Guidance on Messaging Standards for Ireland

November 2012

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, 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 including, for example, information governance, common data definitions, and the exchange of electronic health information.

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 general practitioner (GP) 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 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 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 need to set standards to enable information to be shared electronically commonly referred to as interoperability standards. A public consultation document on eHealth[¥] was recently published by the Authority (2011). The feedback from the consultation identified the need to provide guidance on messaging standards. This document outlines specific guidance as to the approach to be adopted to support messaging standards for existing and future messaging projects in Ireland.

[¥] '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 characterises 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 healthcare locally, regionally, and worldwide by using information and communication technology.'[1]

Contents

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. 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 healthcare
- 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
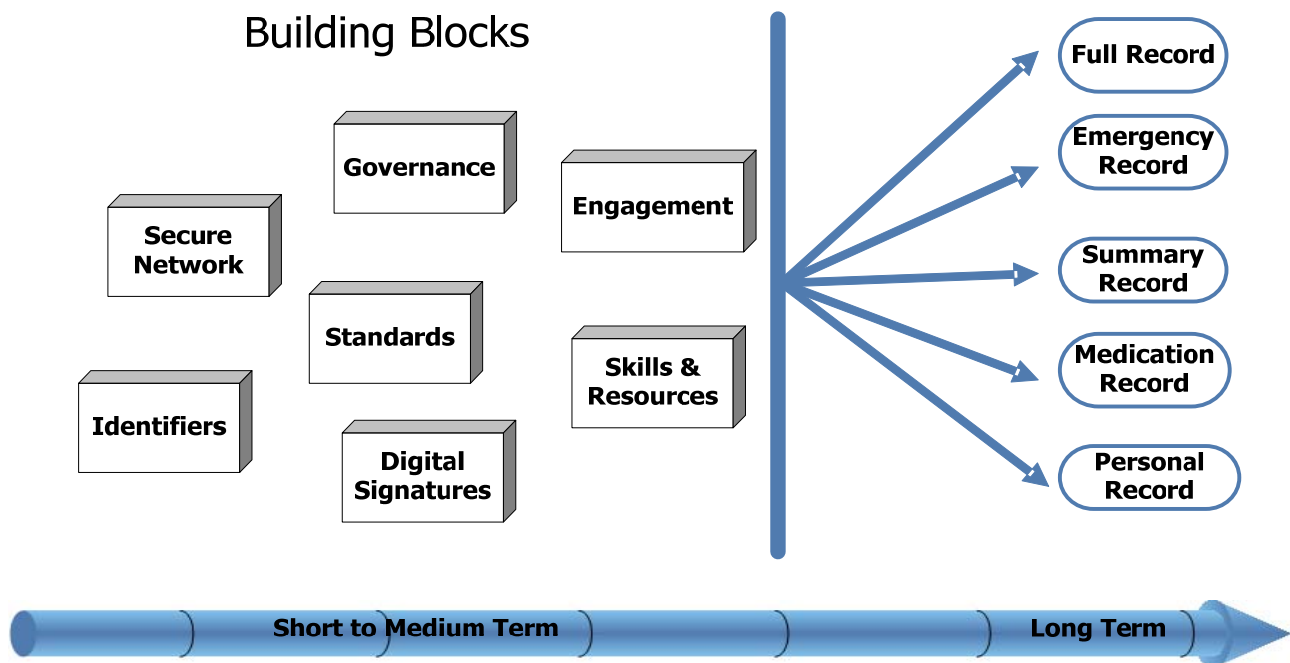- improved support for patient self-management.

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 (see Figure 1 on page 3). The ultimate goal of most national eHealth programmes is generally the development of a national Electronic Health Record (EHR).[‡] However, it is the view of the Authority and many others, that it would be premature for Ireland to begin development of such an EHR without a number of key enablers or building blocks being in place first. Some examples of these building blocks, which must be central to any eHealth programme include:

- a system of unique identification for individuals, organisations and health professionals
- a set of eHealth interoperability standards including messaging and terminology standards based on widely available and implemented international standards.

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, identification, common data definitions, and the exchange of electronic health information. The Authority has already published recommendations in respect of identifiers for individuals[3] and for professionals and organisations.[4]

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

Figure 1. Building blocks towards a national EHR

Building Blocks

Governance	
Secure Network	Engagement
Standards	Skills & Resources
Identifiers	
Digital Signatures	

Full Record
Emergency Record
Summary Record
Medication Record
Personal Record

Short to Medium Term → Long Term

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.*[5] The Authority also established the eHealth Standards Advisory Committee to provide input and feedback on the Authority's standards development process. This consultation identified the need for guidance documents in three areas, namely, general interoperability standards, terminology standards and messaging standards to ensure that information can be exchanged electronically in a safe and efficient way. This document, which is informed by the consultation process, makes recommendations in respect of messaging standards. Guidance in respect of the other two areas will be published in due course.

The consultation document provided a detailed description of messaging standards used internationally. This informed the selection of the four candidate messaging standards to be used to support healthcare: Health Level Seven (HL7) version 2.x (v2.x), HL7 version 3 (v3 messaging), the Clinical Document Architecture (CDA) and the Electronic Data Interchange for Administration, Commerce and Transport (EDIFACT) standard. It emphasised that any eHealth initiatives selected for use and endorsed in Ireland should be underpinned by internationally proven standards. This is also the case for messaging standards as any messaging standard adopted or adapted by the Authority will be derived from international standards and a localised specification maintained by the Authority. The eHealth document recognised the current dominance of HL7 version 2.4 Extensible Markup Language (XML) encoded messaging in Ireland. The development and progression of HL7 messaging in Ireland

over the years is mainly attributed to collaborative work between the Department of Health, the Health Service Executive and their predecessors, the Health Boards Executive. Healthlink is also a major player in messaging in Ireland acting as the national messaging broker supporting electronic communication of patient information (e.g. laboratory results, referrals) between primary and secondary care settings (www.healthlink.ie). Healthlink currently has 32 hospitals and 1134 GP practices registered as users and brokers approximately 7.5 million messages per annum.

The purpose of this document is to provide high level guidance in respect of messaging standards in Ireland for the short to medium term. The Authority has developed this guidance to provide the health information community in Ireland with an understanding of the general direction of standards development and implementation that the Authority is progressing towards and to support better decision making and consistency around future eHealth investments. The Authority will review the document in 18 months' time and update the recommendations should new evidence become available.

1.1   Background

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.

A messaging standard, such as the HL7[6] or the Electronic Data Interchange for Administration, Commerce and Transport (EDIFACT)[7] standard specifies the structure and order of the many elements that make up a message such as the patient information, the laboratory information, the test undertaken and the results. It defines which elements are required and which are optional. Coding systems such as the International Classification of Diseases revision 10 (ICD-10)[8] and Logical Observation Identifiers Names and Codes (LOINC)[9] 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 common semantics.

Specific messaging standards for the healthcare context, such as the General Practice Messaging Specification(GPMS)[10] published by the Authority, are an essential way of improving how we use technology to enable safe and effective information exchange, including the exchange of clinical, administrative and patient information, for the benefit of the quality and safety of patient care.

Messaging standards have the potential to enable the following benefits to patients:

- speeding up the patient referral process to enable the patient to start on their journey of care more quickly
- reducing the need for duplicate and repeat diagnostic testing
- speeding up the sharing of patient discharge details and facilitating continuing care for patients during transfer between secondary care (for example, hospital) and primary care (for example, GP)
- complete, accurate and searchable health information, available at the point of diagnosis and care, allowing for more informed decision making to enhance the quality and reliability of healthcare delivery
- more efficient and convenient delivery of care, without having to wait for the exchange of records or paperwork and without requiring unnecessary or repetitive tests or procedures
- earlier diagnosis of disease, with the potential to improve outcomes and reduce costs
- reductions in adverse events through an improved understanding of each patient's particular medical history, reducing the potential for harmful drug interactions in the course of treatment
- the outcome of patients' out-of-hours consultations are available to the GP, thus facilitating continuity of care for the patient.[10]

1.2   Intended audience

This guidance is being developed to inform key stakeholders such as public and private service users, vendors, purchasers and implementers of health information systems, healthcare providers, the wider health informatics community and any other interested parties, about the proposed future direction of messaging standards in Ireland, and to encourage wider participation in standards development. The guidance 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.

1.3   Drivers for change

The recommendation of a national messaging standard for healthcare is based on key considerations including work completed to date by the Authority on interoperability standards that includes messaging, a review 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[10] and for other eHealth initiatives including work on the Individual Health Identifier (IHI)[3] and health identifiers for practitioners (HPI) and organisations (HOI),[4] information governance[11] and the eHealth consultation.[12] Further work is in progress on high level guidance documents on interoperability and clinical terminologies. The guiding principles to assist the development of interoperability standards for Ireland are also applicable to messaging standards and are outlined below:

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.[13]
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.

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.

1.4   Synopsis of international review on messaging standards

There are important lessons for Ireland to learn from international experience regarding the use of messaging standards. An international review was undertaken by the Authority on messaging standards adopted by five countries including Australia, Canada, Denmark, England and the Netherlands. The review also covered the current state of messaging in Ireland.

Key themes emerged from the international review regarding the selection of an appropriate messaging standard. V2.x is the messaging standard of choice for Australia,[14] Ireland[15] and the Netherlands.[16] The Netherlands advocate the use of v2.x for local and regional implementations and recommend v3 messaging for the national communication of messages. Historically, it has used EDIFACT for regional implementations. Denmark has a long history of messaging based on the EDIFACT standard.[17] Canada and England embarked on large scale national health IT programmes that warranted the use of v3 messaging solutions.[18] The National Health Service (NHS) Connecting for Health (CfH) programme adopted CDA Release two for its national summary care record and have gained considerable experience working with CDA.[19]

The benefits of v3 messaging, as compared to v2.x, include a top down design approach to give better consistency and extensibility, coverage of the whole lifecycle of a standard, repeatability of implementations, worldwide usability, compatibility with modern development techniques and a reduction in implementation costs.[20] However, the v2.x standard has been successfully implemented worldwide and works

well for specific use cases such as laboratory or radiology messages. Therefore countries do not generally seek to replace existing v2.x systems as the considerable costs involved in such replacement cannot be justified. Messaging in Ireland, via Healthlink, is defined using the v2.4 standard and represented using XML encoding. The XML messages are validated against HL7 schemas and can be rendered or displayed to the end user using an XML style sheet.

Internationally v2.x is by far the most widely used standard for exchanging healthcare messages and continues to be supported by the software and healthcare industry. For new implementations, the v3 messaging standard CDA are gaining momentum with several countries adopting them as the basis for their standards-based health information exchange architecture. Countries who have undertaken CDA projects include Australia, Canada, Germany, Greece, Finland, Japan, UK and US.[21] CDA provides for different levels of conformance to the standard. The different levels enable implementers to develop simple documents known as level 1 that are displayed and presented to clinicians in a readable format or more complex documents that are coded for machine processing, known as level 2 and 3. This feature is referred to as the 'migration path' and enables significant flexibility for implementers giving them the option to decide what content can be exchanged, while still remaining compliant with the standard.

CDA is a good option for countries who have limited resources as they can adopt simple CDA-based architectures. CDA is a more manageable standard to implement than v3 messaging, yet has the benefit of still being based on a common information model known as the Reference Information Model (RIM). An information model provides a framework for organising data so that it can be delivered and re-used in a variety of different ways. CDA ultimately allows for shared information at the point of care and promotes reusability across a sufficiently wide range of documents.[22] Examples of CDA projects based on the countries listed above include:

- Australia – use CDA for EHR interoperability
- Canada – CDA is the electronic source for claims adjudication
- Japan – extensive use of CDA is planned
- UK – the English NHS CDA is the core component of the NHS strategy for interoperability
- Finland – adopted CDA Release 1 in 2000; exchange network covers most of the country; experimenting with distributed decision support using CDA Release 2
- Greece – sophisticated satellite-based telemedicine system using CDA, web services[22]
- US – the Mayo Clinic is the largest producer of CDA documents worldwide generating thousands of CDA documents every week.[23] CDA is also the technology of choice for most US Nationwide Health Information Networks prototypes and many Regional Health Information Networks.[24]

2   Assessment

The key steps in determining a proposed approach to messaging standards in Ireland were to:

- consider existing standards currently used for messaging initiatives in Ireland
- identify key drivers for messaging standards including work emerging from the Authority's business plan on technical standards, the priority areas identified from the eHealth public consultation and international experience with messaging standards
- identify potential candidate messaging standards
- document a set of principles and criteria to assess the candidate standards.

2.1   Candidate Standards

The four candidate standards selected for messaging in Ireland are HL7 v2.x, v3 messaging, CDA and EDIFACT. An overview of each standard is described in the following section.

2.1.1 HL7 v2.x

The v2.x standards provide specifications for messages to support the sharing of information on admission to, transfer within and discharge from hospital. It provides messages to support many scenarios including the ordering of laboratory and radiology tests and medications for patients, and to send results of the tests ordered to the ordering clinicians. It can support transmission of referrals and discharge summaries between clinicians and sharing of information on appointment scheduling for patients.

In order to define messages for the different contexts mentioned above, the standards specify a set of building blocks for messages known as message segments which may be reused when constructing messages (see Figure 2). Each segment consists of multiple fields which are constructed using pre-defined data types.

Figure 2. Structure of HL7 message[25]
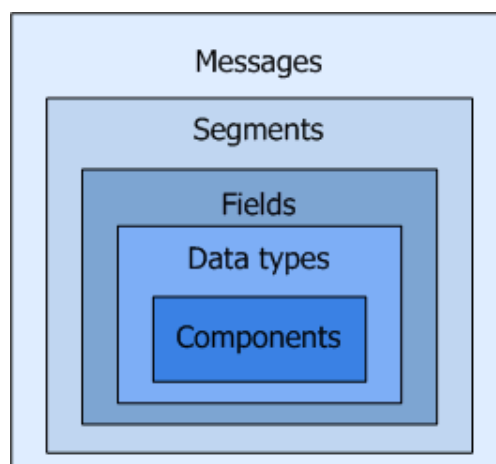
2.x was not originally designed for inter-organisational communication and lacks some functions and features needed to support large scale implementations and eHealth standards frameworks. The strength of the v2.x standard is its ability to support the exchange of information within a single organisation or site because the standard is localised for specific implementations, thereby ensuring that information can be correctly interpreted. Some shortfalls with v2.x include the following:

- It is not based on an explicit underlying information model. An information model is important because it is an effective means of documenting assumptions about data and provides a language that allows the unambiguous expression of information in a particular domain.
- It does not have an explicit development methodology.
- Relationships are not defined formally between fields and events in v2.x (as natural language is used).
- v2 messages do not inform a receiving application what to do having received a message.[25]
- A feature of the v2.x standards is the high degree of flexibility the specification offers, as there are a large number of optional fields. On the one hand, the benefits of such flexibility allow local implementations to constrain or modify the specification to meet their own needs. However, without appropriate guidance and requirements for use, the standard may be open to misinterpretation in its structure and format.[10] Consequently v2.x is sometimes referred to as the 'non-standard standard'.[26]

The v2.4 standard is the predominant messaging standard used in Ireland for communicating health information and is an effective solution for traditional message-based interconnectivity between systems within hospitals. The standard has gained widespread adoption internationally and is one of the most widely used standards for communicating clinical data among clinical information systems in hospitals and general practice worldwide.[27] For example, it is estimated that over 90% of hospitals in the USA use v2.x to support their interoperability requirements. This success is demonstrated by the large number of v2.x implementations in existence internationally, with good support for tooling, implementation guides and extensive experience and knowledge of the standard.

2.1.2 HL7 v3 messaging

The v3 messaging standard was created to support large scale health information systems[25] and attempts to support all healthcare workflows to facilitate benefits such as reduced ambiguity, maximum reuse and increased consistency in HL7 messages.[28] The v3 standard is published as a large web-based document whose content is presented as specific subject areas, also known as domains, such as laboratory, pharmacy, medications and patient administration.[25]

The v3 messaging standard uses the RIM and a formal methodology called the HL7 Development Framework (HDF) to increase the detail, clarity and precision of the message specification.[25] v3 messaging combines a formal methodology with

established models and value sets needed to express the full range of specifications for eHealth interoperability, including specifications for prescribing, referrals, and discharge summaries. Other beneficial features inherent in the standard include its ability to integrate seamlessly with a clinical terminology, such as LOINC[9] or Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT),[29] and easy alignment with structured documents as both CDA and v3 messaging are derived from the same information model.

Some criticisms raised regarding the technical aspects of v3 messaging include the structure of its data types, complexity of its clinical information representation and the size of its messages. However, there have been v3 messaging projects deployed on a large scale in the UK NHS and to a lesser scale in Canada, US, Europe and some other countries. There are increasing levels of technical support and some tooling available for v3 messaging in the international community, although as yet, there are no v3 messaging implementations and very little experience of this in Ireland to date.[24]

2.1.3 Clinical Document Architecture (CDA)

In addition to creating messaging standards, HL7 also develop standards for representing clinical documents, such as referrals and discharge summaries, known as the CDA. The most recent version of the CDA, release two, was published in 2005, with release three currently in development.[30] The development of CDA has been driven by the need for clinical information to be interpreted by both human readers and computer systems. CDA supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing. HL7 include guidelines in the CDA specification for transporting the CDA within either a v2.x or v3 message. The CDA standard does not require that the document is coded but typically implementers or users at a local, regional or national level provide an implementation guide to refine the generic CDA specification by specifying the structure and coding requirements for a particular implementation.

2.1.4 EDIFACT

EDIFACT was developed by the United Nations Centre for Trade Facilitation and Electronic Business, (UN/CEFACT) and was adopted by the International Organization for Standardization (ISO), known as the ISO 9735 standard.[7] It provides a set of syntax rules to structure data, an interactive exchange protocol‡ and standard messages which allow multi-country and multi-industry exchange. Of the four standards reviewed, EDIFACT is a generic standard and is widely used internationally for eBusiness outside of eHealth whereas the other candidate standards are specifically tailored for healthcare.

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‡ The interactive exchange protocol (I-EDI) is defined as the exchange of messages from computer application to computer application, using structures based on national or international standards, such as the EDIFACT standard (http://www.unece.org/trade/untdid/texts/d210_d.htm).

EDIFACT is a text delimited syntax for electronic exchange, popular before XML came to the fore. EDIFACT is similar in structure to v2.x in that it is composed of building blocks known as segments, further divided into fields, which contain a value with a data type specified by the standard. In some cases, fields can be further subdivided into components and subcomponents.[31] Similar to v2.x, EDIFACT does not define the exchange mechanism or communication protocol between messages. EDIFACT defines only the messages and their content. Some discussion and negotiation between trading partners to ensure that messages are exchanged unambiguously is required. In congruence with HL7, the EDIFACT organisation has developed a methodology around message design which promotes the reuse of existing segments and data elements when developing new messages.[32]

EDIFACT implementations include projects in the United Kingdom (UK) and Denmark. The UK's National Health Service (NHS) uses EDIFACT messaging for transferring electronic pathology results between laboratory information systems and GPs' practice management systems.[33] In Ireland, EDIFACT is used for communicating insurance information from hospitals to insurance companies. The Danish health sector made the decision to adopt EDIFACT in 1994 as part of their national messaging programme for message types such as prescriptions, discharge summaries, and laboratory results.[34]

2.1.5 Messaging versus document paradigm

One of the limitations of messaging standards is that they conflate process (services) and content (documents). A common uncertainty for implementers is to know when to use a message or a clinical document for a given use case, otherwise known as the messaging versus document paradigm. Above all, messaging provides poor support for semantics except in the case, for example, of the exchange of quantitative data in laboratory messages.[24] Table 1 on the next page shows a comparison of some key characteristics and usage between messaging and CDA documents.

Table 1. Comparison between messaging and CDA[35]

Criteria	Message	Document
Characteristics	Messages support information which is required to be machine processable, required in real time and uses a dynamic model.

Messages can have receiver responsibilities requiring activity to be undertaken by the receiving systems as a result of receiving the messages.

Messages may require that a response message is sent. | Documents are human-readable, persistent, self-contained and may also be machine-processable. |
| **Usage** | Messages support ongoing process in real time.

Requests transmitted in messages may be accepted or rejected by a system, thereby providing a degree of control to the receiving system.

Messages contain current data and are more appropriate to use when there is tight communication processes between systems. | Documents are passive, contain static content and may not necessarily drive activity.

Documents can be superseded (replaced) and corrected (appended) during their lifecycle.

Document are generally used 'post occurrence' of a healthcare event and are generated after the process is complete.

Contain data 'as it was' when the document was originally completed. |

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

Example scenarios

A whitepaper published by the Ringholm group suggest some examples of where messages or documents are best suited to particular clinical scenarios or use cases and are outlined in Table 2.[35]

Table 2. Examples of use cases for messaging and documents[35]

Clinical scenario	Message	Document
A rough list of patient drugs as part of a referral.		Yes
A prescription that will be manipulated as a patient gets it dispensed, is admitted and then discharged from hospital.	Yes	
A list of patient medications 'as known at admission'.		Yes
What medications are they on right now, not 5 hours ago	Yes	
The order / promise negotiation phase of a business process.	Yes	
If one intends to send clinical summary documents or referrals.		Yes
Messaging is a more natural approach when generation of a real time summary is required based on information stored across a variety of systems in an environment where the data may be maintained by multiple providers and change over time.	Yes	

2.2   Assessment approach

To decide what standards approach is the most appropriate to use in the short to medium term, an options analysis tool was designed. The tool was developed by the Authority as part of its standards development process for health information technical standards and is based on a Canadian model that is used for the selection and approval of their health information standards.[36] It comprises of five principles with each principle consisting of specific criteria (an explanation of each principle is given in Appendix 1 and a brief summary in Appendix 2). All four candidate standards were assessed against each principle and criteria in the options analysis tool (see Appendix 3 for a detailed description).

The following options were identified as potential approaches for messaging standards in Ireland:

- use of the EDIFACT messaging Standard
- continue with v2.x for existing projects. This involves maintaining and extending v2.x by defining extensions to meet local requirements
- develop new specifications using v3 messaging

- migrate to a document approach to share structured documents using CDA and transport the documents using a v2.x message.

2.3   Options analysis tool

A detailed assessment was carried out whereby each of the four candidate standards was assessed against the options analysis tool. The principles and criteria are outlined below in Table 3, alongside the results for each of the candidate standards. All of the candidate standards passed through the options analysis tool were measured against each principle and corresponding criteria and subsequently awarded a pass (P) or fail (F).

Table 3. Options analysis tool for messaging standards

No.	Criteria/Principle	v2.x	v3 messaging	CDA	EDIFACT
1. Standards must be clinically relevant					
1.1	Clinical appropriateness	P	P	P	P
1.2	Cross discipline	P	P	P	P
1.3	Cross healthcare delivery setting	P	P	P	P
1.4	Clinical outcomes	P	P	P	P
2. Standards must meet specific business needs					
2.1	Business need	P	P	P	P
2.2	Maturity/stability	P	P	P	P
2.3	Feasibility	P	F	P	F
2.4	Workflow	P	P	P	P
3. Standards must be vendor neutral and backward compatible					
3.1	Vendor neutral	P	P	P	P
3.2	Backward compatibility	P	P	P	P
4. Standards must be financially viable					
4.1	Affordability	P	P	P	P
4.1	Implementation costs	P	F	P	F

No.	Criteria/Principle	v2.x	v3 messaging	CDA	EDIFACT
5. Standards must have established governance and processes					
5.1	Intellectual property	P	P	P	P
5.2	Governance structure	P	P	P	P
5.3	Irish influence	P	P	P	P
5.4	Sustainability	P	P	P	P

2.4   Analysis

The outcome of the analysis is presented in terms of differentiating and non-differentiating principles. Two of the five principles allow a selection of preferred options between the four candidate standards and hence are considered differentiating principles. The remaining three principles offer similar outcomes across the four candidate standards and do not suggest preferred candidate standards and are considered non-differentiating principles.

2.4.1 Differentiating principles

Standards must meet specific business needs (Feasibility):

Feasibility has been defined as the ability to implement a standard within a reasonable time, budget, and resource skill set. To develop new v3 specifications would require significant upskilling, resources and education as there is a steep learning curve involved with v3 design and development and there is little expertise or experience of implementation in Ireland.

To retrofit EDIFACT to existing v2.x solutions would provide little added value because v2.x and EDIFACT are so similar in structure and purpose. Both standards are suited to traditional message-based interconnectivity between IT systems within hospitals, for example transaction based messaging such as real time laboratory messaging. Although it is feasible to provide upskilling in EDIFACT given the knowledge and experience that already exists with v2.x implementations, there is nothing to be gained from replacing v2.x with EDIFACT.

Standards must be financially viable (Implementation costs):

Feasibility and implementation costs are very much interlinked. In order for a standard to be implementable, it must be financially viable. To implement a messaging solution based on v3 messaging solutions would require significant re-engineering of current v2.x implementations and would accrue significant costs when

the testing, training and development costs are considered. Given the current economic climate in Ireland, the Authority would suggest that the development and widespread implementation of a new messaging specification based on the v3 messaging reference models and methodologies would not be considered a viable solution.

Similarly the Authority would advise that to replace existing v2.x solutions with EDIFACT would not be cost effective given the resources and development required.

2.4.2 Non-differentiating principles

Non-differentiating principles, or principles that are the same across the candidate standards, include clinical relevance, interoperability with an EHR, and established governance and processes.

Standards must be clinically relevant: there is little to differentiate the candidate standards in terms of clinical relevance. The v3 messaging and CDA standard have advantages over v2.x and EDIFACT as they are based on a healthcare specific information model. In the longer term, a messaging specification based on the v3 messaging standard may be the preferred choice, given its reference model, methodology and how it is designed to support all healthcare workflows providing domain specific models supporting all clinical and patient care. However, there is little to differentiate v3 messaging and the other candidates, v2.x, CDA or EDIFACT regarding clinical relevance.

Standards must be vendor neutral and backward compatible: all candidate standards are vendor neutral or non-proprietary. All four candidate standards are backward compatible with previous versions of their own standard. A standard is backward compatible if it is compatible with earlier versions of the same standard. However, it is sometimes necessary to sacrifice backward compatibility to take advantage of a new improved standard with a completely different architecture. For example, v3 messaging was not designed to be backward compatible with v2.x and are therefore considered as separate standards.

Standards must have established governance and processes: the Authority will develop specifications based on standards that have been derived from an international standards development organisation (SDO). The Authority will be responsible for reviewing and maintaining any localised standards.

3   Conclusions and Recommendations

The purpose of this guidance is to provide direction on healthcare messaging standards in Ireland for the short to medium term. The Authority will review the document in 18 months' time and update the recommendations should new evidence become available.

Across Ireland, the exchange of administrative and clinical information is managed using many different types of systems and computer software. The standards that are used to communicate information unambiguously between different systems vary and may include bespoke, proprietary standards, or commonly used international messaging standards such as HL7 or EDIFACT. To safely send and receive information such as referrals and laboratory orders and results between different types of systems, a standard exchange format is required.

Given that v2.4 XML encoded messages are widely used in Ireland presently, the preferred approach to cover all requirements is one based on a combination of messaging and structured documents whereby the CDA document can be transported within either a v2.x or v3 message. On the basis of this assessment and given the current dominance of v2.4 XML encoded standards in Ireland, continued support for the v2.4 was selected as the preferred candidate standard for the exchange of health information in the short to medium term. This was complemented by a strong endorsement to combine the use of the CDA for the exchange of structured clinical documents. V2.x can be used to transport CDA documents.

To provide direction and to assist the health IT community to make decisions in relation to health messaging standards, HIQA makes the following recommendations.

> **Recommendations**
>
> 1. The v2.4 XML encoded messaging standard should continue to be supported as it is the most extensively used health messaging standard in Ireland and is delivering substantial benefits.
>
> 2. Where HL7 v2.x or CDA are not currently supported by a system, consideration should be given to providing such support when major upgrades are taking place.
>
> 3. The CDA standard should be used for the development and exchange of documents.
>
> 4. The GPMS should be included in specifications for new health IT systems or procurement of future health IT systems where it is relevant.

The Authority will continue to maintain and expand the GPMS and will develop messaging specifications to support other prioritised use cases. The Authority will work with the health informatics community to analyse use cases, select the most appropriate standard to use and develop specifications based on project requirements. The Authority will review the document in 18 months' time and update the recommendations should new evidence become available.

These recommendations are based on the existing extensive use of v2.x XML encoded messaging standards in Ireland and for the need to upskill in newer technologies such as CDA so as to take advantage of the opportunities they offer. The need for CDA is driven by the fact that clinical documents are used widely to facilitate clinical activities. CDA supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing. This approach will keep all options open in relation to standards implementation for eHealth initiatives such as ePrescribing and the EHR (see Figure 1 on page 3).

The Authority will keep these recommendations under regular review and will continue to engage and consult with stakeholders and keep abreast of developments in the standards landscape internationally.

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Appendix 1 – Options analysis tool

1.   Standards must be clinically relevant

A standard for messaging in Ireland should be clinically relevant. This ensures standards are clinically appropriate i.e. they are able to support clinical practice. A standard would be considered cross-disciplinary if it supports the clinical practice of clinicians, nurses, pharmacists, laboratory professionals, allied health professionals and all other healthcare practitioners. To satisfy cross-healthcare delivery settings, a standard should support the transmission of messages and clinical documents from primary care, community care, long-term care and acute care. All standards should support clinical outcomes and patient care and define message types across administrative, clinical, requesting and prescribing use cases, support the carrying of clinical information and requests for results and services.

2.   Standards must meet specific Irish business needs

A standard should be developed based on a defined business requirement. Features to ensure specific Irish business needs are met include a standard that is mature and stable, is feasible and adheres to clinical workflow.

Maturity and stability of a standard are demonstrated by how widespread a particular standard is implemented and tested. A good indication of maturity is the degree of penetration of the standard in other countries internationally and nationally. Standards should have a defined release process with normative editions being released on a yearly basis. In terms of feasibility, it should be possible to implement the standard within a reasonable time, budget, and resource skill set. The use of a standard must complement the user's workflow or workload and must be balanced with improvements to patient care either directly or indirectly.

3.   Standards must be vendor neutral and backward compatible

Candidate standards should be vendor neutral and non-proprietary, i.e. they are not privately owned or controlled by one vendor. The presumed advantage of choosing a vendor-neutral model is that the best technology can be used at any time. Candidate standards should also be backward compatible. This is important because it eliminates the need to start over when upgrading to a new version of a standard. A standard is backward compatible if it is compatible with earlier versions of the same standard. However, it is sometimes necessary to sacrifice backward compatibility to take advantage of a new improved standard with a completely different architecture. For example, v3 messaging was not designed to be backward compatible with v2.x and are therefore considered as separate standards.

4.   Standards must be financially viable

The affordability of introducing a messaging standard is a key consideration and must take into account the licensing costs of the standard, and the membership of

the standards development organisation (SDO) if required. The development of specifications based on a particular standard may be expensive to develop, requiring technical expertise and knowledge and upskilling locally before the project can be undertaken. Development and implementation costs of new interfaces to support a new messaging specification based on a particular standard are costly. Additionally, the current economic climate development dictates that any suitable standards selected for messaging in Ireland must be practical.

5.   Standards must have established governance and processes

Any intellectual property rights or licensing issues relating to the standard should be documented. In relation to the governance structure of a standard, the Authority will develop specifications based on standards that have been derived from an international SDO. The Authority will be responsible for reviewing and maintaining any localised standards that are developed. The standards should have an Irish influence, ensuring they are maintained through an open and transparent process with the opportunity for Irish stakeholders to be engaged. Processes and resources should be well established to ensure the sustainability of the standard allowing the standard to be enhanced when needed and to monitor conformance to the standard.

Appendix 2 – Summary of principles for filtering criteria

1. Standards must be clinically relevant

1.1. *Clinical appropriateness* – where relevant, the standard must support clinical practice.

1.2. *Cross discipline* – where relevant, the standard should be provider independent, e.g. use across disciplines (physicians, nurses, pharmacists, laboratory professionals, allied health professionals etc.).

1.3. *Cross-healthcare delivery setting* – the standard should be healthcare-delivery-setting independent, i.e. appropriate for use across health sectors (acute care, community, long-term care, etc.).

1.4 *Clinical outcomes* – the standard should support patient care. Message types should be defined across administrative, clinical, requesting and prescribing use cases, support the carrying of clinical information and requests for results and services.

2. Standards must meet specific Irish business needs

2.1. *Business need* – the standard should be developed based on a defined business requirement and should be validated to ensure it meets the business requirements.

2.2. *Maturity/Stability* – the standard must be assessed to determine how widely it has been implemented and tested as well as to determine if it requires further development.

2.3. *Feasibility* – it should be possible to implement the standard within a reasonable time, budget, and resource skill set. Known critical dependencies impacting implementation must be identified (for example, other components or standards that are not yet developed).

2.4. *Workflow* – the use of this standard must be assessed in regard to the user's workflow or workload. Impact to workflow must be balanced with improvements to patient care either directly or indirectly.

3. Standards must be vendor neutral and backward compatible

3.1. *Vendor neutral* – the standard should be vendor independent.

3.2. *Backward compatibility* – where appropriate, the standard should be backward compatible and interoperable with previous versions of the standard.

4. Standards must be financially viable

4.1. *Affordability* – the standard should have viable licensing and maintenance fees as well as a feasible funding strategy.

4.2. *Implementation costs* – the implementation of the standard should be financially viable.

5. Standards must have established governance and processes

5.1. *Intellectual property* – the intellectual property or licensing issues relating to the standard should be documented.

5.2. *Governance structure* – from the Authority's standards decision-making process, the designation of a standard as an Authority standard is governed by the Authority's standards development process.

5.3. *Irish influence* – the standards should have been developed and maintained through an open and transparent process with opportunity for Irish stakeholders to be engaged.

5.4. *Sustainability* – document the established or planned processes and resources to maintain this standard; to enhance the standard when necessary and monitor conformance to the standard.

Appendix 3 – Options analysis for candidate standards

A.   Options Analysis HL7 v2.x

v2.x passes all principles and criteria, making it a suitable approach for the short to medium term.

1   **Clinical relevance:** from a clinically relevant perspective, a new or existing specification based on v2.x would support clinical practice of physicians, nurses, pharmacists, laboratory professionals and allied health professionals. V2.x supports the transmission of messages and clinical documents from primary care, community care, long-term care and acute care and defines message types across administrative, clinical, requesting and prescribing use cases and ultimately supports clinical outcomes and patient care.

2. **Meet specific business needs**: in the Irish context, v2.x can meet current business needs and covers the current scope of business requirements including patient administration (admission, discharge, transfer and registration), accounting systems and clinical data, such as laboratory orders and reports. It is a mature standard, with a recognised governance structure and a wide scale implementation base. The v2.x standard is now implemented in many countries including the USA, Canada, Australia, Germany, the Netherlands and Japan. Much knowledge and experience exists for implementing interfaces to support messaging based on v2.4, enhancing its feasibility.

3. **Vendor neutral and backward compatible:** v2.x is vendor neutral and backward compatible.

4. **Financially viable**: the level of resources to develop and maintain a standard based on HL7 v2.x is achievable as the level of expertise required to form a working group to develop a v2.4-based specification currently exists and can be leveraged. Also Healthlink, the national messaging broker, has vast experience with HL7 v2.4 messaging.

5. **Established governance and processes**: a key consideration for an appropriate standard is that it has established governance and processes. In terms of intellectual property rights, it is possible to access HL7 standards by obtaining an individual membership. However, it is necessary to have an organisational HL7 membership in order to circulate excerpts of the HL7 material.

B.   Options analysis HL7 v3 messaging

v3 messaging has many attractive features including a healthcare-specific reference model, domain specific reference model, reusable artefacts and a methodology for further defining clinical artefacts specific to the use case. However, as evidenced below, v3 messaging fails on the following principles – feasibility, affordability and implementation costs. The following points outline the main principles and how v3 messaging measures against them:

1. **Clinical relevance**: similar to v2.x, a new or existing specification based on v3 messaging supports the clinical practice of physicians, nurses, pharmacists, laboratory professionals and allied health professionals standard and supports the transmission of messages and clinical documents from primary care, community care, long-term care and acute care. A messaging specification based on a version of the v3 messaging standard gains all the benefits offered by the standard, including the Reference Information Model (RIM), use of existing and future messaging artefacts published within the model and a standard designed to support both the messaging and clinical documents use cases. Regarding clinical outcomes, v3 messaging has domain-specific models supporting clinical and patient care. Messaging specification and common message element types (CMET) are defined and usable in messages conformant to the standards and support the transmission of detailed clinical information in a standard and reusable manner.

2. **Meet specific business needs**: v3 messaging meets the current Irish business need for messaging, as the standard has vast coverage, spanning all healthcare domains. It consists of an elaborate set of ready-to-implement models (for messages, documents, or services) created using the HL7 HDF, which is an integral part of the standard. The HDF documents the processes, tools, actors, rules, and artefacts relevant to the development of all v3 standard specifications. In terms of maturity and stability, there is very little user penetration of v3 messaging in Ireland to date. Internationally there are numerous projects implementing this technology – the UK NPfIT program and the Canadian provider registry. Vendors are also gaining experience internationally but the level of vendor support nationally is minimal and many of the legacy laboratory systems would not support the new v3 messaging solution. With respect to the feasibility of the standard, currently there is very little expertise or experience with v3 messaging in Ireland and implementation of the standards would be constrained by the budget required to increase knowledge, re-engineer interfaces and upgrade source and consumer software, test and deploy the solution. To develop a v3-messaging-based specification would require much initial funding to increase the knowledge base. v3 messaging has a formal methodology and supports workflow.

3. **Vendor neutral and backward compatible:** v3 messaging is vendor neutral. In terms of backward compatibility, when v3 was being developed it was agreed that new versions of the v3 standard must be semantically backward compatible. This means that the information in a new version should contain the same

information as the old version but there is no requirement that this information be communicated in the same way or even using the same data type.

4. **Financially viable**: a new specification based on v3 messaging would be expensive to develop, requiring technical expertise, knowledge and upskilling locally before the project could be undertaken. Development and implementation of new interfaces to support a new messaging specification based on v3 messaging specifications would cost considerably more, and to gain a similar coverage as the existing interfaces would indeed be expensive when the testing, training and development costs are considered. Given the current economic climate in Ireland, development and widespread implementation of a new messaging specification based on the v3 messaging reference models and methodologies would not be considered viable.

5. **Established governance and processes**: in terms of intellectual property rights, it is possible to access HL7 standards by obtaining an individual membership. However, it is necessary to have an organisational HL7 membership in order to circulate excerpts of the HL7 material.

C.   Options analysis HL7 CDA

Clinical activities are typically document driven making the use of structured documents, such as the CDA, a more suitable approach for the mapping of real world requirements to electronic form easier than mapping to messages. The following points outline the main principles of the options analysis and how CDA measures against them:

1. **Clinical relevance**: a structured document implies that health information can be more easily presented in a human readable form than it is in a message. The CDA standard is clinically appropriate, covers cross-discipline and healthcare delivery settings, supports the clinical practice of physicians, nurses, pharmacists, laboratory professionals and allied health professionals and the transmission of clinical documents from primary care, community care, long-term care and acute care. Regarding clinical outcomes, CDA defines domain specific models such as medication and observations, supporting clinical and patient care.

2. **Meet specific business needs**: CDA meets the current Irish business need for specific use cases such as transmitting a clinical summary. In terms of maturity and stability, there is very little penetration of CDA in Ireland to date. However, internationally CDA is the most widely utilised and best developed approach to structured documents and is now accepted as the norm in several national programmes. With respect to the feasibility of the standard, currently there is very little expertise or experience with CDA in Ireland, however, because of the migration path or the ability to implement CDA at different levels of conformance, it is deemed a more straightforward standard to migrate to rather than v3

messaging. In terms of workflow, CDA is very much aligned with clinical workflow particularly for supporting clinicians and healthcare professionals with processes and tasks around referrals, discharge and producing clinical summaries.

3. **Vendor neutral and backward compatible:** CDA is vendor neutral and backward compatible.

4. **Financially viable**: a new specification based on the CDA would be less expensive to develop than v3 messaging, and although it would require technical expertise and knowledge and upskilling locally, there is evidence to suggest that it is a more cost-effective alternative than implementing v3 messaging.

5. **Established governance and processes**: a key consideration for an appropriate standard is that it has established governance and processes. In terms of intellectual property rights, it is possible to access HL7 standards by obtaining an individual membership. However, it is necessary to have an organisational HL7 membership in order to circulate excerpts of the HL7 material. It is a mature standard, with a recognised governance structure and a wide implementation base.

D. Options analysis EDIFACT

As evidenced below, EDIFACT fails on the following criteria: feasibility and implementation costs. The following points outline the main principles and how EDIFACT measures against them:

1. **Clinical relevance**: EDIFACT supports the transmission of messages from primary care, community care, long-term care and acute care and defines message types across administrative, clinical, requesting and prescribing use cases and ultimately supports clinical outcomes and patient care. Although EDIFACT is a good choice of syntax to use in high volume, point-to-point exchanges within a confined setting such as a hospital, it is not the most suitable choice for inter-organisational exchange e.g. to facilitate messaging for a wider audience. The EDIFACT standard supports patient care, with the EMEDI working group having defined their major message types such as person identification, medical prescription, medical service request, medical service report, medical resource usage and cost, health insurance eligibility and benefit inquiry and healthcare claim or encounter request.[37]

2. **Meet specific business needs**: EDIFACT meets current Irish business needs and covers a range of business requirements including patient administration, healthcare insurance and claims data and clinical data such as prescribing. It is a mature standard, and was adopted early in Europe where consequently there is a large uptake of the EDIFACT standards.[7] In Ireland, there is little penetration of EDIFACT messaging, except for communicating insurance forms from hospitals to insurance companies. The EDIFACT standard is released twice a year, and can be downloaded as text files from a UNECE website with message types and their

components being added, modified, and sometimes removed.[37] The structure and purpose of v2.x and EDIFACT are very similar so the learning curve involved would not be as substantial as migrating to a v3 messaging standard. It would be expensive to reengineer existing v2.x interfaces and upgrade source and consumer software, test and deploy an EDIFACT solution. It is questionable if the EDIFACT solution is justifiable as the standards are so similar.

3. **Vendor neutral and backward compatible**: EDIFACT is vendor neutral and backward compatible.

4. **Financially viable**: a new specification based on EDIFACT would be associated with development and implementation costs, requiring skilled technical expertise and upskilling locally before a project could be undertaken. Development and implementation of new interfaces to support a new messaging specification based on EDIFACT would be costly when the testing, training and development costs are considered. Given the current economic climate in Ireland, development and widespread implementation of a new messaging specification based on the EDIFACT messaging would not be considered viable.

6. **Established governance and processes:** there are no known intellectual property rights affecting an EDIFACT messaging specification implementation. The UN grants a licence to use the standard in the country where the organisation is located.