Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Overview of Healthcare Interoperability Standards

July 2013

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive continuous improvement in Ireland's health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

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

Overview of Health Information function

Health is information-intensive, generating huge volumes of data every day. It is estimated that up to 30% of the total health budget may be spent one way or another on 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 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 Authority has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, the Authority is charged with evaluating the quality of the information available on health and social care [section (8)(1)(i)] and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available [section (8)(1)(j)].

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. It can also support a much faster, more reliable and safer referral system between the general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in health and social care in Ireland is highly fragmented with major gaps and silos of information. This results in patients and service users being asked to provide the same information on multiple occasions.

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 – patients and service users, health professionals, policy makers and the general public – to make choices or decisions based on the best available information. This is a fundamental requirement for a highly reliable healthcare system.

Through its health information function, the Authority 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.

One of the areas currently being addressed through this work programme is the development of standards to enable information to be shared electronically, commonly referred to as interoperability standards. A public consultation document on eHealth[†] was published by the Authority in 2011. The feedback from the consultation identified the need to raise awareness of interoperability standards in health and social care. This document provides background information on healthcare interoperability including the levels and types of interoperability, benefits and barriers to interoperability, the standards development organisations (SDOs) that develop interoperability standards, and a discussion on standards harmonisation. Throughout, examples are provided to illustrate where interoperability standards in healthcare are applied.

[†] 'eHealth is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. The term characterizes not only a technical development, but also a state of mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology' (1)

Table of Contents

About the Health Information and Quality Authority 2
Overview of Health Information function 3
1 Introduction 6
2 Background 6
2.1 Intended audience 7
2.2 Definitions 8
3 Benefits of interoperability in healthcare 9
4 Challenges to healthcare interoperability 11
5 Interoperability standards 12
5.1 Levels of interoperability 12
5.2 Dimensions of interoperability 13
5.3 Interoperability standards 14
5.4 Standards development organisations 15
5.5 Interoperability standards 17
5.6 Harmonisation between interoperability standards 21
6 International review 22
6.1 Australia 22
6.2 Canada 23
6.3 Denmark 24
6.4 England 24
6.5 Netherlands 25
6.6 Ireland 26
6.7 Summary of findings 28
7 Conclusion 29
References 30
Appendix 1 – Guiding principles 37

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.

In order to deliver these benefits, several key building blocks must 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 including communication and terminology standards based on widely available and implemented international standards
- a system of unique identification for individuals, organisations and health professionals
- an Electronic Health Record[‡] (EHR) model often regarded as the ultimate goal of eHealth.

Under section (8)(1)(k) of the Health Act 2007, the Authority has responsibility for setting standards for all aspects of health information including, for example, information governance, common data definitions and the exchange of electronic health information.

In order to consult with stakeholders on the development of eHealth standards the Authority produced the consultation document *Developing National eHealth Interoperability Standards for Ireland: A Consultation Document.*(2) The consultation identified the need for guidance documents in three areas: general interoperability standards, messaging standards and terminology standards. This document provides a background into general healthcare interoperability, examples of healthcare interoperability standards and a high level review of the types of standards developed.

2 Background

Currently a patient's medical records can be recorded on paper, electronically or a combination of both, and are typically held in different locations. This makes it difficult to get a complete picture of the patient's healthcare journey. Additionally, fragmentation of services, locally within hospitals and between primary, secondary and tertiary care settings, alongside the use of different clinical information systems in different care settings can make it difficult to safely communicate clinical information. This may lead to miscommunication or missing patient information,

[‡] An electronic health record (EHR) is a longitudinal record of patient health information across multiple care settings.

ultimately compromising patient safety. Such limitations can be improved with the adoption of information and communications technology (ICT) in healthcare. ICT initiatives can facilitate the timely sharing of clinical information between healthcare providers, allowing health information systems to communicate or interoperate, thereby facilitating the possibility for health information to be shared both within and across organisational boundaries.

eHealth initiatives such as the electronic transfer of prescriptions and the development of an electronic health record (EHR) require that health information is shared across organisational boundaries. Interoperability standards provide a standardised approach to facilitate seamless sharing of information between health information systems.

The recommendation for interoperability standards for healthcare in Ireland is based on work completed to date by the Authority on interoperability standards that includes the General Practice Messaging Specification (GPMS),[3] reviews of international experience and guiding principles on interoperability standards developed by the Authority.

The Authority's work programme to date has included initiatives specifically for messaging standards such as the GPMS[3] and for other eHealth initiatives including work on the Individual Health Identifier (IHI)[4] and health identifiers for practitioners and organisations,[5] information governance[6] and the eHealth consultation.[2] Further work has been completed on high level guidance on messaging standards[7] and guidance on clinical terminologies is due for publication in the second quarter of 2013. The guiding principles to assist the development of interoperability standards for Ireland are outlined in Appendix 1.[2]

2.1 Intended audience

This overview of healthcare interoperability standards is being developed to inform key stakeholders such as public and private patients and service users, vendors, purchasers and implementers of health information systems, healthcare providers, the wider health informatics community and any other interested parties, about the nature and benefits of interoperability standards, and to encourage wider participation in standards development. The overview is targeted principally at those involved in specifying the requirements for and the development and implementation of new health information systems and eHealth applications, both locally and nationally.

2.2 Definitions

Many definitions are available to describe interoperability. However, a frequently used definition is:

> 'Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.'[8]

There are many different types of interoperability pertinent to health.[9] Interoperability standards can be considered from three different viewpoints to maximise business benefit:[10]

- Technical interoperability is the exchange of data between computer system A and computer system B. The computers do not know about the meaning of what is exchanged. For example, emails transmitted from one computer to another generally contain content information that is not understood by the sending or receiving computer.
- Semantic interoperability guarantees that computer system A and computer system B understand the meaning of data in the same way and use and interpret the data that is exchanged. Semantic interoperability is central to healthcare interoperability. For example, a laboratory information system transmits results to a practice management system at a GP practice. The practice management system recognises the structure, format, units and meaning of the result sent by the laboratory system. In order to achieve this, both systems use a common terminology or language to communicate.
- Process interoperability incorporates business processes. It is important that business processes also interoperate and the people involved share a common understanding to enable computer system A and computer system B to work together. For example, healthcare professionals must standardise business rules to ensure that health information is recorded in a uniform and timely manner such that the transfer of information between systems is consistent and complete.

To support interoperability between systems and meaningful sharing of data, health information standards must cover both the syntax (*structure*) and semantics (*meaning*) of the data exchanged. Interoperability standards are not software or hardware, but are the blueprints that technology developers can use to develop health information systems that will be inherently compatible with other systems adhering to these same standards.[11;12]

3 Benefits of interoperability in healthcare

> *'Interoperability will bind together a wide network of real-time, life-critical data that not only transform but become health care.'* Brailer, DJ.[13]

The benefits of the use of interoperability standards in healthcare are well established, mainly due to the fact that many eHealth initiatives and benefits of ICT in general cannot be realised in the absence of interoperation between health information systems. The use of interoperability standards delivers key benefits in a number of areas. Specifically, standards enable and support health service improvements, deliver economic benefits and, most importantly, result in benefits for individuals through safety improvements in front-line service delivery.[2] In the area of implementation, standards can act as the middle ground where coordination between different software systems is needed. For example, systems that have very different user interfaces can still communicate meaningful data if they capture information using similar terminologies or terminologies which can be mapped to each other.[14]

Interoperability can greatly benefit all involved in the delivery and receipt of healthcare:

- Individuals can benefit from enhanced quality and safety of treatments received, delivery of healthcare when and where it is required and integrated care plans developed by providers across one or more organisations. Furthermore, interoperability across national borders could facilitate better and more informed emergency care abroad.

- The electronic transfer of prescriptions (ETP) can be enabled through interoperability of pharmacy systems with primary care information systems facilitating a reduction in the potential for harmful drug interactions and transcription errors, better clinical decision making leading to safer and higher quality care through timely access to selected health information about an individual if the ETP solution is linked to an electronic patient record.

- Healthcare professionals can potentially improve the quality and safety of the care they provide through strengthened coordination across the various points of care delivery. This can result in access to timely patient safety information and evidence-based clinical guidelines which in turn supports a better decision-making process.

- Individuals and healthcare professionals can benefit from efficiency gains due to a reduction in duplication of data entry, such as recording of the same demographic information at multiple locations.

- Insurance companies can benefit from the potential cost savings resulting from the reduction in duplicate diagnostic testing, earlier disease diagnosis, a

reduction in costs associated with adverse events and general improvements in outcomes for individuals.

- Interoperability standards can benefit the software industry by enabling a single market for digital healthcare, thereby reducing the cost of developing health information systems and opening up competition in the market.[12]

- Efficiency gains brought about by the implementation of healthcare interoperability standards can benefit the provider, individual and insurance providers by facilitating faster access to care, diagnosis and treatment of disease, thereby reducing costs significantly.[3]

4 Challenges to healthcare interoperability

One of the key challenges to the implementation of interoperability standards for health is the heterogeneity of health information systems in Ireland, as in other countries. Most large hospitals will use many different ICT systems from different suppliers, each supporting different functions. There is no single health information system that could facilitate all administrative, clinical, technical and laboratory ICT requirements of a large healthcare organisation. In such a fragmented environment, the requirement to achieve interoperability is critical and the need for interoperability standards becomes evident.(13)

Cultural change within the health sector is required to ensure independent healthcare organisations are willing to share health information beyond the confines of their own systems. Standardisation removes an element of local autonomy for providers and the perception may exist that independent control of health information systems by providers is compromised.(15)

The changes required in business processes and operations at local level also act as a barrier to implementation as providers and local ICT professionals must be educated about new processes and methods of recording health information with the introduction of standardised terminologies.(15)

Although the benefits of interoperability in healthcare are considerable, they may be difficult to realise as the benefits are dispersed across a large number of stakeholders such as vendors, providers, policy makers and the individual. Some vendors use a lack of interoperability to their advantage as a customer retention strategy by building systems that can only interoperate with their own products.(13)

Investment is required in terms of standards-compliant systems development and implementation, and considerable effort is required in terms of change management in order to achieve interoperability. The investment required by early standards adopters at the leading edge of new initiatives is typically significantly higher and the benefits slower to accrue, than that required by implementing standards-based systems that are already widely in use. The late adopter benefits from the investment and effort of the early adopter in terms of time and money needed to ensure any failures and barriers to success are dealt with. This means that vendors and providers in particular may be hesitant to bear the cost of progressing the implementation of interoperability standards until many other organisations have already achieved interoperability.(13)

5 Interoperability standards

Standards for healthcare interoperability exist to allow health information systems to communicate in the same way across system, organisational, regional and national boundaries. By agreeing upon standards at regional and national level, the potential for sharing health information is increased significantly and large national eHealth initiatives are enabled, such as the implementation of the Individual Health Identifier (IHI) or a national EHR. Alongside the types of interoperability, interoperability can also be categorised into various levels, each indicating a level of complexity of health information exchange. In order to facilitate complex levels of interoperability, a number of standards development organisations (SDOs) exist. These organisations develop adoptable standards for the various types or categories of interoperability, many of which can operate in tandem to allow functional and semantic interoperability.

5.1 Levels of interoperability

There are four levels of interoperability, each demonstrating a level of sophistication and standardisation of health information interoperability:[16]

1. **Non-electronic information** – there is minimal use of technology to share data and most health information is recorded and shared on paper. For example, referral from primary care to secondary care by paper-based referral letter sent via standard postal service.

2. **Machine transportable information** – transmission of non-standardised data using basic information technology. This data cannot be electronically manipulated. For example, sharing of paper-based health information via fax or email attachment.

3. **Machine organisable information** – transmission of structured electronic messages containing non-standardised data. This means that information can be shared electronically. However, an interface is required between one or more systems to translate the data from the structure used by the sending system to the structure used by the receiving system. For example, the exchange of electronic health information between a hospital system and a General Practice Management System at a GP practice via the national Healthlink project.

4. **Machine interpretable information** – transmission of structured messages containing standardised and coded data. This means that systems exchange health information electronically using a format and vocabulary that is readable and interpretable by the receiver without the requirement for an interface to decode the information. For example, a discharge summary is transmitted electronically from the hospital information system to the primary care electronic record of the patient in a structured and coded format that is

used by both systems, such as HL7 Clinical Document Architecture (CDA) and SNOMED CT.[16]

5.2 Dimensions of interoperability

In order to better understand the type and level of interoperability that are needed when planning to share health information, it is useful to document the requirements necessary to facilitate the desired outcome of integrating any systems. The Healthcare Information and Management Systems Society (HIMSS) Integration and Interoperability Steering Committee (I&I) defined six dimensions of interoperability in order to provide a framework for considering the types of interoperability concerns to be addressed when developing integrated healthcare solutions. These dimensions can aid providers in planning and selecting the type and level of interoperability required to achieve the successful exchange of health information:[17]

1. Uniform movement of healthcare data is achieved between systems such that the clinical purpose and meaning of the data is preserved. For example, the units of measurement denoted in a laboratory result are preserved during and following transmission of the result.

2. Uniform presentation of data is achieved enabling various providers using different systems to view information in the same visual format when this is required. For example, the visual indication of an abnormal laboratory result is consistent across all systems ensuring providers are alerted consistently to any detected abnormalities.

3. Uniform user interface controls are established enabling consistent context and navigational control across various underlying systems. For example, the controls used to log out of various systems are consistent across these systems ensuring the likelihood that providers successfully exit systems without compromising the privacy and confidentiality of individuals.

4. Uniform safeguarding of data security and integrity is achieved by ensuring that data in transmission between systems is only accessible to authorised users and programs. For example, when an electronic prescription is transmitted from a primary care system to a pharmacy system, only the users authorised to prescribe, dispense or administer the prescription can access the information. Any interception of the information in transit should be detectable by the receiving system.

5. Uniform protection of confidentiality is achieved by ensuring strong information governance controls are in place across organisations involved in the sharing of health information. For example, a healthcare organisation in receipt of personal health information from another organisation will not release any of that information without the prior consent of the individual to whom the information pertains.

6. Uniform assurance of a common degree of system service quality is achieved by ensuring that interoperable systems are reliable and that robust emergency plans are in place in the event of a breakdown of communication between systems. For example, access to an individual's healthcare record is usually available electronically in an emergency department, but there are manual procedures for retrieval in place in the event that there is a breakdown of communication between systems.[17]

5.3 Interoperability standards

As mentioned above, interoperability depends upon both syntax and semantics. A number of interoperability standards have been developed to address the requirements of both types of interoperability. The following types or categories of standards are used in healthcare:[15]

- **Messaging standards** – messaging standards outline the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of information. 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 GP's clinical information system. Examples of messaging standards include HL7 v2.x for administrative data and Digital Imaging and Communications in Medicine (DICOM) for radiology images. The Authority published guidance on messaging standards for Ireland in December 2012.[7]

- **Terminology standards** – terminology standards provide specific codes for terminologies and classifications for clinical concepts such as diseases and medications. Terminology systems assign a unique code or value to a specific disease or entity, for example, the ICPC-2 code for 'asthma' is R96.[18] Terminologies are used primarily to capture clinical information at the point of care. As such, they are highly detailed, have predefined relationships and are fine grained. Classification systems – such as ICD-10-AM – group related concepts together to satisfy a specified use case, for example, causes of disease. Classifications are more suited to the recording and analysis of secondary use data such as research or epidemiology purposes. It is necessary to select different classifications and terminologies in combination to enable complete coverage across all of healthcare. Examples of terminology standards include ICPC-2, ICD-10-AM, SNOMED CT for clinical terms and LOINC for laboratory results. The Authority is due to publish guidance on terminology standards for Ireland in the third quarter of 2013.

- **Document standards** – document standards indicate the type of information included in a document and also the location of the information. Examples of document standards include the paper-based Subjective, Objective, Assessment, Plan (SOAP) standard and also HL7 Clinical Document Architecture (CDA) for electronic sharing of clinical documents. HL7 have developed document-standard

specifications for a continuity of care document (HL7 CCD) and a discharge summary (HL7 DS).[19]

- **Conceptual standards** – conceptual standards allow the transmission of information between systems without any loss of the meaning or context of that information. For example, the HL7 Reference Information Model (RIM) provides a framework for describing health information and the context around it, i.e. who, what, when, where and how.

- **Application standards** – application standards determine the implementation of business rules for software systems to interact with each other. For example, application standards can allow a single user to log in to multiple information systems in one environment allowing efficient access to the required health information. This can facilitate the simultaneous viewing of health information across multiple databases that are not electronically integrated.

- **Architecture standards** – architecture standards define a generic model for health information systems. They allow the integration of health information systems by providing guidance to aid the planning and design of new systems and also the integration of existing systems. This is achieved by defining common data elements and business logic between systems. For example, the CEN standard ENV12967 (Healthcare Information Systems Architecture or HISA) provides an open architecture that is independent of technical specifications and applications. This standard enables integration of common data and business logic between systems, which is achieved via a middleware[§] layer allowing information exchange between different systems.[20]

5.4 Standards development organisations

Health information interoperability standards are developed by a wide variety of healthcare organisations including regulators, vendors, consultants and healthcare providers. Most often, the development of interoperability standards involves technical committees that define methods and groups representing communities of interest. There are a number of international standards development organisations (SDOs) that have developed standards that have achieved widespread adoption around the world. Below is a description of the major SDOs involved in the development of interoperability standards to facilitate the exchange of health information.

[§] Middleware can be defined as software that enables two separate applications to interact and communicate.

5.4.1 International Standards Organisation (ISO)

ISO (www.iso.org) is an international standards development and accreditation organisation with a network of national standards institutes in 157 countries. The ISO technical committee, ISO/TC215, was established for the area of health informatics with the scope of:

- standardisation in the field of information for health, and health information and communications technology to achieve compatibility and interoperability between independent systems
- ensuring compatibility of data for comparative statistical purposes, (i.e. classifications) to reduce duplication of effort and redundancies.

ISO/TC215 collaborates with a number of other SDOs including Comité Européen de Normalisation (CEN) and HL7 and has a membership of over 20 participating countries involved in developing health information and interoperability standards. Standards developed by working groups within ISO/TC215 receive ISO accreditation, thereby ensuring a strong likelihood of international adoption.

5.4.2 Comité Européen de Normalisation (CEN)

CEN, or the European Committee for Standardisation (www.cen.eu), is involved in developing multidisciplinary standards including standards for healthcare systems and interoperability. It is a private non-profit organisation whose mission is to foster the European economy in global trading, the welfare of European citizens and the environment by providing an efficient infrastructure to interested parties for the development, maintenance and distribution of coherent sets of standards and specifications. TC 251 is the health informatics technical committee in CEN with responsibility for publishing standards addressing aspects of health information representation including messaging, electronic health records and eHealth initiatives. The Committee is also responsible for addressing the European Commission's health interoperability mandate known as Mandate 403.[(21)] CEN membership consists of most European countries, including Ireland.

5.4.3 Health Level Seven (HL7)

The HL7 (www.hl7.org) organisation is an SDO accredited by the American National Standards Institute (ANSI) with the purpose of developing and publishing healthcare-specific standards. It publishes messaging standards for healthcare interoperability that aim to enhance care delivery, knowledge transfer and optimise workflow. HL7 products include HL7 version 2.x (v2.x), HL7 version 3 (v3) messaging standard, Clinical Document Architecture (CDA), Clinical Context Object Workgroup (CCOW) and Arden Syntax. These standards are described below in section 5.5.

5.4.4 OpenEHR

The OpenEHR Foundation (www.openehr.org) is a not-for-profit organisation established in 1999, by Ocean Informatics, Australia and the Centre for Health Information and Multi-professional Education (CHIME) department in University College London, UK. OpenEHR is a virtual community working on interoperability and computability in eHealth. Its mission is to enable semantic interoperability of health information, within and between EHR systems. The openEHR Foundation has published a set of specifications defining a health information reference model, a language for building 'clinical models', or archetypes, which are separate from the software, and a query language. The architecture is designed to make use of external health terminologies, such as SNOMED CT, LOINC and ICD. Its main focus is EHRs and clinical information systems.[22]

5.4.5 Integrating the Healthcare Enterprise (IHE)

IHE (www.ihe.net) is an initiative by healthcare professionals and ICT professionals to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. It is claimed that systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. The aim of IHE is to improve the state of systems integration and remove barriers to optimal patient care by creating and operating a process through which interoperability of healthcare IT systems can be achieved.[23]

5.5 Interoperability standards

5.5.1 HL7 suite of standards

The HL7 v2.x suite of standards is one of the most widely used standards for communicating clinical data among clinical information systems in hospitals and general practice in the world.[24] V2.x standards provide specifications for messages to support the sharing of information including referral information, appointment information, admission, transfer and discharge information from hospital. The ordering of laboratory and radiology tests and pharmaceutical products for patients and reporting test results are also supported by v2.x standards. HL7 v2.x is the most commonly used standard for health information exchange in the world.[25]

The HL7 v3 messaging standard uses an information model called the Reference Information Model (RIM) and a formal methodology called the HL7 Development Framework (HDF) to increase the detail, clarity and precision of the message specification.[26] The v3 messaging standard was developed in response to a need to reduce the level of optionality available in v2.x.[25] The HL7 v3 Reference Information Model (RIM) provides a conceptual shared generic model that facilitates interoperability by standardising all data models to a norm. The RIM seeks to portray the entire healthcare domain and is the fundamental model from which all HL7 v3

messages are derived. It is populated by classes such as entities or roles, descriptive attributes and relationships between classes. The classes are an abstraction of subjects and other concepts of interest within the healthcare domain. As a starting point to message development for a particular healthcare domain, relevant classes, attributes and relationships from the RIM are selected to construct a Domain Message Information Model (D-MIM). The D-MIM needs to include all the elements required to develop the complete set of messages planned for a chosen domain such as the 'laboratory' domain. The D-MIM may be further refined to a more specific set of classes, attributes and relationships needed for a particular message or group of messages to produce a Refined Message Information Model (R-MIM). R-MIMs are developed for a related group of messages, for example, those used in laboratory orders. While the RIM represents an abstract view of the healthcare domain, the D-MIM and R-MIM each refine this view to facilitate the development of actual messages.[25]

CDA is a suite of HL7 v3 standards for representing clinical documents such as a referral form or a discharge summary.[27] The development of CDA has been driven by the need for health information to be both human and computer readable and supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing.[25] CDA Release 2 is the current version in use. However, work is ongoing within HL7 International to finalise Release 3. The criteria for CDA document use are:

- persistence – a clinical document continues to exist in an unaltered state, for a period defined by local and regulatory requirements
- stewardship – a clinical document is maintained by an organisation entrusted with its care
- potential for authentication – a clinical document is an assemblage of information that can be legally authenticated. For example, an electronic prescription which must be verified and authenticated
- context – a clinical document establishes the default context for its content
- wholeness – authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document. For example, a discharge summary where all parts are related and relevant
- human readability – clinical documents are human readable.[27]

The criteria for CDA documents are useful when considering whether to use a message or document to convey clinical information. If the use case meets the criteria above then a CDA document may be more appropriate than messaging. CDA is defined as independent of the messaging or transport mechanism and therefore does not define trigger events (an event that must occur in order to initiate the sending of a message) or interactions. Thus, CDA can be sent between systems using any interoperability protocol, including those that HL7 defines for messaging. The CDA specification provides guidelines for sending CDA within either HL7 v2.x or HL7 v3 messages.[25]

The Clinical Context Object Workgroup (CCOW) provides an HL7 standard protocol designed to enable different applications to synchronise in real-time at the user-interface level. For example, a laboratory system result is available via a Patient Administration System (PAS). It is vendor-independent and allows applications to present information at the desktop and/or portal level in a unified way. CCOW is the primary standard protocol in healthcare to facilitate a unified comprehensive view and single login capability across systems without integrated databases. The CCOW standard exists to facilitate a more robust and 'plug-and-play' interoperability across various different applications.[15]

Arden Syntax, currently maintained by the HL7 organisation, is a standardised language used to represent and share clinical knowledge through Medical Logic Modules (MLMs). An MLM is a hybrid between a production rule (i.e. an 'if-then' rule) and a procedural formalism. Each MLM is invoked as if it were a single-step 'if-then' rule, but then it executes serially as a sequence of instructions, including queries, calculations, logic statements and write statements. The Arden Syntax was introduced in 1989 and was first adopted in 1992 by the American Society for Testing and Materials (ASTM). It was developed for embedding MLMs into proprietary clinical information systems and designed to support clinical decision making in particular. Sequencing tasks can be modelled by chaining a sequence of MLMs. MLMs have been used to generate clinical alerts and reminders, interpretations, diagnoses, screening for clinical research studies, quality assurance functions and administrative support. The Arden Syntax makes knowledge portable, but MLMs developed for one environment are not easily embeddable within another. Most commercial applications incorporating MLMs are developed by individual vendors primarily for use within their own environments.[28]

5.5.2 Electronic Data Interchange for Administration, Commerce and Transport (EDIFACT)

EDIFACT is a messaging standard maintained by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) and adopted by the ISO as ISO 9735 standard.[29] EDIFACT is a less commonly used standard in healthcare messaging and is now considered an 'older' standard to work with. With the exception of Denmark, use of the EDIFACT messaging standard has been largely superseded by HL7 v2.x in healthcare. It provides a set of syntax rules to structure data, an interactive exchange protocol (I-EDI) and standard messages which allow multi-country and multi-industry exchange.[29]

5.5.3 Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT)

SNOMED CT is the largest clinical terminology currently available internationally and covers many aspects of healthcare, including diseases, symptoms, procedures and medical devices. It was developed jointly by the National Health Service (NHS) in the United Kingdom and the College of American Pathologists, and provides a mapping of clinical concepts with comprehensive multilingual standard descriptive terms to

facilitate semantic interoperability. It aims to improve the quality and safety of healthcare by improving the accuracy of storage and/or recording of clinical data in patient records, by recording healthcare encounters and by delivering decision support to healthcare providers. Clinical information is coded in order to become machine processable, thus enabling consistent health information exchange, which is fundamental to semantic interoperability. SNOMED CT is currently owned and maintained by the International Health Terminology Standards Development Organisation (IHTSDO) based in Denmark.[30;31]

5.5.4 International Classification of Diseases (ICD)

ICD is the standard tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. ICD is an international coding system of diseases, signs, symptoms, abnormal findings, complaints, social circumstances, underlying causes of death and external causes of injury or diseases. ICD is used for health information purposes in public health, primary, secondary and tertiary care settings. It enables the storage and retrieval of diagnostic information for epidemiological, health management purposes and clinical use. It is also used for collating national mortality and morbidity statistics and for reimbursement. ICD is sponsored by the United Nations (UN) and developed by the World Health Organization (WHO).[32]

5.5.5 Digital Imaging and Communications in Medicine Committee (DICOM)

DICOM is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two systems that are capable of receiving image and patient data in DICOM format. The National Electrical Manufacturers Association (NEMA) holds the copyright to this standard. It was developed by the DICOM Standards Committee, whose members are also partly members of NEMA. DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). DICOM is known as NEMA standard PS3, and also as ISO standard 12052:2006, Health informatics – Digital Imaging and Communication in Medicine (DICOM) and includes workflow and data management standards.[33]

5.5.6 Logical Observation Identifiers Names and Codes (LOINC)

The LOINC system is a widely used terminology system, developed to provide a definitive standard for identifying clinical information in electronic laboratory reports. One of the main goals of LOINC is to facilitate the exchange and grouping of test results for clinical care, healthcare management and research. It provides a universal code system that includes a set of names and ID codes for identifying medical laboratory information and clinical test results. LOINC is distributed to the public by

providing a database of these codes at no cost. LOINC was developed in Indiana and is maintained there by the Regenstrief Institute, a non-profit medical research organisation.[34]

5.6 Harmonisation between interoperability standards

There are many healthcare interoperability standards in use globally with many standards developed specifically for a single aspect of healthcare, such as LOINC for laboratory coding. It seems unlikely that a single global set of standards will emerge that is adopted by all given the success of, and investment into, existing standards. Therefore, in order to achieve true interoperability, it is vital that steps are taken to ensure that the use of different standards is not a barrier to interoperability.

Harmonisation between standards and convergence of standards is a positive step in ensuring that health information systems are, or have the potential to be, interoperable with each other and share health information. This increases the potential for any given system to be compliant with an increasing number of interoperability standards, which could reduce the need for procurement of new systems to facilitate interoperability. Current areas of standards harmonisation include the harmonisation of data types between HL7 CDA and CEN 13606 Reference Models. The OpenEHR Reference model utilises the CEN 13606 Reference model and is thereby automatically harmonised with the HL7 CDA Reference Model.[35] HL7 is also collaborating with IHTSDO to establish interoperable vocabularies and semantics between HL7, LOINC and SNOMED CT.[36]

6 International review

There are important lessons for Ireland to learn from international experience in relation to the adoption of interoperability standards. The following section will give a brief outline of the types of interoperability standards adopted by five countries: Australia, Canada, Denmark, England and the Netherlands. Additionally, it is fitting to give a brief overview of the current situation regarding health information standards in Ireland. To add context, a brief introduction to the eHealth strategy adopted in each country will be outlined given that interoperability standards are one of the key building blocks of any eHealth strategy.

6.1 Australia

The National eHealth Transition Authority[37] is a not-for-profit agency established by the Australian government in 2005. NEHTA is responsible for delivering the National eHealth Strategy.[38;39] Its strategic priorities and initiatives include outlining a national infrastructure for the delivery of a future individual EHR. Significant progress has been made with eHealth activities at a national level. For example, development is ongoing in the areas of health information interoperability standards, identifiers and clinical terminologies.[40;41]

As part of the development of its interoperability strategy, NEHTA undertook an audit of the existing use of messaging standards throughout the healthcare sector. This showed that by far the most widely used standard was v2.x. It therefore concluded that whatever approach to eHealth interoperability was adopted, which would ultimately lead to a national EHR, it would need to accommodate migration from v2.x if it was to be able to retain the significant investment in existing systems and be future-proofed against whichever of the competing standards available at the time (2007) became the international norm.

The choice was between ISO CEN 13606, OpenEHR or v3 messaging with CDA. Its recommendation was to continue with the use of v2.x messaging as the primary means of exchanging health information in areas where it is currently delivering benefit until superseded by v3 messaging and CDA. SNOMED CT has been endorsed by the Australian state and territory governments and identified as the preferred national clinical terminology with a constrained set of LOINC codes used for pathology requests and results for Australia.[42] ICD 10-AM is used for coding of inpatient episodes.

The primary standards adopted in Australia include:

- HL7 v3 messaging and CDA for all new initiatives with continued use of v2.x where established
- SNOMED CT, LOINC and ICD 10-AM standards are the terminology and classification systems in use.

6.2 Canada

Canada Health Infoway, which was established in 2001, has the mandate to provide investment and support for the development of a pan-Canadian EHR infostructure[‡] to significantly advance the use of health ICT in Canada. It has developed an EHR blueprint or technology framework detailing the vision and direction for the delivery of ICT projects to support an interoperable EHR.

The most recent Canadian health strategy, *2015: Advancing the Next Generation of Health Care in Canada*, [43] is a roadmap for advancing Infoway's infostructure, investments and priorities. An incremental and phased approach was taken to complete the infostructure. While good progress is evident in some jurisdictions, particularly in the area of standards, it has been slow to progress and somewhat inconsistent in other jurisdictions with a truly interoperable EHR (iEHR) still a future aspiration. Projects completed first across all jurisdictions were the public health surveillance system, identifier registries and diagnostic imaging, with drug, laboratory and the iEHR lagging behind.[44]

Infoway provides 100% of the funding required for the development of messaging, terminologies and interoperability standards. It also provides services for the ongoing maintenance, support, education and training and conformance of standards that have been formally endorsed for use or are 'stable for use'. There is a dedicated team to liaise with health-related SDOs such as HL7, ISO and SNOMED CT. Canada has an extensive track record with involvement in the HL7 organisation and is well represented on the HL7 Technical Committees, and contributed to the work to evolve the HL7 messaging standards from v2.x to v3.[45]

The v3 messaging standard was selected for the electronic exchange of health information and is required for all new message development in the EHR domain. If the existing v2.x messages are well established, then these should remain in place until opportunities arise for the upgrade of related software systems to v3 messaging.

The primary standards adopted in Canada include:

- v3.0 was selected for all 'new' message development in the EHR domain
- CDA was selected for claims settlement
- SNOMED CT, LOINC, ICD-10 CA, the Canadian Classification of Interventions (CCI) standards for laboratory data and imaging (X-rays) were the terminology and classification systems selected.

[‡] The term 'health infostructure' refers to the development and adoption of modern systems of information and communications technologies (ICTs) in the Canadian healthcare system.

6.3 Denmark

Denmark is one of the countries that ranks highest internationally in terms of the utilisation of eHealth initiatives and has achieved widespread use of ICT in the health sector.[46] The Ministry of Health is responsible for Danish eHealth policy and strategies. Denmark has a history of eHealth strategies where the EHR and the use of common standards are the central themes. In 2007, an organisation called Connected Digital Health in Denmark was formed by the Ministry of Health, the Danish Regions and the Danish municipalities to develop a new strategy for the digitalisation of the health service.[47] This new strategy marked a radical change in direction from the three previous eHealth strategies. It focused on supporting business processes, governance of national projects and stakeholder engagement and not 'just the technology'. The strategy's key point on standards is that they should be based on international, market-driven common public standards.[46]

Denmark was an early adopter of electronic messaging (1994) and adopted the EDIFACT standard for electronic communication between healthcare professionals.[48] Over the past 20 years, a number of IT systems were integrated to facilitate the secure exchange of clinical information using messaging. Examples of message types exchanged include discharge letters, referrals, laboratory request and results.[49] Recognising the benefits of standards, Denmark has continued to adopt various international messaging standards and clinical terminologies which are now in widespread use. It also embarked on developing its own bespoke national standards such as coding tables and laboratory display guidelines.[50] The XML standard has been adopted for the public exchange of information.

The healthcare organisation MedCom is responsible for the development and deployment of standards with a remit to set standards for IT systems and to act as a coordinating body to bring together healthcare providers, laboratories, vendors and others in order to develop interoperable standards.[46]

The primary interoperability standards adopted in Denmark include:

- EDIFACT is the main messaging standard
- classifications and terminologies such as ICD10, ICPC and SNOMED CT
- standards for laboratory data and imaging using the DICOM standard
- MedCom's standards for communication of messages are based on CEN standards and are in widespread use in Denmark.[46]

6.4 England

England has pledged a strong commitment to eHealth having published five key eHealth policy documents. In 2002, a policy paper was launched entitled *Delivering 21st century IT support for the NHS: national strategic programme*,[51] outlining the major eHealth applications to be deployed in the NHS. The National Programme for Information Technology (NPfIT) was initiated in 2005 led by the NHS Connecting for

Health, with responsibility for the delivery of a programme to provide a shared, centralised electronic health record.[52] The size and complexity of NPfIT was vast, with an original forecast of £12.7 billion (pounds) to fund the 10-year initiative making it the largest civil, non-military IT project ever undertaken[53] and was described by critics as ambitious and 'inherently risky'. [54]

Following elections in the UK in May 2010 the NHS came under review, significantly impacting the eHealth policy for the NHS England.[55] NPfIT had fallen significantly behind schedule and due to a change in government in May 2010 the strategy was halted. However, some successful national projects were delivered from NPfIT including a secure national network infrastructure called the N3, a picture archive and communications system (PACS), an electronic booking service called Choose and Book and finally a project for the electronic transmission of prescriptions (ETP).

In May 2012, the Department of Health in England published *The Power of Information: Putting all of us in control of the health and care information we need*. This document provides the formal government response to the NHS consultation document *Liberating the NHS: An information Revolution*, and should be cross referenced with *Equity and Excellence: Liberating the NHS.*[56;57] It is intended as a ten-year strategy with the aim of harnessing information and new technologies to achieve higher quality care and improve outcomes for patients and service users.

The Department of Health's informatics directorate manages health informatics standards outlined in the NHS Data Standards and Products. The primary interoperability standards adopted in England include:

- v3 is used as the basis of all clinical communication between CFH systems
- CDA is used for clinical documents
- classifications and terminologies such as SNOMED CT, ICD 10, OPCS-4 and the Read Codes have been selected as national coding systems
- the dictionary of medicines and devices (DM+D)[55] is used and maintained as the national drug reference catalogue.

6.5 Netherlands

The primary aim of the Dutch government's eHealth strategy is to improve the quality and access of healthcare through the safe and appropriate use of ICT with a particular focus on the EHR.[58]

The international development of interoperability standards is of great importance to ICT in healthcare in the Netherlands. Several organisations are involved in the development and promotion of standards for eHealth. One of the key standards organisations is the Dutch National IT Institute for Healthcare (NICTIZ), an independent foundation mandated and largely funded by the Ministry of Health, responsible for the development and maintenance of standards.[58] NICTIZ uses international standards where possible, such as ISO, CEN and HL7.[59]

A national ICT infrastructure, AORTA, was developed to facilitate the exchange of data between healthcare providers. AORTA uses the HL7 v3 standard and is the underlying national infrastructure for a national EHR called the Electronisch Patientdossier (EPD).[59]

Three major projects were prioritised in the eHealth roadmap (2008): the electronic medication record, an electronic out-of-hours locum information service containing patient summaries and an electronic expense claims procedure.

However, in 2010 the Dutch government put on hold plans for the national EHR due to the lack of clinical acceptance (with one-third of clinicians taking the view that national implementations were unnecessary), issues surrounding security and privacy, amendments to data protection legislation and uncertainty regarding the type of technology model that was selected.[60] The primary standards adopted in the Netherlands include:

- HL7 v2.x is mainly used in regional and local communications
- HL7 v3 is used as a standard for the communication using the national infrastructure
- classifications and terminologies such as SNOMED CT and ICD 9 have been endorsed for use
- EN/ISO 13606 and the process of IHE are being researched as part of the national information structure.[58]

6.6 Ireland

One of the roles undertaken by the Authority is to identify and perform reviews of work areas to highlight gaps and opportunities where the application of eHealth interoperability standards will improve patient safety and quality. The Authority has developed a standards development process which determines whether it is most appropriate to adopt or adapt an existing standard or to develop a new standard in order to fill a particular business need.

The Authority has so far published two messaging standards using HL7 v2.x with XML encoding, namely the *General Practice Messaging Standard* [3] and *National Standard for Patient Referral Information*, [61] both of which are available from www.hiqa.ie.

The first standard has been approved by the Minister for Health and has been incorporated into the national health messaging broker, Healthlink (www.healthlink.ie). The second standard is currently being piloted as part of the National Electronic Generic GP Referral Project. Once that has been piloted and the lessons learned have been incorporated into the standard, it is expected that the Minister will mandate the standard.

In addition, the Authority established an Advisory Group to consider whether or not Ireland should purchase a licence for SNOMED CT. There was unanimous support among the Advisory Group that Ireland should adopt SNOMED CT as the national terminology standard but it was agreed it was not cost-effective to purchase a national SNOMED CT licence at this time. This decision is currently under review.

Healthlink is a national health messaging service which provides the electronic communication of patient information between primary and secondary care settings. This project was initiated in the Mater Hospital, Dublin, in 1995 and is funded by the Health Service Executive (HSE). With the introduction of Healthlink Online in 2003, the work of this group came to be considered as a national project. Healthlink Online allows for the secure transfer of clinical information between GPs and hospitals.

Healthlink works with a range of groups including GPs, hospitals, HSE areas and other healthcare agencies, for example, health centres and daycare facilities. Healthlink provides a range of messaging services to over 2,600 GPs in almost 1,100 general practices nationwide. It also supports discharge summaries between GP out-of-hours cooperatives and the GP practices. In addition to GPs and out-of-hours cooperatives, there are, at present, 32 hospital sites which are availing of the Healthlink service.

In general, GPs download their messages from Healthlink, either by web services or manually. GPs tend to view the messages in their own practice software systems rather than viewing the results on Healthlink Online. When the message files are downloaded they integrate into the individual electronic patient record in the GPs' systems. This allows a GP to view, print or export information into a practice management system. Currently, the HL7 v2.4 standard is the specification used by Healthlink for the exchange of messages. Healthlink is not currently available nationwide. Outside of the Healthlink project four former health boards (North Western Health Board, North Eastern Health Board, South Eastern Health Board and Southern Health Board) developed their own regional messaging services. Healthlink has been working with these implementations to migrate their implementation of messaging services to Healthlink.[3;62]

While the Authority is not aware of any formal audit of the use of interoperability standards in healthcare in Ireland, anecdotal evidence would indicate that, as in Australia, HL7v2.x is the most widely used. Examples of where classifications are used in specific contexts in Ireland include ICD-10-AM in HIPE, and LOINC codes for laboratory and referral messaging between primary and secondary care. In an Irish context:

- HL7 v2.x is the most widely used messaging standard in Ireland
- the Authority has published two messaging standards, the *General Practice Messaging Standard* [3] and *National Standard for Patient Referral Information* [61] using HL7 v2.x
- Healthlink is the national health messaging broker for healthcare messaging in Ireland

- the decision to adopt SNOMED CT as the national terminology standard for Ireland is currently under review.

6.7 Summary of findings

There are some key themes emerging from the countries reviewed in relation to messaging standards. Internationally HL7 v2.x is by far the most widely used standard for exchanging healthcare messages. OpenEHR and CEN13606 are similar but neither has reached critical mass in terms of adoption. The HL7 v3 standard with CDA is gaining momentum with several countries adopting it as the basis for their standards-based health information exchange architecture.(63) HL7 v2.x has been the messaging standard of choice for Australia, Ireland and the Netherlands. Interestingly, the Netherlands has distinguished the use of v2.x for its local and regional implementations and advocate v3 for the national communication of messages. Denmark has a long history of messaging and aligned with the 'older' EDIFACT standard for messaging purposes. Commonly used terminology systems include LOINC, the most widely used lab reporting terminology worldwide and SNOMED CT, which is becoming known as the de facto terminology standard worldwide.

Canada and England embarked on large health IT national programmes allowing them to facilitate the national rollout of v3 projects. A trend that has emerged suggests that the v2.x messaging will eventually be replaced by the v3 messaging and CDA standards for new projects mainly because of the benefits of an underlying data model. However, the v2.x standard has been successfully implemented and works well for specific use cases, hence the 'rip and replace' approach of existing systems would not be beneficial.

CDA has gained widespread implementation worldwide as implementation tends to be more manageable than the v3 messaging standard, yielding substantial benefits and thus making it an attractive choice. From the countries reviewed, there has not been any uptake on the openEHR/CEN standards approach. However, the Netherlands undertook a process of evaluating the ISO/EN 13606 and should it add value, it will be used as part of the national information structure.

7 Conclusion

The Authority published a paper in December 2011 entitled *Developing National eHealth Interoperability Standards for Ireland: A Consultation Document.*[2] Its purpose was to inform key stakeholders including service users, suppliers, purchasers and implementers of eHealth applications, healthcare providers and any other interested parties about the proposed future direction of eHealth standards in Ireland, and to encourage wider participation in standards development. The work outlined a set of key principles to guide the Authority's work in this area, and this overview of healthcare interoperability standards has been undertaken as a recommendation following the consultation process.

The key issue for Ireland is to determine what set of standards to adopt in order to facilitate interoperability. It is essential that the selected standards are future-proofed against the changing standards landscape, including, for example, the attempts at harmonisation between the various standards development organisations (SDOs) such as CEN, ISO and HL7. As national and international evidence currently suggests that HL7 v2.x is the most widely adopted messaging standard, the Authority has so far developed two messaging standards using HL7 v2.x, the *General Practice Messaging Standard* [3] and *National Standard for Patient Referral Information* .[61] The use of HL7 v3 with CDA is also gaining momentum with several countries adopting it as the basis for health information exchange. Examples of where classifications are used in specific contexts in Ireland include ICD-10-AM in HIPE, and LOINC codes for laboratory and referral messaging between primary and secondary care. In order to ensure continuity between terminological systems, it is possible to cross map from SNOMED CT to ICD-10 and LOINC. SNOMED CT is likely to continue to gather momentum as the de facto terminology standard for semantic interoperability and it is likely that Ireland will follow suit at a time when purchase of a national licence is a cost-effective option.

References

(1) Eysenbach G. What is eHealth? *Journal Medical Internet Research.* 2001; 3(2) [Online]. Available from: http://www.jmir.org/2001/2/e20/. Accessed on: 4 July 2012.

(2) Health Information and Quality Authority. *Developing National eHealth Interoperability Standards for Ireland: A Consultation Document.* 2011 [Online]. Available from: http://www.hiqa.ie/publications/developing-national-ehealth-interoperability-standards-ireland-consultation-document. Accessed on: 3 July 2012.

(3) Health Information and Quality Authority (HIQA). *General Practice Messaging Standard*. 2010 [Online]. Available from: http://www.hiqa.ie/media/pdfs/General_Practice_Messaging_Standard_Outline_Summary.pdf. Accessed on: 5 July 2012.

(4) Health Information and Quality Authority (HIQA). *Recommendations for a Unique Health Identifier for Individuals in Ireland*. 2009. Available online from: http://www.hiqa.ie/system/files/Unique_Health_Identifier_Report.pdf. Accessed on: 12 September 2012.

(5) Health Information and Quality Authority (HIQA). *Recommendations for Unique Health Identifiers for Healthcare Practitioners and Organisations*. 2011 [Online]. Available from: http://www.hiqa.ie/publications/recommendations-unique-health-identifiers-healthcare-practitioners-and-organisations. Accessed on: 22 October 2012.

(6) Health Information and Quality Authority (HIQA). *What you should know about Information Governance: a Guide for health and social care staff*. 2011 [Online]. Available from: http://www.hiqa.ie/publications/what-you-should-know-about-information-governance-guide-health-and-social-care-staff. Accessed on: 4 November 2011.

(7) Health Information and Quality Authority. *Guidance on Messaging Standards for Ireland*. 2012 [Online]. Available from: http://www.hiqa.ie/publications/guidance-messaging-standards-ireland. Accessed on: 3 April 2013.

(8) International Organisation for Standardisation (ISO). *ISO/IEC Guide 2:2004, definition 3.2*. 2005 [Online]. Available from: http://www.iso.org/iso/iso_iec_guide_21-1_2005.pdf. Accessed on: 29 June 2012.

(9) Healthcare Information and Management Systems Society. *HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organisations* . 2010 [Online]. Available from: http://www.himss.org. Accessed on: 29 June 2012.

(10) Benson T. *Training Material on Principles of Healthcare Interoperability HL7 and SNOMED*. 2009. Available online from: http://www.abies.co.uk/. Accessed on 13 February 2013

(11) International Telecommunication Union. *E-Health Standards and Interoperability. ITU-T Technology Watch Report*. 2012 [Online]. Available from: http://www.itu.int/en/ITU-T/techwatch/Pages/ehealth-standards.aspx. Accessed on: 28 January 2013.

(12) European Communities ISaMD. *Connected Health: Quality and Safety for European Citizens*. 2006 [Online]. Available from: http://ec.europa.eu/information_society/activities/ict_psp/documents/connected-health.pdf. Accessed on: 1 February 2013.

(13) Brailer DJ. *Interoperability: The Key to the Future Health Care System.* Health Affairs; 2013 [Online]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15659454. Accessed on: 29 January 2013.

(14) Stead WKB, Kolodner RM. Achievable steps toward building a national health information infrastructure in the United States. *Journal of the American Medical Informatics Association.* 2005; 12 pp.113-20.

(15) California Health Care Foundation. *Clinical Data Standards in Health Care: Five Case Studies*. 2005 [Online]. Available from: http://www.chcf.org/publications/2005/07/clinical-data-standards-in-health-care-five-case-studies. Accessed on: 29 January 2013.

(16) Sprivulis P, Walker J, Johnston D, Pan E, Adler-Milstein J, Middleton B, et al. *The Economic Benefits of Health Information Exchange Interoperability for Australia*. Australian Health Review; 2007. Available from: http://www.publish.csiro.au/?act=view_file&file_id=AH070531.pdf. Accessed on: 25 January 2013.

(17) Healthcare Information and Management Systems Society. *Interoperability Definition and Background*. 2005 [Online]. Available from: http://www.himss.org/content/files/interoperability_definition_background_060905.pdf. Accessed on: 1 February 2013.

(18) Meade Dr B. *Clinical Disease Coding and Classification, An overview for General Practitioners*. National GPIT Group; 2011 [Online]. Available from: www.icgp.ie. Accessed on: 25 February 2013.

(19) Health Level Seven (HL7). *HL7 Implementation Guide for CDA Release 2: Care record Summary Discharge Summary*. 2013 [Online]. Available from: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=233. Accessed on: 27 February 2013.

(20) Kalra D. *Electronic Health Record Standards*. IMIA and Schattauer GmbH; 2006 [Online]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17051307. Accessed on: 29 April 2013.

(21) ITU-T Technology Watch. *E-Health Standards and Interoperability*. 2012 [Online]. Available from: http://www.itu.int/dms_pub/itu-t/oth/23/01/T23010000170001PDFE.pdf. Accessed on: 3 April 2013.

(22) OpenEHR Foundation. *OpenEHR*. 2013 [Online]. Available from: http://www.openehr.org/what_is_openehr. Accessed on: 1 February 2013.

(23) Integrating the Healthcare Enterprise. *About Integrating the Healthcare Enterprise*. 2013 [Online]. Available from: http://www.ihe.net/. Accessed on: 1 February 2013.

(24) Detmer D. *Building the national health information infrastructure for personal health, health care services, public health, and research* {Online]. Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC149369/. Accessed on: 2 July 2012.

(25) Health Level Seven (HL7). *HL7 elearning notes.* 2011 [Online]. Available from: http://www.hl7elc.org/campus/. Accessed on: 1 February 2013.

(26) Health Level Seven (HL7). *HL7 elearning notes*. 2011.

(27) Hinchley A. *Understanding Version 3 – A primer on the HL7 version 3 Healthcare Interoperability Standard. Normative Edition, 4th Edition*. Alexander Mönch Publishing; 2007.

(28) Health Informatics Wiki. *Arden Syntax*. 2013 [Online]. Available from: http://healthinformatics.wikispaces.com/Arden+Syntax. Accessed on: 4 February 2013.

(29) United Nations Directories for Electronic Data Interchange for Administration CaT. *Electronic Data Interchange for Administration, Commerce and Transport (EDIFACT)* . 2012 [Online]. Available from: http://www.unece.org/trade/untdid/texts/d100_d.htm. Accessed on: 1 February 2013.

(30) International Health Terminology Standards Development Organisation (IHTSDO). *Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)* . 2012 [Online]. Available from: http://www.ihtsdo.org/snomed-ct/. Accessed on: 1 February 2013.

(31) Wikipedia. *SNOMED CT*. 2013 [Online]. Available from: http://en.wikipedia.org/wiki/SNOMED_CT. Accessed on: 1 February 2013.

(32) World Health Organisation. *International Classification of Diseases (ICD)*. 2012 [Online]. Available from: http://www.who.int/classifications/icd/en/. Accessed on: 1 February 2013.

(33) National Electronic Manufacturers Association. *Digital Imaging and Communications in Medicine Committee*. 2013 [Online]. Available from: http://medical.nema.org/Dicom/about-DICOM.html. Accessed on: 1 February 2013.

(34) LOINC from Regenstrief. *Logical Obdervation Identifiers Names and Codes*. 2013 [Online]. Available from: http://loinc.org/. Accessed on: 1 February 2013.

(35) Begoyan A. *An Overview of Interoperability Standards for Electronic Health Records*. 2007 [Online]. Available from: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.131.4421&rep=rep1&type=pdf. Accessed on: 1 February 2013.

(36) McIlwain J.S. Data Standards Harmonization. *Applied Clinical Trials.* 2010; 19(5) [Online]. Available from: http://202.164.43.200/velos/pdf/Data%20Standards%20Harmonization.pdf. Accessed on: 27 February 2013.

(37) National E-Health Transition Authority Limited. *NEHTA Strategic Plan (2011-2012)*. 2011 [Online]. Available from: http://www.nehta.gov.au/about-us/strategy. Accessed on: 5 July 2012.

(38) The Department of Health and Children. *Audit of Key International Instruments, National Law and Guidelines Relating to Health Information for Ireland and Selected Other Countries*. 2008 [Online]. Available from: http://www.dohc.ie/consultations/closed/hib/draft_audit_paper.pdf?direct=1. Accessed on: 2 July 2012.

(39) Australian National E-Health and Information Principal Committee. *Draft National E-Health Strategy*. 2008 [Online]. Available from: http://www.health.gov.au/internet/main/publishing.nsf/content/604CF066BE48789DCA25751D000C15C7/$File/National%20eHealth%20Strategy%20final.pdf. Accessed on: 2 July 2012.

(40) Australian Health Ministers' Conference. *National E-Health Strategy Summary*. 2008 [Online]. Available from: http://www.ahmac.gov.au/cms_documents/National%20E-Health%20Strategy.pdf.

(41) National E-Health Transition Authority. *Standards for E-Health Interoperability. An E-Health Transition Strategy. Version 1.0*. 2007 [Online]. Available from: http://www.google.ie/#hl=en&biw=1020&bih=539&sa=X&ei=kWaMTfqh F9-

qhAfZisiZCw&ved=0CBQQvwUoAQ&q=An+E-Health+Transition+strategy.%09Version+1.0+May+2007.&spell=1&fp=e308ceef428bb4a8. Accessed on: 22 October 2012.

(42) National E-Health Transition Authority. *National e-Health Standards Development. A Management Framework.Version 1.5*. 2006 [Online]. Available from: http://www.nehta.gov.au/component/docman/doc_details/710-national-e-health-standards-development-a-management-framework-v10. Accessed on: 19 October 2012.

(43) Canada health infoway. *Vision strategy advancing Canada's next generation of healthcare – 2015*. 2010 [Online]. Available from: https://www2.infoway-inforoute.ca/Documents/Vision_Summary_EN.pdf. Accessed on: 5 July 2012.

(44) Canada health infoway. *2015 Canada's next generation of health care at a glance*. 2012 [Online]. Available from: https://www2.infoway inforoute.ca/Documents/Vision_Summary_EN.pdf.

(45) Healthcare Information Technology Standards Panel (HITSP). *HITSP International Standards Landscape Information Gathering Questionnaire - Canada*. 2011 [Online]. Available from: http://www.google.ie/search?source=ig&hl=en&rlz=&=&q=HITSP+International+Standards+Landscape+Information+Gathering+Questionnaire+-+Canada&btnG=Google+Search. Accessed on: 3 July 2012.

(46) European Commission. *Country Brief ERA eHealth Strategies Report – Denmark* . 2010 [Online]. Available from: http://www.ehealth-strategies.eu/database/denmark.html. Accessed on: 3 July 2012.

(47) The Danish Ministry of Interior and Health. *Connecting Digital Health in Denmark. Digitalization of the health care service 2008-2012*. 2008 [Online]. Available from: http://www.epractice.eu/en/library/310063. Accessed on: 5 July 2012.

(48) Castro D, The Information Technology and Innovation Foundation. *Explaining international IT Application Leadership: Health IT*. 2009 [Online]. Available from: http://www.itif.org/files/2009-leadership-healthit.pdf. Accessed on: 2 July 2012.

(49) EHR Implement. *WP5 – National reports of EHR implementation Denmark*. 2009 [Online]. Available from: http://www.ehrimplement.eu/index.cfm?objectid=5BF4F332-1143-DEB7-7424B463EB2D48EE. Accessed on: 3 July 2011.

(50) Murray F. *The Development of Electronic Health Messaging Services in Denmark, and Lessons for Ireland.* 2012 [Online]. Available at: http://lenus.ie/hse/bitstream/10147/55193/1/Development%20of%20Electro

nic%20Health%20Messaging%20Services%20in%20Denmark,%20and%20Lessons%20for%20Ireland.pdf. Accessed on: 3 July 2012.

(51) Department of Health (England). *Delivering 21st century IT support for the NHS: national strategic programme*. 2002 [Online]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008227. Accessed on: 5 July 2012.

(52) EHR Implement. *WP5 – National policies for EHR implementation in the European area: social and organizational issues 2007-2010 National reports of EHR implementation. "United Kingdom".* 19 May 2011. 2010 [Online]. Available from: http://www.ehr-implement.eu/index.cfm?objectid=5BF4F332-1143-DEB7-7424B463EB2D48EE.

(53) Brennan S. *The NHS IT Project: The Biggest Computer Programme in the World Ever.* Oxford: Radcliffe Publishing Ltd; 2005.

(54) e-Health Insider. *Gershon says NHS national programme is inherently 'risky'*. 2003 [Online]. Available from: http://www.ehi.co.uk/news/ehi/568. Accessed on: 3 July 2012.

(55) European Commission. *Country Brief - ERA eHealth strategies Report: England*. 2010 [Online]. Available from: http://www.ehealth-strategies.eu/database/england.html. Accessed on: 5 July 2012.

(56) Department of Health (England). *The Power of Information: Putting all of us in control of the health and care information we need.* 2012 [Online]. Available from: http://informationstrategy.dh.gov.uk/. Accessed on: 3 July 2012.

(57) Department of Health (England). *Equity and Excellence: Liberating the NHS*. 2010 [Online]. Available from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf. Accessed on: 3 July 2012.

(58) European Commision. *eHealth Strategies Country Brief – The Netherlands*. 2010 [Online]. Available from: http://zorginnovatieplatform.nl/upload/file/Rapport%20eHealth%20Strategies.pdf. Accessed on: 3 July 2010.

(59) eHealth ERA. *eHealth strategy and implementation activities in the Netherlands – Report in the framework of the eHealth ERA project*. 2007 [Online]. Available from: http://www.ehealth-era.org/database/documents/ERA_Reports/eHealth-ERA_Report_Netherlands_03-10-07_final.pdf. Accessed on: 3 July 2012.

(60) eHealth Europe. *Dutch eHealth plans on hold*. 2010 [Online]. Available from: http://www.ehi.co.uk/insight/analysis/608/dutch-ehr-plans-put-on-hold. Accessed on: 3 July 2012.

(61) Health Information and Quality Authority (HIQA). *Report and Recommendations on Patient Referrals from General Practice to Outpatient and Radiology Services, including the National Standard for Patient Referral Information*. 2011 [Online]. Available from: http://www.hiqa.ie/publications/hiqa%E2%80%99s-gp-referral-report-published. Accessed on: 5 July 2012.

(62) *The National Healthlink Project*. 2012 [Online]. Available from: http://www.healthlink.ie/. Accessed on: 3 July 2012.

(63) Dolin RH,Alschuler L,Boyer S,Beebe C, Behlen F, Biron P.et al. *HL7 Clinical Document Architecture, Release 2.* Journal of the American Informatics Association:JAMIA. 2006; 13 pp.30-9 [Online]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16221939. Accessed on: 5 July 2012.

(64) World Trade Organization. *Agreement on Technical Barriers to Trade, Annex 3: Code of Good Practice for the Preparation, Adoption and Application of Standard*. 2012 [Online]. Available from: http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm. Accessed on: 22 October 2012.

Appendix 1 – Guiding principles

Below are the guiding principles adopted by the eHealth Standards Advisory Group and assist in the development of interoperability standards for Ireland.

1. The development of standards and associated technical materials to support eHealth will be based on the Authority's standard procedures and processes for the development of technical standards. These are broadly in line with the World Trade Organization (WTO) Code of Good Practice for the Preparation, Adoption and Applications of Standards.[64]
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, will the Authority consider developing a new standard for Ireland.
6. Industry developments and health service delivery opportunities will be taken into account.
7. The standards proposed will ensure value for money and minimise cost of compliance.[2]

Adherence to these principles will ensure that we 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.

Published by the Health Information and Quality Authority.

For further information please contact:

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

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