legislative organisations, HSE eHealth and disruptive technologies, HSE clinical programmes, national standards organisations including HIQA, National Standards Authority of Ireland (NSAI), professional representative bodies, such as for general practice and pharmacy, patient and public organisations, public and private hospitals, academics and subject matter experts, broader governmental bodies and the health IT vendor community in Ireland.

Recommendation 2.0 Standards development process	
Number	**Recommendations**
2.1	A standards setting function in collaboration with expert working groups should develop specific, fit-for-purpose standards and ensure whole-of-lifecycle maintenance and support using a robust standards development process and complete the following recommendations from 2.2 – 2.8 below.
2.2	Develop digital maturity assessments using a consultation process with key stakeholders to identify main gaps in the adoption of national standards and highlight the level of standardisation maturity across Ireland.
2.3	Maintain a standards development framework model to highlight types of standards, that is to say, catalogue of appropriate standards to use depending on the use case and where standards need to be applied in various domains of healthcare. Similar to the NHS Digital which published a draft framework — NHS digital, data and technology standards framework describing their expectations around the use of data, interoperability, and design standards within the NHS.[26]
2.4	Develop standards for specific use cases, to integrate standards from different healthcare domains, and ensure they are fit for purpose. This should incorporate modern standards, such as HL7 FHIR.
2.5	Provide support for implementation through education and training, tooling and guidance documents to assist with implementation for all stakeholders implementing standards.
2.6	Ensure that nationally agreed standards are included in procurement specifications.
2.7	Establish conformance assessment and certification processes to assure that specific products are compliant with standards. Develop certification for vendors of IT solutions and digital tools for compliance with national standards.

2.8	Develop an evaluation framework to continuously improve the standards development process to takes account of lessons learned from the implementation of previous health information standards.

Recommendation 3.0 Stakeholder engagement

Based on international best practice, collaboration with key stakeholders plays an integral and important role in the development of health information standards. Internationally countries have affiliations to HL7 International. In Australia, HL7 Australia supports the health informatics community by developing, coordinating, and championing standards and through education. A memorandum of understanding exists between the HISO and HL7 New Zealand to recognise their respective roles and the ways they can work together to use standards for the purpose of interoperability in the New Zealand.

There is a need for a strategic independent entity to undertake the role of formally establishing collaborations with national and international healthcare organisations and establishing affiliations to international standards development organisations such as HL7. Based on international best practice in the area and on the current situation in Ireland, HIQA makes the following recommendations on stakeholder engagement:

Recommendation 3.0: Stakeholder Engagement	
Number	**Recommendations**
3.1	A standards setting function should establish international and national collaborations and undertake engagement with key stakeholders through functions 3.2-3.7
3.2	Undertake stakeholder engagement and public consultation about national health information standards and their implementation, adoption and use; and provide public transparency through clear communication about health information standards.
3.3	Develop a comprehensive stakeholder engagement plan – for both national and international stakeholders. This should identify all stakeholder groups needed for the development, deployment and maintenance of health information standards. Stakeholders should be engaged with consistently and appropriately as needed through a variety of means, including discussion groups and forums, reference

	groups and peer networks, and patients and patient representative organisations to share knowledge and best practices.
3.4	Build consensus regarding national health information standards across a broad spectrum of stakeholders, and position the health information standards function to expand its leadership role in healthcare information standards across Ireland.
3.5	At local level, establish a network or forum to support IT departments and software developers, and for people responsible for managing and delivering health and social care services at a service provision level. The aim of this network should be to assist and guide in developing consistent standards and guidance for implementing health information standards, and enhancing upskilling and training people delivering services within health and social care services.
3.6	Establish relationships and participation in leading International Standards Development HL7, Organisations such as OpenEHR, and continued participating in ISO, SNOMED International.
3.7	Establish HL7 Ireland to support and collaborate with the health IT community in Ireland and to contribute to national and international standards development.

4.0 Next Steps

HIQA is developing recommendations for a model for health information standards to support the delivery of health and social care services in Ireland. These draft recommendations have been published for public consultation to ensure that members of the public have an opportunity to engage in, feedback on, and inform the final recommendations.

As part of the development process, and in line with its legal remit, HIQA will undertake a six-week public consultation on the draft recommendations running from **Tuesday 21 June 2022 to Tuesday, 2 August 2022.** In parallel to the public consultation, a series of information sessions with selected stakeholder groups will be held. The draft recommendations will also be communicated to senior management in the Department of Health, Health Service Executive, National Standards Authority of Ireland and other key stakeholders. Having analysed all submissions from the public consultation and feedback from key informant interviews, the draft recommendations will be revised where appropriate. The draft recommendations will then be presented at a third meeting of the specially convened Advisory Group. A stakeholder engagement report from the public consultation will also be prepared, providing a detailed analysis of all feedback received through public consultation and interviews.

After consideration of their advice, the final recommendations document will be drafted. Subject to the HIQA Board approving the recommendations, they will be submitted to the Minister for Health and will also be published on the HIQA website.

Appendix A: Membership of the Advisory Group

Members of the specially convened Advisory Group are listed here:

Membership of the Advisory Group

- Department of Health – R&D and Health Analytics Division
- Department of Health – eHealth & Health Information Systems team, Health Infrastructure Division
- Health Service Executive – Office of the Chief Clinical Information Officer
- Health Service Executive (eHealth & disruptive technologies) – Digital Nursing and Midwifery
- Health Service Executive (eHealth & disruptive technologies) – Enterprise Architecture
- Health Service Executive (eHealth & disruptive technologies) – Integrated Information Division
- Health Service Executive (eHealth & disruptive technologies)– Access to Information and Health Identifier Programme
- Health Service Executive (eHealth & disruptive technologies) – Engagement & Delivery EHR programme
- Health Service Executive – Department of Public Health
- Health Service Executive – eHealth and Social Care Professionals Group
- Health Service Executive – National Patient and Service User Forum
- Health Service Executive – National Screening Service
- Irish College of General Practitioners
- Irish Pharmacy Union
- Irish Medical Organisation
- The National Coagulation Centre
- National Clinical Strategy and Programmes Division Epilepsy National Clinical Programme
- Dublin City University

Appendix B: National Standards on Health Information

National standards on health information

National Standard on information requirements for a national electronic patient summary	2019
National Standard on information requirements for national community-based electronic prescribing	2018
General Practice Messaging Standard (Version 4.0)	2017
National Standard for a Dispensing Note including a Clinical Document Architecture specification	2016
National Standard for a Procedure Dataset including a Clinical Document Architecture specification	2016
National standard demographic dataset and guidance for use in health and social care settings in Ireland (Version 2.0)	2016
Information Governance and Management Standards for the Health Identifiers Operator in Ireland	2015
Data model for an electronic medicinal product reference catalogue – a National Standard	2015
National Standard for a Clinical Summary (Patient Discharge)	2013
Report and Recommendations on Patient Referrals from General Practice to Outpatient and Radiology Services, including the National Standard for Patient Referral Information	2011

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Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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

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