Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Developing National eHealth Interoperability Standards for Ireland: A Consultation Document

August 2017

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** — Registering and inspecting designated centres.
- **Monitoring Children's Services** — Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality** — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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. It is, therefore, 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 a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has 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)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving 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 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 is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, 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 high reliability 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. A subset of the standards developed by HIQA are technical standards that support eHealth interoperability. This consultation document has been developed in order to support interested people make submissions on which technical standards HIQA should develop over the next few years. Submissions will help inform HIQA's work plan in this area. The technical standards will be developed in conjunction with the eHealth Standards Advisory Group, which was established by HIQA to advise it when developing technical standards supporting eHealth interoperability.

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1. Introduction

Safe, reliable healthcare depends on access to, and use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. Ensuring that information can be shared efficiently and effectively and in a manner which protects the privacy and confidentiality of patients is critical.

The inability to share information leads to unnecessary duplication of tests and delays in patients receiving appropriate treatment, with potentially serious consequences which threaten both the safety and quality of care provided. Information should accompany the patient along the entire care pathway.

eHealth can enhance quality, accessibility and efficiency across all healthcare services through the secure, timely, accurate and comprehensive exchange of clinical and administrative data. This offers a number of benefits, including:

- better and safer care
- improved integration and sharing of health information to enable patient-centred integrated care
- more cost-effective delivery of healthcare
- more efficient national planning
- improved research through the provision of more timely and higher quality information
- reduced medication errors through ePrescribing
- access by health professionals to the right medical information at the right time
- improved support for patient self-management.

To deliver these benefits, several key building blocks have to be put in place which can, importantly, bring benefits in their own right and, together, provide the basis for building a robust eHealth infrastructure. Some examples of these building blocks or eHealth initiatives include a set of eHealth interoperability standards such as communication and terminology standards based on widely available and implemented international standards; a system of unique identification for individuals, organisations and health professionals; and an electronic health record (EHR) model, which is often regarded as the ultimate goal of eHealth.

In addition to the EHR, a common objective of eHealth internationally is to support electronic prescribing or ePrescribing, which is defined as the transmission, using electronic media, of prescription or prescription-related information between a prescriber and dispenser either directly or through an intermediary.

The purpose of this document is to support a public consultation on the areas of eHealth interoperability standards development that HIQA should prioritise. The document includes a set of guiding principles that will govern HIQA's work in this area, which will be undertaken in conjunction with the eHealth Standards Advisory Group (eSAG), a technical standards advisory group that has been established by HIQA. HIQA is fully committed to stakeholder consultation and values all feedback provided as part of its standards development process. In particular, it welcomes views as to where eHealth interoperability standards are required and where the work of HIQA and eSAG should be targeted.

A wide range of stakeholders will benefit from having eHealth interoperability standards in place, including healthcare professionals, service planners, healthcare organisations, healthcare software suppliers, standards development organisations, policy makers and regulators. The benefits to stakeholders include the following:

- Service users benefit from the use of eHealth interoperability standards in a number of ways. By ensuring that all relevant information relating to their care is available when and where it is needed, 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 more timely care. By facilitating the efficient sharing of information, interoperability standards play a crucial role in patient-centred shared care, providing the patient with services in the most appropriate setting, which will increasingly be in the community.

- For suppliers, standards provide greater market certainty, a basis for certification (a marketable asset), simpler procurement processes and, where the standards used are international, the prospect of growth in export markets.

- For purchasers and implementers, standards simplify procurement, including the assessment of compliance, improved confidence that the product purchased will be interoperable and greater potential to avoid vendor 'lock-in'.

- For policy makers and regulators, there are clear benefits in the use particularly of international standards through the promotion of solutions which have proved to be successful elsewhere as well as providing insights into where problems have been encountered.

- For standards developers, there is a keen interest in ensuring the adoption of 'their' standards.

1.1 Background

In the Irish context, many reports and strategies have highlighted the need for a national electronic health record, including the Commission for Patient Safety and Quality Assurance (2008) and the eHealth Strategy for Ireland (2013). Subsequent to the publication of the eHealth Strategy, the Office of the Chief Information Officer was established with the responsibility for implementing Ireland's eHealth Strategy. The Office of the Chief Information Officer is responsible for the delivery of technology to support healthcare across Ireland and have published the Knowledge and Information Strategy in this regard. One of the key building blocks central to any eHealth programme is a set of eHealth interoperability standards, including messaging and terminology standards based on widely available and implemented international standards.

The responsibilities of HIQA in relation to health information are outlined in the Health Act 2007:

- Section 8(1)(i): to evaluate available information respecting the services 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 Health Service Executive (HSE) about deficiencies identified by HIQA in respect of the information referred to in paragraph (i)
- Section 8(1)(k): to set standards as HIQA considers appropriate for the HSE and service providers respecting data and information in their possession in relation to services and the health and welfare of the population.
- Section 8(1)(l): to advise the Minister for Health and the HSE as to the level of compliance by the HSE and service providers with the standards referred to in paragraph (k).

Under Section 8(1)(k) of the Health Act 2007, HIQA is charged with setting standards for health information. In the technical standards area, some of the most recent standards that HIQA has published in this regard include:

- *National Standard for a Dispensing Note including a Clinical Document Architecture specification* (November 2016)
- *National Standard for a Procedure including a Clinical Document Architecture specification* (November 2016)
- *National Standards for Diagnosis Datasets and Clinical Document Architecture Templates* (February 2016)
- *National Standards for Adverse Reaction Datasets and Clinical Document Architecture Templates* (February 2016)
- *National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland* (October 2015)
- *ePrescription dataset and clinical document architecture standard* (March 2015)
- *General Practice Messaging Standard, Version 3.0* (May 2014)
- *National Standards for Patient Discharge Summary Information* (August 2013)
- *National Standards for Patient Referral Information* (June 2011).

Under Section 8(1)(j) of the act, HIQA has the responsibility 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). HIQA is charged with undertaking guidance in relation to gaps in the health information community. Some of the recent guidance published includes:

- *Guidance on terminology Standards for Ireland* (July 2017)
- *Guidance on Messaging Standards for Ireland* (June 2017)
- *Overview of Healthcare Interoperability Standards* (July 2013)

1.2 eHealth Standards Advisory Group

HIQA develops standards for the health and social care sector. Following approval by the Board, standards are submitted to the Minister for Health for approval. The technical standards team within HIQA works with the eHealth Standards Advisory Group (eSAG) who advise us on our work programme and specific standards developed. The eSAG ensure a coherent and consistent approach to the development of standards. The areas on which eSAG offer advice includes:

- data definitions and minimum datasets
- clinical concepts and archetypes
- messaging standards and specifications
- terminology systems including classification and terminology systems.

For full terms of reference and membership of the eSAG please see Appendix 1.

1.3 Guiding principles

Based on work completed to date and a review of international experience, HIQA proposes the following set of guiding principles to assist the development of interoperability standards for Ireland:

1. The development of standards and associated technical materials to support eHealth will be based on HIQA's standard procedures and processes for the development of technical standards.
2. Open non-proprietary standards will be preferred over proprietary ones.
3. International standards which have been fully implemented and validated will be preferred.
4. There should be minimum adaptation of the international standards to meet the requirements of the Irish health sector.
5. Where there is no international standard available, and only as a last resort, HIQA will consider developing a new standard for Ireland.
6. Industry developments and opportunities to improve delivery of health and social care services will be taken into account.
7. The standards proposed will ensure value for money and minimise cost of compliance.

Adherence to these principles will ensure that HIQA can leverage best international practice and avoid duplication of effort as well as ensuring that only tried and tested standards which are already available in software products are selected for use.

2. Interoperability standards

This section considers the various standards development organisations in existence and describes the different ICT standards in healthcare, focusing particularly on messaging and terminological systems standards.

2.1 International standards development organisations

There are two main types of standards — proprietary standards and open standards. Proprietary standards are developed by industry, often by a single vendor with a large market share (for example, the Windows Operating System). Open standards, on the other hand, which may or may not be mandatory, are developed collaboratively with all the key stakeholders involved, generally under the auspices of a standards development organisation. Crucially they also promote competition.

There are currently seven major international organisations involved in eHealth standards:

- The International Organisation for Standardization (ISO), which is the largest developer of world-wide standards
- The European Committee for Standardization (CEN), which is the principal standards development organisation in Europe
- SNOMED International, which is the developer of SNOMED-CT terminology standard
- Health Level Seven (HL7), which is the developer of the most widely used standards for electronic health messages
- Digital Imaging and Communications in Medicine (DICOM), which is the de facto standard for electronic medical imaging
- OpenEHR, which is an open source activity supporting the development of standards for electronic health records (EHRs)
- Integrating the Healthcare Enterprise (IHE), which is a major industry-led eHealth systems interoperability initiative.

2.2 Standards and eHealth and electronic health records

Health information standards are intended to remove ambiguity and ensure that there can be mutual understanding between software systems. To support the much-needed interoperability between systems and meaningful sharing of data, health information standards must cover both syntax and semantics. As a result, two distinct groups of standards are required — one for defining a common syntax and the other for defining a common semantics.

Messaging standards define a common syntax. They specify the structure and order of the elements that make up a message, such as patient information, laboratory information, the test undertaken and the results. They define which elements are required and which are optional. Coding systems define a common syntax. Systems such as the International Classification of Diseases revision 10 (ICD-10) and Logical Observation Identifiers Names and Codes (LOINC) assign meaning to the characters in the message.

2.2.1 Messaging standards

Messaging standards outline the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of information — the syntax. The term 'message' refers to a unit of information that is sent from one system to another, such as between a laboratory information system and a general practitioner's clinical information system.

There are multiple internationally recognised messaging standards for EHRs with varying levels of support for each. Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing standards for the exchange, integration, sharing and retrieval of health information. HL7 have multiple standards specific to the messaging of healthcare information — the HL7 v2.x family of standards, the HL7 v3 messaging standard, the clinical document architecture standard (CDA) and, in recent years, the Fast Healthcare Interoperability Standard (FHIR).

One of the limitations of certain messaging standards is that they conflate process (services) and content (documents), whereas newer standards such as the HL7 Clinical Document Architecture (CDA) standard have been developed to deal with such limitations. A common uncertainty for implementers is to know when to use an electronic message or an electronic

clinical document for a given use case, otherwise known as the messaging versus document paradigm.

There are no definitive rules to mandate the use of either a message or a document, and the choice will depend on the clinical scenario in question. If the information to be exchanged is a summary or snapshot in time, such as a discharge summary that needs to be human-readable, then an electronic document could be the most appropriate choice. If the information is suitable for transmission in real time, such as appointment scheduling, or is transaction-based, such as an acknowledgement to a query message, then a message will be the best solution.

2.2.2 Terminological standards

Terminology standards support a strategy of collecting data once and then using it multiple times, where possible. They can ensure that higher quality data is recorded during the patient visit and that this high quality data is available for epidemiological research and statistical reporting after the visit. Terminology standards ensure semantic interoperability — that is, that healthcare systems understand and use data in the same way, as defined by the terminology standard. Systems using different terminology standards can communicate using one of the mappings developed between the standards. Terminologies may be classified into three types:

- Reference terminology — sometimes known as a nomenclature, a reference terminology defines the meaning of all terms in a clinical domain unambiguously and independent of any specific purpose. Often known simply as terminologies, international reference terminologies such as SNOMED CT and LOINC are widely used in clinical coding. Reference terminology-based coding at the point of care has been shown to significantly improve the overall quality of clinical data.

- Aggregation terminology — an aggregation terminology defines a set of 'non-overlapping classes in single hierarchies' according to aggregation terminology rules. Also known as classifications, international aggregation terminologies are more suited to the recording and analysis of secondary use data, such as for epidemiological research or to generate health statistics. Aggregation terminologies provide the framework to generate administrative, public health and research information from

routinely collected clinical data. Specific national level aggregation terminologies are sometimes used for reimbursement.

- User interface terminology — also known as entry terms, a user interface terminology defines 'a collection of terms that are used in written and oral communication by a group of users'. Each term is described in terms of the natural language they belong to, as well as by dialect, time, clinical specialty and professional group.

Reference terminology and aggregation terminology standards are independent of spoken language. A user interface terminology standard defines the set of spoken language terms that correspond to the reference terminology or aggregation terminology standard in question. For example, where a localized version of a reference terminology or aggregation terminology is not available, a user interface terminology can be useful for defining the set of local language terms that correspond to the reference terminology or aggregation terminology.

Designed to serve different purposes, reference terminologies and aggregation terminologies should be considered complementary. Alone, neither a reference terminology nor an aggregation terminology can serve all purposes for which health information is currently used or likely to be used in the future. However, when each is used appropriately, they combine to provide a common medical language for epidemiology, for clinical trials, for bio surveillance, for reimbursement and, ultimately, for an electronic health record. They also significantly improve the quality of data collected.

3. Consultation questions and process

A key issue for Ireland is to determine what set of standards to adapt in order to facilitate interoperability. This document is available for public consultation for a six-week period. In this way, the public, service users and service providers will have the opportunity to provide feedback and participate in the development process. We invite all interested parties to submit their views on this document.

Two consultation questions are posed. These questions are not intended, in any way, to limit feedback — all other comments and more general feedback are welcome.

Question 1: Which area of work should be prioritised by the eHealth Standards Advisory Committee?

Question 2: Please provide us with any general comments you would like to make in relation to this consultation document.

There are several ways to tell us what you think.

You can complete the Polldaddy questionnaire at http://hiqa.polldaddy.com/s/technical-interoperability-standards.

You can also submit your comments by downloading and completing the consultation feedback form available from www.hiqa.ie and e-mailing your completed forms to technicalstandards@hiqa.ie

Alternatively, you can print off a copy of the feedback form from our website and post it to us at:

Health Information and Quality Authority
eHealth Consultation
George's Court
George's Lane
Smithfield
Dublin 7

For further information or if you have any questions, you can talk to the consultation team by calling (01) 8147683. The closing date for receipt of comments is 5 pm on Friday 22 September 2017.

3.1 How we will use your comments

The submissions will be used to inform the work of HIQA and of the eHealth Standards Advisory Group (eSAG) in the development of national standards for eHealth interoperability. HIQA will work with eSAG to prioritise areas of work where standards should be developed in line with our guiding principles. We would like to thank you for taking the time to submit your comments.

Appendix 1 – eHealth Standards Advisory Group

The terms of reference of the Advisory Group are:

- agree terms of reference and working procedures and processes and document these
- advise the Authority on the identification and prioritisation of those areas in which standards are required bearing in mind where there are short, intermediate and long term priorities
- agree and maintain a work plan of projects for the eHealth Standards Advisory Group
- advise the Authority on mechanisms for raising awareness of standards and the benefits of taking a standards based approach when developing health information systems to the broader stakeholder community
- advise the Authority on the additional domain expert members required to undertake aspects of the work plan or specific projects
- delegate specific tasks to members of the eHealth Standards Advisory Group or domain experts co-opted to projects undertaken by the eHealth Standards Advisory Group, revoking and amending those delegations as required
- advise the Authority on the identification of key stakeholders e.g. user communities, professional bodies and domain experts who should be consulted on depending on the particular standard being developed
- work to ensure the ongoing development and implementation of health information standards.

Membership of the Advisory Group includes representatives from:

- Health Information and Quality Authority (Chair)
- Health Service Executive — Commercial and Support Services ICT Directorate
- Health Service Executive — Clinical Strategy and Programmes Directorate
- Health Service Executive — Quality and Patient Safety Directorate
- Department of Health
- General Practice IT Group
- Irish College of General Practitioners
- National Standards Authority of Ireland

- Irish Pharmaceutical Union
- Royal College of Surgeons in Ireland
- Royal College of Physicians of Ireland
- Irish Association of Directors of Nursing and Midwifery
- Faculty of Radiologists — Royal College of Surgeons in Ireland
- Faculty of Pathology — Royal College of Physicians of Ireland

The Advisory Group may co-opt representatives from other bodies if required. Membership of the Advisory Group will be reviewed annually. It is estimated that the Advisory Group will meet face-to-face 3 – 4 times yearly.

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