Developing National eHealth
Interoperability Standards for Ireland:
A Consultation Document

December 2011

*Safer Better Care*

# About the Health Information and Quality Authority

The Health Information and Quality Authority (the Authority) is the independent Authority established to drive continuous improvement in Ireland's health and social care services.

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

**Setting Standards for Health and Social Services** — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland (except mental health services)

**Social Services Inspectorate** — Registration and inspection of residential homes for children, older people and people with disabilities. Inspecting children detention schools and foster care services.

**Monitoring Healthcare Quality** — Monitoring standards of quality and safety in our health services and investigating as necessary serious concerns about the health and welfare of service users

**Health Technology Assessment** — Ensuring the best outcome for the service user by evaluating the clinical and economic effectiveness of drugs, equipment, diagnostic techniques and health promotion activities

**Health Information** — Advising on the collection and sharing of information across the services, evaluating information 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, 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 appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions – for example 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) 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 support a much faster, more reliable and safer referral system between the GPs and hospitals.

Although there are a number of examples of good practice the current ICT infrastructure in health and social care is highly fragmented with major gaps and silos of information. This results in 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 individual 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 well-being, 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 towards high quality health and social care information being available to support the delivery, planning and monitoring of services.

One of the areas currently being addressed through this work programme is the need to set standards to enable information to be shared electronically commonly referred to as interoperability standards. This document makes specific recommendations as to the approach to be adopted to support syntactic and semantic interoperability standards.

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# 1    Introduction

## 1.1    Purpose

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, 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.

Under section (8) (1) (k) of the Health Act 2007, the Health Information and Quality Authority (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.

Internationally there is widespread investment in eHealth, broadly defined as the exploitation of information and communication technologies (ICT) in healthcare to enhance the quality and safety of patient care.  A comprehensive definition covering all facets of eHealth is found below:

> 'e-health 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]

eHealth can enhance the quality, accessibility and efficiency across all healthcare services through the secure, timely, accurate and comprehensive exchange of clinical and administrative data[2] offering 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 health care
- more efficient national planning
- improved  research through the provision of more timely, and higher quality information
- reduction in medication errors through ePrescribing
- more timely access by health professionals to the right medical information at the right time
- improved support for patient self-management.

But 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 a 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 and an Electronic Health Record (EHR) model often regarded as the ultimate goal of eHealth.

While there are many different definitions of electronic records, a consensus appears to be emerging and for the purpose of this document the following definition will be used:

- An **electronic health record (EHR)** is a longitudinal record of patient health information across multiple care settings

- An **electronic patient record (EPR)** is a longitudinal record of patient health information within a single institution e.g. a GP practice or a single hospital, or confined to a single domain/disease e.g. an epilepsy patient record

- A **personal health record (PHR)** is a patient-held record owned and managed by the patient; it may include information provided by a healthcare provider as well as information provided by the patient

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[3]

The purpose of this document is to set out the principles which will govern the Authority's approach to setting standards for the exchange of electronic health information within the broader context of eHealth. The approach proposed, is based on international experience in relation to eHealth, highlighting important lessons learned and evidence as to how Ireland should proceed. It will provide the basis for an eHealth infrastructure which can, in due course, deliver the EHR and ePrescribing.

This document is being produced now in order to inform key stakeholders – service users, suppliers, purchasers and implementers of eHealth applications, and 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. In addition to a set of key principles which will guide the Authority's work in this area, a new eHealth Standards Advisory Group (eSAG) will be established to provide input and feedback to the standards development process (see Appendix 3 for the Terms of Reference of this group).

The Authority's intention is to establish a clear roadmap for the development of eHealth interoperability standards which will ensure that the key building blocks for the introduction of a national EHR at some time in the future.

The Authority is fully committed to stakeholder consultation and values all feedback provided as part of its standards development process. In particular, the Authority welcomes the views and input of all stakeholders as to where eHealth interoperability standards are most urgently required and where therefore the work of the Authority and the eSAG should be targeted.

**This document contains two key consultation questions for people to consider. You will find them in Section 4.4 of this document. These questions can also be found in the Consultation Feedback Form which is available on www.hiqa.ie.**

## 1.2    Consultation process

The *Developing National eHealth Interoperability Standards for Ireland: A Consultation 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.

**The closing date for receipt of comments is 1pm on Friday 27 January 2012.**

### 1.2.1 How to make a submission

Two key consultation questions are posed (see Section 4.4). These questions are not intended, in any way, to limit feedback - all other comments and more general feedback are welcome.

There are several ways to tell us what you think:

> Your comments can be submitted by downloading and completing the consultation feedback form available from www.hiqa.ie and e-mailing your completed forms to ehealthconsultation@hiqa.ie

> 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) 8147436.

### 1.2.2 How we will use your comments

Following the consultation, all submissions will be considered and used as appropriate to inform the work of the Authority and of the eSAG in the development of national standards for eHealth interoperability.

We would like to thank you for taking the time to submit your comments.

## 1.3 Background

A core principle which underpins current health strategy, both in Ireland and internationally, is the need to move from an organisation-centric model of care delivery to one which is patient-centred based on shared care [4-7]. Under this model, patients move seamlessly between primary, secondary and tertiary care sectors, receiving care in the most appropriate setting.

Fundamental to the successful implementation of this new model of patient-centred shared care, is that vital information about the patient, such as their medical history, previous test results and diagnostic information, accompanies them at all times along the care pathway. In this way, the high-quality, up-to-date information required by healthcare professionals to treat patients in the best and most appropriate way possible is available when and where it is needed. The ready availability of such information improves patient safety and reduces any unnecessary duplication of tests and investigations. This approach also enables the provision of more cost-effective and timely services.

Without the appropriate use of Information and Communications Technology (ICT) this vision of patient-centred shared care will be impossible to realise. The application of ICT to health, which is commonly referred to as eHealth in Europe or Health Information Technology (HIT) in the United States (USA), is increasingly regarded as fundamental to the delivery of a modern healthcare system, with many countries including Canada[8], Australia[9], New Zealand[10], Denmark[11], France[12;13] and Sweden[14] now investing heavily in the area as a result.

There is a growing body of evidence that widespread diffusion of eHealth applications including electronic prescribing and the EHR will lead to major cost savings, improved quality and safety and increased efficiency[15-22].

In Ireland, the Commission for Patient Safety and Quality Assurance[23] also made a number of recommendations in relation to ICT, including emphasising the importance of national standards in this area to support eHealth and stating that "sharing of information within and between providers so that critical information about the care of patients is available at the point of care".

While a number of countries had set out to establish a national (summary) EHR as the ultimate goal of their eHealth strategies, the emphasis for many has now shifted more towards focusing on the development of eHealth building blocks such as: robust, reliable, secure network, digital signatures, eHealth interoperability standards, unique identifiers; and an EHR model [24]. This is not just because achieving a national EHR is proving so difficult and costly, but also because there is a growing body of evidence challenging the urgent clinical need [25].

A recent systematic review of the impact of eHealth on the quality and safety of healthcare [26] concluded that: "despite support from policy makers, there was relatively little empirical evidence to substantiate many of the claims made in relation to [eHealth] technologies". The authors went on to say that even in the case of systems that have proven to be successful "there is little evidence to show that such tools would continue to be successful beyond the contexts in which they were originally developed".

While the conclusion of this systematic review might seem negative, the authors point out that the absence of evidence does not equate with evidence of ineffectiveness – in other words, they are not saying that eHealth technology, including EHRs, EPRs and ePrescribing, do not contribute to improvements in the quality and safety of healthcare but rather, that there is very limited objective scientific evidence to support such assertions. As a result, they call for much more thorough, rigorous and independent evaluations of the impact of eHealth tools "before substantial sums of money are committed to large-scale national deployments under the auspices of improving healthcare quality and/or safety".

Another systematic review of electronic patient record (EPR) research [27] concluded that while secondary uses of the data in EPRs for audit and research may be rendered more efficient by the deployment of EPRs, there is evidence from some studies that primary work could be made less efficient largely because of the unique characteristics which paper offers.

However, it is important to observe that most of the positive evidence surrounding electronic records relates to EPRs which are either confined within a single organisation or are domain-specific especially for chronic conditions such as diabetes or epilepsy[20;28-30].

As a general conclusion, and reflecting the overall importance of eHealth infrastructure and provisions, it has been said that:

> "You can't do modern healthcare without a computer system. It would be like trying to do healthcare without telephones. The benefits from having an integrated electronic record in terms of the quality of care you can give are really indisputable. You do need the system. The big question is: is it best done nationally as part of a very big programme or is it better done locally but making sure that the bits that are put in place locally all fit together and talk to each other"[31].

## 1.4    What this means for Ireland

There are important lessons for Ireland to learn from international experience in relation to eHealth and there is a growing body of evidence as to the best, most appropriate next steps towards the introduction of policy and standards here[32].

International experience with the development of national EHRs highlights the complexity of EHRs and challenges involved. Moreover, while evidence in relation to the cost benefits of major EHR programmes is beginning to emerge, the indications are that it takes a long time to realise the benefits with the European Commission concluding that: "EHRs and ePrescribing are not quick wins.... It takes at least four and more typically, up to nine years before initiatives produce their first annual socio-economic returns, and six to eleven years to realise a cumulative net benefit" [32]. And, in the case of the European Commission's review, on which this conclusion was based, only two of the systems covered were national, the rest were either regional or local.

The consensus internationally recommends an incremental step-by-step implementation strategy underpinned by supporting a standards-based approach to eHealth which will allow more information to be made available electronically including, for example, patient identification, medication, referrals, and discharges.

Each individual building block offers benefits in its own right while at the same time providing a future-proofed path towards ultimate realisation of the EHR. The EU-funded EHR Impact report [32] made five key strategic recommendations:

1. Policymakers should create an enabling framework and context.
2. Development should be a never-ending story.
3. The right approach is the one that fits the specific needs and the context.
4. The right strategic goal is better healthcare, not cash.
5. Interoperability and engagement are requirements for success.

The Programme for Government proposes a radical restructuring of the health service placing emphasis on providing safer, more efficient care in the best interests of patients and service users. Many of the efficiencies sought can be achieved through the more effective use of ICT (eHealth) within the system, clearly outlining a role for eHealth. In the current economic climate however, Ireland is not in a position to proceed with the implementation of a national EHR at this time.

Nonetheless, improvements can be achieved through the appropriate use of ICT within the system such as through standardised general practice messaging standards[33] and the implementation of good information governance practices [34]. In order to maximise the benefits of improved information sharing, a number of major deficits must first be addressed including those outlined in the EHR Impact report[32].

Some of the recognised deficits include the lack of a system of unique identifiers for individuals, health professionals and organisations [35]the legal impediment to the use of digital signatures in the context of eHealth applications, and the absence of a coherent set of national standards including communication and terminological systems for example, coding and terminology[36;37]. Addressing these deficits now will provide immediate benefits as well as laying future-proofed foundations for an EHR in due course.

Another common theme from all those countries that are in the process of implementing or have implemented eHealth initiatives is the importance of the use of standards to support the sharing of electronic information. 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 information.

This consultation document focuses on the development of what might be termed 'technical standards' to support electronic sharing of health information. These are commonly referred to as interoperability standards. Interoperability is defined as "the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities" [38].

More specifically, it is "the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged " [39]. In particular, the availability of technical standards such as those proposed here, is a fundamental enabler for eHealth [24;40].

The purpose of this document is to consult on the areas of work which the Authority should prioritise. It includes a set of guiding principles which will govern the Authority's work in this area, and details of a new eHealth Standards Advisory Group (eSAG) to be established by the Authority to assist in providing feedback and input to the standards development process.

The technical standards are being produced for consultation in order to inform key stakeholders including: 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.

# 2    Importance of standards

Above all, standards have a major role to play in improving safety, whether it is in the airline industry, banking or in healthcare. For example, the standard surgery checklist, *Safe surgery saves lives,* developed by the World Health Organisation (WHO) is to improve the safety of surgical care around the world. In a comprehensive study carried out in 2010, the use of the checklist resulted in a significant reduction in surgical morbidity and mortality. Complications from surgery in the hospitals using the checklist were reduced by almost one third compared to the control sites and mortality by almost a half [41].

The use of standards delivers key benefits in a number of areas. Specifically, standards enable and support health service improvements – they can deliver economic benefits and, most importantly, result in benefits for patients and service users through safety improvements in frontline service delivery.

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 the same terminology using an agreed standard [42].

One of the key challenges in the implementation of technical standards for health is the fragmentation of the health software market.  There are many local suppliers and, as a result of mergers and take-overs, a diminishing number of big international players. Any typical healthcare organisation will have dozens of different ICT systems from different suppliers, each supporting different functions. Therefore, even if desirable, it is inconceivable that any one system could meet all the ICT requirements of a single healthcare organisation covering functions from medical imaging to biochemistry, and clinical information to patient administration.

In such a heterogeneous environment the ability to share information between systems – interoperability - is critical and the real need for technical standards becomes apparent.

## 2.1    Health service improvement

The nature of modern healthcare which is highly information-intensive, coupled with the need for patient-centred shared care, demands the effective use of ICT. The ability to share information both within and between healthcare providers is of fundamental importance to ensuring the delivery of safe, high quality care to patients and for the timely and accurate monitoring and planning of services. Yet, despite this, it is recognised that the "…seamless electronic communication between systems and between health professionals is not the rule but rather the exception" [43].

There is widespread agreement that the adoption of proven international standards has a critical role to play in supporting efficient and cost-effective information sharing (interoperability) [44].

A number of countries which have major eHealth programmes underway, including Canada, Australia, England and Denmark, have placed a strong emphasis on eHealth interoperability standards. Furthermore, the lack of such standards has been identified in numerous studies as a major impediment towards the adoption of ICT in health [43;45].

## 2.2   Economic benefits

eHealth has been identified as an important potential area for growth in Ireland both as part of the current national research prioritisation exercise [46] and by the ICT health industry group±.

> "The existence and use of standards makes it easier to produce, sell and buy products and services. Standards enable a market. They are part of the infrastructure for innovation-led growth" [47].

The telecommunications market represents an excellent example of the economic advantages of standards. The advent of the Global System for Mobile communications (GSM) standard launched in 1990 opened up a world-wide market for mobile phones whose impact continues to grow∉.

## 2.3   Stakeholders

A wide range of stakeholders will benefit from having eHealth interoperability standards in place including healthcare professionals, service planners, healthcare organisations, healthcare software suppliers, implementers together with the standards development organisations, policy makers and regulators. The overriding impetus for the introduction of eHealth interoperability standards in Ireland however, remains the ultimate benefit to all those who use health and social care in terms of better quality and safer care specifically. 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 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 the prospect of growth in export markets where the standards used are international [48]

- 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" [48]

- 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. Finally, the standards developers themselves have a keen interest in ensuring the adoption of "their" standards.

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± http://www.hisi.ie/media/Report_of_the_Health_ICT_Industry_Group_November_2009.pdf
∉ http://www.etsi.org/WebSite/AboutETSI/Introduction/history.aspx

# 3    Interoperability standards

This section considers the current international eHealth standards landscape including the various Standards Development Organisations in existence, the different ICT standards in healthcare, focusing particularly on messaging and terminological systems standards. It outlines the relationship between eHealth interoperability standards and their role in supporting a roadmap towards a national EHR.

## 3.1    International Standards Development Organisations

A report prepared by Empirica GmbH on behalf of the European Commission, identified some 22 different ICT standards in healthcare [43] (see Appendix 1 for a summary).

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. In terms of adopting and adapting standards, there is a heavy reliance on the work carried out by the SDOs.

Internationally, SDOs are facing major challenges - it is generally accepted that the requirement to achieve consensus is too slow, there is an over-reliance on voluntary participation as government funding has reduced, insufficient resources are allocated to standards-development work, they are being exposed to increased competition from industry de facto standards, and they are facing problems with assessing compliance.

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 an SDO, and crucially also promote competition.

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

- The International Organisation for Standardization, ISO (www.iso.org); the largest developer of world-wide standards
- The European Committee for Standardization, CEN (www.cen.eu), the principal SDO in Europe
- The International Health Terminology SDO, IHTSDO (www.ihtsdo.org), the developer of SNOMED-CT terminology standard
- Health Level Seven, HL7, the developer of the most widely used standards for electronic health messages (www.hl7.org)
- Digital Imaging and Communications in Medicine, DICOM (http://medical.nema.org/), the de facto standard for electronic medical imaging
- OpenEHR, an open source activity supporting the development of standards for EHRs (www.openehr.org)
- Integrating the Healthcare Enterprise, IHE, a major industry-led eHealth systems interoperability initiative (www.ihe.net) [43].

## 3.2    Standards and the EHR

The fact that Ireland is not currently in a position to proceed with the implementation of a national EHR may be regarded as an advantage. Given the rapidly evolving standards and technology landscape, coupled with increased international experience (both positive and negative), the additional time in advance of implementation allows us to concentrate on the development of key interoperability standards which will not only facilitate the exchange of existing health information, including referrals, discharges and prescriptions, but will also provide a cost-effective future-proofed route towards an EHR.

To support the much-needed interoperability between systems and meaningful sharing of data, health information standards must cover both the *syntax* and *semantics*. Messaging standards specify the syntax (structure) of an electronic message and Terminological Systems (for example, coding and terminology standards) specify its semantics (meaning).

Consider for example, the international postal conventions governing postcards. The sender writes the message on the left hand side, the addressee's name and address on the right in a standard order and position with the stamp in the top right hand corner (the syntax of the postcard). The meaning of the letters within a given item (its semantics) is determined by entirely different conventions, namely the language employed by the correspondent.

The HL7 messaging standard for communicating laboratory results specifies the order of the many elements that make up the message such as the test, units and patient identifier (the syntax) and which elements are required and which are optional. Coding systems such as the International Classification of Diseases version 10, ICD-10$^{\Phi}$ and Logical Observation Identifiers Names and Codes, LOINC$^{\Upsilon}$ assign meaning to the characters in the message (the 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. Health information standards are intended to remove ambiguity and ensure that there can be mutual understanding between software systems.

### 3.2.1 Messaging Standards

One of the limitations of certain messaging standards is that they conflate process (services) and content (documents), whereas newer standards such as the HL7v3 Clinical Document Architecture (CDA) have been developed to deal with such limitations.  This is particularly important in the context of the development of EHRs. Above all, messaging provides poor support for semantics except in the case, for example, of the exchange of quantitative data in laboratory messages [49].

There are four internationally recognised candidate standards for EHRs, namely HL7 v2.x based messaging standards (www.hl7.org); and CEN EN 13606 (www.cen.eu), HL7 v3 and CDA and OpenEHR (www.openehr.org), which are underpinned by a data model. Figure 1.0 summarises the pros and cons of these standards and is adapted from NEHTA's *Standards for E-Health Interoperability. An E-Health Transition strategy (2007)* [50].

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$^{\Phi}$ http://www.who.int/classifications/icd/en/
$^{\Upsilon}$ www.loinc.org

| EHR Standard | Advantages | Disadvantages |
|---|---|---|
| HL7 v2.x | <ul><li>widely used and</li><li>supported</li><li>good tool support</li><li>mature</li><li>flexible</li><li>skills widely available</li><li>many examples of successful implementation across a wide range of applications</li></ul> | <ul><li>flexibility leads to inconsistent implementation and hence poor interoperability</li><li>no underlying information model to underpin the content</li><li>may be difficult to exploit services-oriented architecture</li><li>no terminology support</li><li>does not support semantic interoperability</li></ul> |
| HL7 v3 | <ul><li>supports clinical terminology</li><li>supports structured clinical documents (CDA 2)</li><li>integrated support for services (SOA)</li><li>growing community support internationally</li><li>increasing tool support available</li><li>growing number of successful deployments</li></ul> | <ul><li>lack of maturity</li><li>skills deficit</li><li>does not support full semantic interoperability</li></ul> |
| EN13606 | <ul><li>adopted European standards</li><li>comprehensive</li><li>supports semantic interoperability</li><li>supports backwards compatibility with message-based implementations</li></ul> | <ul><li>poor community support</li><li>lack of skills</li><li>absence of tool support</li><li>very limited implementation experience</li></ul> |
| OpenEHR | <ul><li>open standard</li><li>supports semantic interoperability</li><li>provides service-oriented interfaces</li></ul> | <ul><li>mixed support</li><li>assumes information is in the form of EHR extracts</li><li>unnecessarily complicated for simple messages</li><li>limited implementation experience</li></ul> |

**Figure 1.0 - Pros and cons of EHR standards**

While the situation has changed since 2007 when NEHTA's report was published, the basic assessment of the competing standards remains more or less the same. HL7 v2.x is by far the most widely used standard for exchanging healthcare messages but it has limitations for use in communicating EHRs or EHR extracts.

OpenEHR and EN13606 are similar but neither has reached critical mass in terms of take-up internationally. HL7 v3 with CDA is gaining momentum with several countries adopting it as the basis for EHR interoperability, namely UK, Australia, Canada, US, Japan, Germany, Finland and Greece [51].

## 3.2.2 Terminological Systems

A terminological system (TS) is "essentially a representation of concepts, attributes and relationships pertaining to medical terms" [52]. The two categories of terminological systems in use in healthcare are classifications and clinical terminologies.

### Classification Systems

Classification systems are by far the most widely used approach to coding data in healthcare today. They group together similar diseases and are typically used for reporting requirements. For example, ICD-10 is widely used to code data for case-mix and reimbursement in many countries including the Hospital In-patient Enquiry System (HIPE) in Ireland.

However, they are inadequate to support the requirements of clinical coding because they are not sufficiently fine-grained and fail to define all of the individual concepts within a given healthcare domain.

### Clinical Terminologies

Clinical terminologies, when compared to classifications, are generally more comprehensive, precise and offer a more accurate representation of the healthcare domain. However, clinical terminologies are not suitable for all applications. For example, they are not suitable for reporting because of their immense size, fine granularity and complex hierarchies.

The full benefits of clinical terminologies are realised when they are used to collect clinical information as part of the clinical encounter and are linked and integrated with classifications for the purpose of generating data for secondary use, for statistical and epidemiological analysis, external reporting requirements, measuring quality of care and monitoring resource allocation [53].

Clinical terminologies such as SNOMED CT are essential to support full semantic interoperability so as to ensure that the information shared/sent can be mutually and unambiguously understood.

So, as the Empirica survey of ICT standards for eHealth puts it "the probability of the continued success of the standard [SNOMED-CT] is likely" [32]**.** The Authority has investigated the use of SNOMED CT as the national terminology standard (see Section 4.2 below).

### Summary

In summary, neither a classification system nor a clinical terminology system alone can serve all purposes for which health information is currently used or indeed, will likely be used in the future. For example, both classifications and clinical terminologies are required across the healthcare system as the collection and analysis of basic clinical facts multiple times is needed from slightly different perspectives and for different purposes. Importantly to ensure continuity between terminological systems (and ultimately clinical documentation), it is possible to cross map from SNOMED CT to ICD-10, Laboratory LOINC and OPCS-4.

Classifications and clinical terminolgies have different origins, purposes and size.  Typical uses cases for classifications and clinical terminologies are illustrated in Figure 2.0 below.

| | Classifications | Terminologies |
|---|---|---|
| | | *Use cases for terminologies and classifications* |
| Actor | Healthcare records departments personnel | Healthcare providers |
| Available Information | The healthcare record as documented during the patient encounter | Whatever the provider can observe, test or obtain otherwise |
| Timing | After the patient has left | While the patient is present |
| Goal | Identify a single primary discharge diagnosis or procedure for the purposes of morbidity and mortality statistics OR for reimbursement purposes | Document information about the patient and the encounter according to professional standards and to meet the information needs of the heath system |
| Code system | • Mono-hierarchical, with inclusion and exclusion criteria to avoid overlap<br>• Not Otherwise Specified (NOS) categories to code cases where the clinical record is not specific enough for the code system<br>• Not elsewhere classified (NEC) categories to code cases where the clinical record is more specific that the code system | • Multi-hierarchical terminology<br>• Clinician may be as general or a specific as they want<br>• Specificity is served by allowing multiple codes, combination of codes and where necessary uncoded free text<br>• NOS and NEC values are meaningless |
| Examples | ICD 9, ICD 10, ICD-10-AU, OPCS | SNOMED CT, LOINC |
| Size | 10k | 100k |

**Figure 2.0 – Use cases for classifications and clinical terminologies**

# 4    Findings

In the current economic climate, where it is unlikely that there will be significant investment in the development of EHRs, it is important to use the opportunity to work on those initiatives which can be progressed and which will result in fairly immediate benefits, and those which will constitute important building blocks for the future. An example of the former is the National Integrated Medical Imaging System (NIMIS) and of the latter is the development of standards.

The forthcoming Health Information Bill will establish the necessary legislative framework to support eHealth initiatives including it is hoped legal provision for the introduction of digital signatures. The Authority has commenced a programme of standards development working with stakeholders. The Health Service Executive (HSE) is finalising its ICT Strategy while at the same time progressing a number of key national initiatives notably NIMIS and the Laboratory Information Management System (LIMS).

## 4.1 Work to date

The Authority has so far published two standards, namely the *General Practice Messaging Standard* [33] and *National Standard for Patient Referral Information* [54] 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 lessons learned incorporated, 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 license for SNOMED CT. There was unanimous support 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.

The decision will be reviewed in approximately one year towards the end of 2012. Additionally, the Authority is working with a small expert group on the development of standard code sets for laboratory and radiology investigations.

## 4.2 Key issues for Ireland informing future work

The key issue for Ireland is to determine what set of standards to adapt 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 SDOs such as CEN, ISO and HL7.

As part of the development of their interoperability standards strategy, the National eHealth Transition Authority (NEHTA) in Australia 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 HL7 v2.x. They therefore concluded that whatever approach to eHealth interoperability which would ultimately lead to a national EHR they decided to adopt, it would need to accommodate migration from HL7 v2.x if they were 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 CEN 13606, OpenEHR or HL7 v3 with CDA. Their recommendation was to continue with the use of HL7 v2.x messaging "as the primary means of interchanging eHealth information in areas where it is currently delivering benefit until superseded by HL7 v3 and CDA" [48].

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.

## 4.3 Guiding principles

Based on work completed to date, and a review of international experience, the Authority 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 the Authority's standard procedures and processes for the development of technical standards. These are broadly in line with the World trade Organisation (WTO) Code of Good Practice for the Preparation, Adoption and Applications of Standards (See Appendix 2.).
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 a minimum of 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.

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.

It is also important for Ireland to participate in leading SDOs, both to keep up to date with standards development, and to influence the eventual outcome of standardisation. This is best done in association with the Health Informatics Standards Consultative Committee of the National Standards Association of Ireland (www.nsai.ie), with whom the Authority has established a good working relationship. However, ensuring Ireland's active, appropriate and sustainable participation in SDOs needs to be considered further by the proposed eHealth Standards Advisory Group (eSAG).

## 4.4 Next steps

The next steps that the Authority intends to undertake in relation to eHealth interoperability standards include the following:

1. The Authority will establish an eHealth Standards Advisory Group (eSAG).The scope of the advisory group work streams will principally cover the following: messaging standards, terminological systems – classifications and clinical terminologies, and clinical concepts/ archetypes. (See Appendix for draft Terms of Reference).

2. The Authority will work with the Health Information Standards Committee (HISC) of the National Standards Authority of Ireland (NSAI) to ensure that Ireland is represented at an appropriate level on relevant SDOs.

## 4.5 Consultation questions

**Question 1**: In the first instance, 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.

# 5    Conclusions

The information-intensive nature of modern healthcare delivery coupled with patient-centred shared cared, demands the effective use of ICT or eHealth (as it is referred to in Europe). It is well documented that the widespread diffusion and uptake of eHealth applications including the electronic patient/health record and ePrescribing will lead to major cost savings, improved quality and safety and increased efficiency. For the patient, this ultimately means improved safety and more timely care.

A key component of eHealth is the ability to share meaningful information both within and between healthcare providers e.g. among secondary, primary and community care both for safe and effective care delivery. This concept is known as "semantic interoperability" and will allow more information to be made available electronically including, for example, patient identification, medication, referrals, and discharges. There are many proven international standards available to support information sharing (interoperability) and a number of countries internationally including Canada, Australia and Denmark have placed a strong emphasis in this area, with many recommending a strategy that takes an incremental step-by-step approach to implementation. A lack of agreed standards for information sharing has been identified in numerous studies as a major impediment towards the adoption of eHealth.

This document outlines the approach to be taken by the Authority in the development of eHealth standards for Ireland taking into account the current eHealth landscape and context. It specifically focuses on and differentiates interoperability standards for communication (i.e. syntactic or messaging standards) and semantic interoperability standards i.e. terminological systems used in classification systems and clinical terminologies). Equally, it is recognised that all stakeholders are consulted in the development of eHealth standards for Ireland and this report is therefore being made available for public consultation. It makes recommendations presented in the form of a set of guiding principles which will govern the Authority's approach, and includes the establishment of a new eHealth Standards Advisory Group (eSAG).

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# Appendix 1 - ICT standards domains

Domains of ICT standards in the health sector, explanations and examples

| Domain | Explanation | Examples |
|---|---|---|
| Architecture Standards – focus on the EHR | Standards for an overall structure or plan of a health information system, including components and their connections and relationships. A particular type of architecture standards is that for Electronic Health Records (EHRs). | CEN EN 13606, CEN EN 12967 Service Architecture (HISA), HL7v3, openEHR |
| Modelling Standards | Standards for ways to design and define architectures of a health information system. | CEN TR 15300 Framework for Formal Modelling of Healthcare policies, ISO 10746 ODP |
| Communication Standards | Bi-directional exchange of information between two health system entities. | CEN EN 13606 EHR communication, CEN EN 13609-1:2005 Messages for maintenance of supporting information in healthcare systems, Part 1: Updating of coding scheme, DICOM, HL7v2.x, HL7v3 ISO 11073 Point of Care Medical Device Communications |
| Infrastructure Standards | Standards for a group of communication components to collectively provide support for distribution of information within a network of peers within the health system, e.g. machines and institutions. | CEN ENV 13729 Secure User Identification, Strong Authentication using microprocessor cards, ETSI TS 101733 Electronic Signature Formats, HL7 Service-oriented architecture, ISO 17090 Public Key Infrastructure |
| Data Security Standards | Standards for protection of patient data by means of e.g. data encryption and electronic signatures to prevent loss and theft. | DICOM, ISO DTS 25237 Psuedo-anonymisation ISO 22600 Privilege Management and Access Control |
| Safety Standards | Standards in healthcare to emphasize and support the reporting, analysis and prevention of medical error and adverse healthcare events. | CEN TR 13694 Safety and Security Related Software Quality Standards for Healthcare |
| Terminology and Ontology Standards | Standards for health sector specific vocabulary to describe concepts and their interrelationships. | CEN EN 13940 System of Concepts to Support Continuity of Care, ISO/CD 17115 Vocabulary on Terminological Systems, LOINC, SNOMED CT |

**Figure 3.0 - Source: Table reproduced from Exhibit 2-1 on page 15 of report on ICT standards in Healthcare from Empirica GmbH on behalf of the European Commission (2008) [43]**

# Appendix 2 - WTO Code of Good Practice

Key elements of the WTO Code of Good Practice for the Preparation, Adoption and Application of Standards (Quoted in NEHTA 2006, p10):

- Transparency, including publishing the work program; and enabling all stakeholders to access and comment on standards developed – including via public comment periods of at least 60 days

- Making "every effort" to achieve consensus, including clear processes for reconciling comments received

- Coordination/harmonisation of the work of national standardization bodies, to avoid duplication or conflict

- Use of international standards, where they exist or their completion is imminent, in preference to local developments

- Participating in the development of international standards, and not duplicating the work of other standards agencies

- Focusing on specification of requirements based on performance rather than design or descriptive characteristics and

- Prompt publication of and non-discriminatory charging for standards.

# Appendix 3 - eHealth Standards Advisory Committee (eSAG) Terms of reference

Draft Terms of Reference of the eHealth Standards Advisory Committee on Health Information Standards.

The terms of reference of the technical committee 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 committee
- 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 committee or domain experts co-opted to projects undertaken by the committee, 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

The scope of the technical committee includes:
- data definitions
- clinical concepts and archetypes
- messaging standards
- terminological Systems including classifications (ICD) and clinical terminological systems (SNOMED CT).