

An investigation into the use of HL7 Clinical  
Document Architecture as a standard for Discharge  
Summaries in Ireland

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the requirements for the Degree of Masters in Science in Health Informatics.**

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## Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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## **Summary**

It is widely accepted that the provision of safe quality healthcare depends amongst other things, on the availability of reliable and high quality patient information at the point of care. The fragmented nature of healthcare systems is one of the major challenges in the healthcare informatics domain. To address this problem, standards and technical specifications are being developed with the aim to structure the clinical content for the purpose of exchange with the goal of providing interoperable solutions.

The primary objective of this research was to review the HL7 v2.4 referral message (REF\_I12) used for electronic discharge summaries in Ireland and investigate whether the structure of the message provided a solution that was scalable and interoperable. The second objective was to review the HL7 v3 Clinical Document Architecture Release 2 and see if the structure of this standard could potentially provide a more scalable interoperable solution.

Initially the importance of the discharge summary document was identified and its importance in relation to the overall longitudinal electronic health record of a patient. Research has highlighted that transition points in care where a patient's care was transferred from secondary care to primary care, required extra attention in relation to information quality. The structures of both the HL7 v2.4 REF\_I12 message and the HL7 v3 CDA R2 were analysed. Various case studies were identified which provided an insight into international implementations of the CDA.

The research concluded that the HL7 v3 CDA R2 could provide a more scalable interoperable solution with regard to discharge summaries. The evidence suggests that the HL7 v3 CDA has been successfully implemented worldwide.

The fact that the HL7 v3 CDA R2 can be transported in a HL7 v2.4 message could provide a cost effective solution as the current infrastructure could be used and the benefits of the improved HL7 v3 standard utilised.

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## **Abbreviations**

IOM - Institute of Medicine

EHR - Electronic Health Record

HL7 - Health Level Seven International

CDA - Clinical Document Architecture

SDO - Standards Developing Organizations

ISO - International Organization for Standardization

ANSI - American National Standards Institute

CEN - Comité Européen de Normalization

HIQA - Health Information and Quality Authority

OSI - Open Systems Interconnection

HSE - The Health Service Executive

GPMS - General Practice Messaging Standard

ECCI - The Electronic Clinical Communication Implementation

CIHI - The Canadian Institute of Health Information

DAD - Discharge Abstract Database

SDO - Standards Development Organisations

RIM - Reference Information model

DMIM - Domain Message Information Model

RMIM - Refined Message Information Model

PRA - Patient Record Architecture

XML - Extensible Markup Language

PDF - Portable document format

SOA - Service Oriented Architecture

ASTM - American Society for Testing and Materials

NHS - National Health Service

CSP - Clinical Statement Pattern

NEHTA - National E-Health Transition Authority

AMA - Australian Medical Association

OID - Object Identifiers

ASP - Application Service Provision

GMS - General Medical Services

DoHC - The Department of Health and Children

LOINC - Logical Observation Identifier Names and Codes

NCI - National Cancer Institute

EVS - Enterprise Vocabulary Services

HCI - Human Computer interaction

## **Chapter 1. Introduction**

## 1.1. Background

*"A journey of a thousand miles begins with a single step"*

LAO-TZU, CHINESE PHILOSOPHER (604 BX – 531 BC)

When we wish to achieve something or excel in any field, we must take the first step and continue to move and evolve from where we are, to ensure constant progression and improvement.

Medicine has evolved through the century's however the last century has seen some of the most significant technological advances.

Such advances include the emergence of enhanced medical imaging techniques such as magnetic resonance imaging (MRI), positron emission tomography (PET), 3-D ultrasound scanning, computer-assisted tomography (CAT) ,and digital X-ray imaging (Beutel, 2000).

Health care organisations have embraced these new technologies and utilised their benefits to improve patient care in relation to early disease detection and diagnosis. The one outstanding area of technology that has yet to be fully embraced by the medical community is the area of electronic medical records and health informatics.

In the majority of countries worldwide healthcare budgets contribute to the bulk of government spending, however healthcare IT still lags 15 to 20 years behind the technological capabilities of other global businesses including banking, telecommunications and the media (Goldschmidt, 2005, Arnold et al., 2007).

The availability to health care professionals, of reliable and high quality data is critical for the provision of safe healthcare (IOM Institute of Medicine, 2004). Healthcare information systems have developed from the isolated software systems in hospitals and primary care organisations to solutions that are required to provide support for continuity of patient care across multiple institutions (Begoyan, 2007).

Due to the unstructured evolution of healthcare software systems since the 1960's, heterogeneities exist in both hardware and software applications. Interoperability among such interactive and diverse systems requires the development of communication standards to enable the accurate exchange of data. Not only is the establishment of communication standards necessary but any standards developed must be extensible to enable their evolution in an ever changing complex environment. Maintenance and upgrading of the standards must therefore be an ongoing process, enabling the development of health care systems that are centered on high quality patient care as recommended by the Institute of Medicine (Corrigan, 2005).

Presently the focus is on care decentralization mainly due to an aging population and economic constraints. Primary care teams and outpatient care has been seen as a cost effective approach while at the same time striving to maintain quality results(Roland M et al., 2006, Vrangbæk, 2008). This model of decentralization has an indispensable requirement for accurate data interchange among health applications in order to have high-quality, contextual, up-to-date clinical information at the point of care. Such a requirement implies new challenges for the design and development of information systems some of which include:

1. Integrated lifetime electronic health record
2. Physical, semantic and syntactic interoperability among different organizations
3. Information exchange standards
4. Identification services including
  - a. Person identification services
  - b. Terminology services.



### **1.1.1. Electronic Health Record and Interoperability**

The Electronic Health Record (EHR) has become one of the central frameworks and has evolved to become centre stage in the national health informatics strategies of most European countries, and internationally.

An electronic health record is a repository for data collected during a patient's interactions with health care professionals. It is a legal medical document that allows, among other things, a global and longitudinal understanding of the patient's health status, and therefore can be an invaluable information source. The Electronic health record (EHR) has been the cornerstone of medical Informatics research for many years. The EHR has been defined as

*"Digitally stored health care information about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times". (Iakovidis, 1998)*

The development of an electronic health record has been at the heart of the European Union's Health Telematics Framework Programmes, beginning in 1992 and continuing through to the Seventh Framework Programme (FP7)(V STROETMANN et al., 2007).

The EHR is perceived as a tool for supporting the continuity of care resulting in improved quality, access and efficiency of health care delivery. The EHR can be viewed as a collection of health data that is recorded at the point of care but more importantly is accessible at the point of care to enable accurate and timely medical decision making.

The EHR includes information such as observations, laboratory tests, imaging reports, treatments, drugs administered, patient identifying information, legal permissions, and allergies (Eichelberg et al., 2005).

Clinical information is complex in nature and the requirement is for clinical meaning to be expressed consistently within EHR systems. This is required to ensure the accurate interpretation of clinical data from diverse sources.

The heterogeneity of health information systems is one of the major challenges in the healthcare informatics domain, as each system which has proprietary formats results in severe interoperability problems. A significant contribution to both effective and efficient patient care can be achieved by making EHR's interoperable, therefore enabling the retrieval and processing of clinical information across patient sites.

To address this interoperability problem, standards and technical specifications are being developed with the aim to structure and mark up the clinical content for the purpose of exchange (Eichelberg et al., 2005).

### **1.1.2. Discharge Summary**

The discharge summary is a key document in the patient's journey through the healthcare system. It can be viewed as a subset of the patient's Electronic Health Record (EHR) recording data collected for a specific episode of care and is thought to be the most comprehensive document in the health record (Kripalani et al., 2007).

Kripalani (2007) stated that the discharge summary contains relevant data about diagnostic findings, treatment, complications, consultations, tests pending at discharge, and arrangements for post discharge follow-up, data which could improve the continuity of patient care. Substantial implications to for continuity of care, patient safety, patient and clinician satisfaction, were attributed to delayed communication or inaccuracies in information transfer (Coleman and Berenson, 2004, Coleman et al., 2005).

Recent Irish research into discrepancies at discharge from hospital found that 65.5% of patients had an unintended discrepancy in their prescription. The most common inconsistency being drug omission (20.9%) (Grimes et al., 2008).

These results were supported by a systematic review which also demonstrated that discharge summaries lack information on discharge medication (Kripalani et al., 2007).

The Department of health and children also produced a report in 2008 (Department of health and children, July 2008) corroborating this evidence that an estimated 46% of all medication errors occur at transition points when patients move from one care setting to another e.g. secondary care to primary care.

An integral part of the communication is the methodology and format of the discharge summary. The Health Level Seven International(HL7) organisation(HL7, 2011a) is a standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management(HL7, 2011a).

## **1.2. Motivation for research topic**

The primary motivation for this body of research came from the author's collaboration on a medicine reconciliation project. The project's scope included the reconciliation of the patient's medication for the entire patient journey from admission through to discharge in an acute Irish hospital. The importance of accurate and timely data exchange from secondary to primary care in order to improve patient safety was the principal motivation.

The Health Information and Quality Authority (HIQA) are responsible for health informatics standards in Ireland. It was established in 2007 and the main tasks of the HIQA include the following:

1. Setting standards for all aspects of health and social care information;
2. Developing guidelines for the collection and use of information in health and social care;
3. Identifying gaps in health information and making recommendations to fill them;

4. Making relevant information about health and social care services available to the public.

(HIQA, 2011)

The Health Information and Quality Authority (HIQA) in 2010 developed the General Practice Messaging Standard (GPMS)(Health Information and Quality Authority, 2010) which is a messaging standard that was developed to standardise the electronic transmission of messages between the primary secondary care interfaces. This standard focuses on the structure and content of electronic messages used to communicate between the practice management systems of general practitioners, secondary care and out of hours care systems.

Healthlink (Healthlink, 2011b) is a HSE-funded national ICT project. The objective of the Healthlink project is to implement a prototype healthcare communications network with specific reference to GPs and acute hospital relationships through data exchange. The service is available to all GPs although some initial investment is required by hospitals to become involved. Some key initiatives at Healthlink revolve around supporting ICT-links between primary and secondary care to allow the secure transfer of patient information over the internet to general practitioners.

Discharge summary messages are provided by the Healthlink network in Ireland. The message type used for the discharge summary message is the HL7 v2.4 referral message (REF\_I12 message) type.

On initial investigation of the structure of the discharge summary message it became apparent that the segments contained in this message may limit the content and quality of the data that could be transferred especially in the area of medications and prescription information. Due to the importance of discharge summaries as part of a patient's EHR as outlined previously in this chapter it became apparent that further investigation was required to

determine if the solution provided was sufficient or was there other solutions available?

The HL7 International organization has developed a version 3 standard as a response to issues arising from the increasing use of V2 messaging. The HL7 Clinical Document Architecture (CDA) was developed for document exchange as part of the version 3 standard.

Could this be a more semantically interoperable solution than the HL7 v2.4 standard?

The focus of this research is on the messaging standards required at the transition of patients from secondary care to primary care which is a critical point in the care process. In order to ensure optimal continuity of patient care the accurate transfer of information at hospital discharge is essential (Kripalani et al., 2007).

### **1.3. Research Question**

When considering the background issues and the reasons outlined in the previous section, the primary research question chosen for the purpose of this study was as follows:

*Is the current HL7 v2.4 discharge summary message a semantically interoperable solution or would the HL7 v3 Clinical Document Architecture provide a more scalable and semantically interoperable solution for discharge summaries in the Irish context?*

A number of sub questions are suggested by the main question:

- *What is semantic interoperability and why is it important?*
- *Why did HL7 develop a new standard and what were the reasons for its development?*

- *What were the experiences to date of countries utilising the Clinical Document Architecture?*
- *Do the HL7 v2.4 and / or the HL7 v3 Clinical Document Architecture provide a semantically interoperable structure to exchange patient information for discharge summaries?*

## **1.4. Research Objectives**

In order to address the research question above, the research was conducted as follows:

1. A detailed literature review of discharge summaries and how they can be integrated with the EHR has been carried out.
2. Investigate the current status and the trends for electronic health messaging internationally.
3. A detailed investigation into what interoperability is and the challenges facing an interoperable implementation.
4. A detailed review of the relevant standards including the HL7 standard. An investigation into the motivations for HL7 developing a new standard and the benefits of the new standard
5. A review of selected case studies from countries using the CDA and for what purposes the CDA has been useful.
6. Development of a storyboard narrative, for a patient discharge summary in order to provide the descriptive content to develop a HL7 v2 message, HL7 v3 CDA to facilitate the comparative analysis methodology.

7. Develop a detailed comparative analysis of the HL7 v2.4 message and HL7 v3 Documents (CDA) discharge summaries providing a technical investigation at the segment level into both HL7 standards.
8. Evaluate the results of the comparative analyses with respect to the levels of semantic interoperability provided by each standard.

A literature review was carried out initially to establish what existing work has been done in the area of electronic discharge summaries, interoperability and HL7 standards. This aimed to identify gaps in the literature that could be developed further.

The main gaps that were identified in the existing literature:

- No practical examples of the technical benefits of upgrading from the HL7 V2 message to the HL7 CDA Document structure
- Lack of a detailed review of the differences that exist between standards in relation to the reasons why upgrading to new standards could be beneficial.
- Research has been carried out on the benefits of accurate discharge summaries however there is a lack of detailed practical implementations of the use of HL7 V2 as a discharge summary message structure.
- There is a lack of detailed information relating to human semantic interoperability in relation to discharge summaries.
- A technical comparison of the data that can be represented by different HL7 standards in relation to discharge summaries is not available.

The author believes that the need for this analysis is necessary for two reasons:

1. To understand the potential benefits that can be realized from an upgrading from HL7 v2.4 to HL7 3 CDA for discharge summaries in an Irish context.
2. A lack of practical knowledge in the literature in relation to detailed comparisons between HL7 v2 and v3 standards.

## **1.5. Outline of Dissertation**

The remainder of this work is laid out as follows:

Chapter 2 provides a detailed overview of HL7 international standards along with other relevant standard bodies and details interoperability issues to be addressed.

Chapter 3 provides a selection of international case studies demonstrating the use of the Clinical Document Architecture.

Chapter 4 outlines the research approach taken to answering the research question(s) and describes the research methodology.

Chapter 5 develops the discharge summary narrative and outlines the creation of the HL7 v2 message and HL7 CDA.

Chapter 6 develops the comparative analysis and provides detailed analysis on the findings.



Chapter 7 provides a summary of the conclusions and recommendations of this dissertation, and identifies areas where further research is needed.

## **Chapter 2. Literature Review**

## 2.1. Introduction

Creswell (Creswell, 2009) states that the literature review

*"Provides insight into the ways in which the researcher can limit the scope to a needed area of inquiry"*

In line with this and with the research objectives described in Chapter 1, the key literature review requirements and associated goals were identified and a detailed literature review was carried out. The requirements along with the research goals that they aim to address can be seen in Table 1 below.

Literature Review Requirements	Research Goals
To obtain an overview of the discharge process and the clinical need for discharge summaries.	To develop a clear understanding of the history and importance of the discharge summary process and the relevance the discharge summary has in relation to the longitudinal patient electronic health record.
Identify a minimum data set applicable for a discharge summary.	To define the minimum data set that is required for a discharge summary and forms the basic data set to enable the construction of the HL7 v2 message and HL7 v3 Clinical Document Architecture for the comparative analysis.
To understand the role that Interoperability plays in health information systems with specific focus on semantic interoperability.	To identify what are the principle requirements for an electronic discharge summaries with specific focus on the issues related to interoperability.
To understand the role of HL7 and	To identify the importance of standards in

standards as part of the development process of the Electronic Health Record.	the area of health informatics and assess how HL7 international standards perform and their level of maturity in relation to other standards.
Identify key case studies of countries adopting the Clinical Document Architecture to see what the CDA is being used for and what success has it achieved.	Identify any lessons that could be learned from its adoption in other countries
Identify technical documents and tutorials on the HL7 international standards.	Develop a working knowledge of the HL7 v2 and v3 message structure to enable the development of example discharge summaries in the v2, v3 format to enable a technical analysis of both structures.

**Table 1: Literature Review requirements and research goals**

## **2.2. Discharge Summary**

A discharge summary is a document produced during a patient's stay in hospital and issued when or after a patient leaves the care of the hospital. The primary recipients of the discharge summary are healthcare providers who were providing the patient care prior to the hospital admission and will provide care to patient after discharge.

### **2.2.1. Importance of discharge process**

Hospital discharge is a necessary process for all patients and requires effective integrated discharge planning as part of the patient hospital encounter.

Statistics from the Department of Health and Children reported that there were over 1.4 million patients discharged from Acute Irish Hospital in 2009. Table 2 below shows the details of these discharge numbers (Department of health and children, 2010). The safe care of these patients requires adequate discharge planning.

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
<b>IN-PATIENTS</b>										
Beds	11,190	11,373	11,686	11,806	11,887	12,094	12,110	12,123	11,847	n/a
In-Patients Discharged	515,025	532,559	528,882	540,032	553,102	555,726	574,348	593,315	592,153	584,928
Bed Days Used	3,136,925	3,271,038	3,256,311	3,339,833	3,462,452	3,517,986	3,550,850	3,601,349	3,572,563	3,486,063
% Bed Days Used by Patients Aged 65+	44.5	45.0	46.2	47.0	47.9	48.7	48.2	47.3	47.6	48.4
Average Length of Stay in Days	6.09	6.14	6.16	6.18	6.26	6.33	6.18	6.07	6.03	5.96
Surgical In-Patients	130,111	132,361	131,456	133,228	136,386	138,665	141,393	145,756	143,453	140,673
<b>DAY CASES</b>										
Beds	721	771	812	909	1,132	1,253	1,418	1,545	1,737	n/a
Day Cases	273,277	314,971	353,179	389,244	425,205	442,692	661,589	718,238	770,546	819,711
% Day Cases Aged 65+	23.7	24.5	25.4	26.7	26.8	28.0	33.7	33.4	33.8	35.3
Surgical Day Cases	67,853	73,801	76,148	78,034	82,001	84,219	86,931	92,208	98,819	107,596
<b>TOTAL DISCHARGES</b>										
In-Patients and Day Cases	788,302	847,530	882,061	929,276	978,307	998,418	1,235,937	1,311,553	1,362,699	1,404,639
Daycases as a % of Total Discharges	34.7	37.2	40.0	41.9	43.5	44.3	53.5	54.8	56.5	58.4
A&E Attendances	1,211,279	1,225,735	1,211,499	1,210,150	1,242,692	1,249,659	1,245,001	1,296,091	1,150,674	n/a
Out-patient Attendances	1,996,474	2,057,989	2,185,028	2,255,998	2,363,821	2,453,000	2,796,331	3,087,448	3,288,917	n/a

**Table 2: Acute Hospital Summary Statistics, 2000 – 2009**

HSE National Integrated Discharge Planning Steering Committee produced a report in 2008 entitled 'The code of practice for integrated discharge planning' which states that

*"A coordinated and patient centred approach to planning for discharge can lead to increased satisfaction with healthcare services, reduced length of stay and prevention of unplanned readmissions".*

*(HSE National Integrated Discharge Planning Steering Committee, 2008)*

The code of practice, describes a framework for the Health Service Executive (HSE) to provide consistent, coherent management of integrated discharge planning to include continual improvement and consultation. The report also stated that integrated discharge planning systems should include transfer

and discharge communication including information on medications and administration details.

Recent Irish research into discrepancies at discharge from hospital found that 65.5% of patients had an unintended discrepancy in their prescription. The most common inconsistency being drug omission (20.9%) (Grimes et al., 2008).

These results were supported internationally by a systematic review which also demonstrated that discharge summaries lack information on discharge medication (Kripalani et al., 2007).

The Department of health and children also produced a report in 2008 (Department of health and children, July 2008) corroborating this evidence that an estimated 46% of all medication errors occur at transition points when patients move from one care setting to another e.g. secondary care to primary care.

These issues further highlight the need for an effective mechanism for transferring information at these transition points of care.

Electronic discharge summaries have the potential to reduce discharge medication errors and ensure the safe handover of care to the primary care provider.

The Electronic Clinical Communication Implementation (ECCI)(Pagliari et al., 2004) is a programme developed by the NHS Scotland to ensure that staff share appropriate information about patients electronically. The main aim is to break down the barriers between GP and hospital services by enabling patient information to flow between different healthcare sectors using electronic discharge summaries.

However as seen in pilot studies by NHS Scotland even though the electronic delivery method of discharge summaries has many advantages over paper the results of these surveys suggest that the content of the discharge summary is more important than delivery method. The report concludes that a greater emphasis needs to be placed on the standards, quality and quantity of the discharge summary content (Pillai et al., 2004).

### **2.2.2. Discharge summary evolution**

Studies have been conducted since the 1970's on electronic discharge summaries, after much frustration with immature systems and new technologies their benefits were quickly realised. Some of the initial benefits realised were:

1. Elimination of dictated charts
2. Search and retrieval databases
3. More complete content
4. Fewer errors
5. More timely completion and delivery

(Kaur et al., 2009)

The delivery times for the discharge summary were reduced from an astonishingly long 16-180 days down to 4-5 days (South, 1972). Hospital neonatal units and nurseries were the first adopters of this technology and the reduced time for information exchange supported their ability to deliver improved care where time is a critical issue.

Poor communication between primary care and secondary care providers remained a concern throughout the 1980's. A study of geriatric patients discharged from acute hospitals to long term placement concluded that effective and timely discharge information could reduce the time of patient transfer considerably (Barker et al., 1985) with a significant positive financial benefit by reducing the patient hospital stay.

The introduction of hand written interim discharge summaries were started in the 1980's also thereby transferring the initial onus on the patient to deliver the initial summary. These interim summaries were welcomed by hospital doctors as the summary was produced prior to discharge when the patient information was readily available. This process resulted in reducing the workload and reducing time of delivery of the information to the primary care

practitioner (Kaur et al., 2009) . The discharge summary was followed by a mailed version posted to the general practitioner.

The 1990's was the decade for researching the quality of discharge summaries and studies reported that computer generated discharge summaries produced more relevant, legible, timely and better quality reports(Brazy et al., 1993). In the late 90's research conducted by Van Walraven et al concluded that database generated reports were further improved, as the information produced was of an improved content and of a shortened nature (Van Walraven et al., 1999) .

There was a change in the focus of research in the 2000's (noughties); researchers have widened their area of research, from viewing the discharge summary in a standalone context to it being an intrinsic component of a larger system namely the EHR(Kaur et al., 2009). It became apparent that standardization of messaging and terminology were required components that also needed to be addressed to enable the electronic discharge summary's integration. Further research has also been carried out on the effect of electronic discharge summaries on hospital readmissions and patient outcomes, a random controlled trial in Canada found that there was a trend towards a lower readmission for patients who were seen by a follow up physician who had received a discharge summary (van Walraven et al., 2002).

### **2.2.3. Secondary uses of the discharge summary**

The information source of the discharge summary should not be underestimated. As the demand for health information rises and health budgets continue to face fiscal challenges the discharge summary data contains vital information to enable researchers to identify at-risk populations.



Schoenman et al (2005) reported that information collected from inpatient hospital discharge data could be utilised in a wide variety of applications namely:

- a) Public Safety and Injury Surveillance and Prevention
- b) Public Health, Disease Surveillance and Disease Registries
- c) Public Health Planning and Community Assessments
- d) Public Reporting for Informed Purchasing and Comparative Reports
- e) Quality Assessment and Performance Improvement
- f) Private sector and commercial applications
- g) Health Services and Health Policy Research Applications
- h) Informing Policy Deliberations and Legislation

(Schoenman et al., 2005)

The Canadian institute of Health Information (CIHI) plays a critical role in the development of Canada's health information. One of its databases is the Discharge Abstract Database (DAD) which records all admissions and discharge to Ontario hospitals and documents demographic, diagnostic, procedural, and hospitalization information in a standardized fashion. Information mined from the DAD provides a major source of information for its annual Health Report. The DAD is widely used by researchers an example of this was a study conducted by van Walraven et al (2002) to determine if communication between hospitals and patients general practitioners by the use of discharge summaries effected patient outcomes. The results indicated that early post hospital follow up improved patient outcomes.(van Walraven et al., 2002). This random controlled trial by van Walraven could only have been achieved through the use of data from the DAD.

## **2.3. Standards Organizations**

The success of any ICT system depends on its ability to communicate and share data with other systems and the end user. Interoperability standards are essential to enable this communication. Standards Development Organisations (SDO's) are voluntary bodies that define develop and agree these standards.

Standards development goes through a number of stages prior to being published and accepted into mainstream use. A summary of the steps are as follows:

Stage 1:- The identification of all issues that are covered by the standard.

Stage 2:- Conceptualization of the problem to be solved and how the standard will be created.

Stage 3:- Member countries negotiate the detailed specifications within the standard and on agreement, a draft specification is published.

Stage 4:- Formal approval of the draft standard and agreed standard is published.

Stage 5:- Adoption where industry implements the standard.

The International Organization for Standardization (ISO), Comité Européen de Normalization (CEN) and The American National Standards Institute (ANSI) are three internationally recognised bodies that represent the area of health and ICT, HL7 international is an international standards development organisation accredited by ANSI and specialising in health care.

### **2.3.1. ISO – International Organisation for Standardization**

The International Organization for Standardization (ISO) was established in 1947 in Geneva and defines itself as a

“Network of the national standards institutes of some 163 countries that coordinate the system and publishes the finished standards”

(ISO, 2011)

ISO/TC 215 is the technical committee that deals with Health Informatics and acts as a bridge between standards development organisations like CEN and ANSI, by reviewing submissions and enabling harmonization and international agreement before publishing the standards. The ISO have an arrangement whereby they can publish certain HL7 standards as full ISO standards. ISO is the most influential of the standards development organisations.

The ISO development principles are based on the following:

- Each member institute can participate in the development of any standard which it judges to be important to its country
- ISO standards are voluntary; however they are developed in response to market demand which ensures widespread applicability of the standards.
- ISO standards are technical agreements which provide the framework for compatible technology worldwide.

(ISO, 2011)

### **2.3.2. CEN - Comité Européen de Normalization**

Comité Européen de Normalization is a European Committee for Standardizations. CEN covers European Union (EU) countries and some affiliated countries outside the EU. CEN's Technical Committee CEN/TC 251 produces the standards required for health informatics; CEN 13606 is a standard produced for a comprehensive EHR interoperability solution (CEN, 2011). CEN 13606 evolved from a previous standard called ENV 13606 however due to various weaknesses in the earlier standard (Eichelberg et al., 2005) ENV 13606 was updated and adopted in 2001 as the openEHR

archetype methodology defined by the openEHR foundation (Beale et al., 2006). CEN EN13606 is a five-part standard consisting of a Reference Model, an Archetype Interchange Specification, Reference Archetypes, Term Lists, Security Features, and Exchange Models.

### **2.3.3. ANSI – American National Standards Institute**

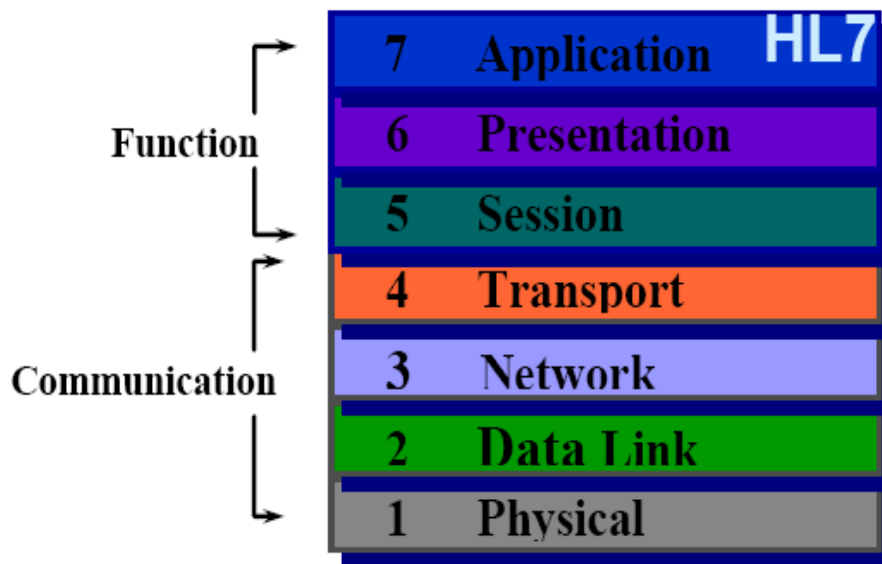
The American National Standards Institute (ANSI) was founded in 1918 and defines itself as

‘A private, non-profit membership organization supported by a diverse constituency of private and public sector organizations’ (ANSI, 2011)

ANSI has approximately 200 members, it does not define the standards itself but is responsible for defining the standards to which the actual standards developers are required to adhere to. HL7 is a standard development organisation accredited by ANSI and remains the most successful messaging standards in the health care industry.

### **2.3.4. HL7 International (HL7)**

Health Level Seven International founded in 1987 is an American National Standards Institute (ANSI) - accredited Standards Developing Organizations (SDOs) committed solely to the healthcare domain. The domain that HL7 concentrates on is clinical and administrative data. The name is derived from the Open Systems Interconnection (OSI) network model as layer 7 relates to information exchange; see Figure 1 below to see the 7 layers.



**Figure 1: OSI Reference Model (HL7, 2011a)**

HL7 standards define messages and message exchange protocols to support clinical practice that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all stakeholders.

HL7 international believe that data exchange between health care applications is essential to achieving that goal (HL7, 2011a).

HL7 standards work on the assumption that as an event is triggered in a health care environment e.g. patient admission, data is required to flow among various systems.

The HL7 standard supports two message protocols: Version 2 and Version 3. As this study involves a comparative analysis between Version 2 and Version 3 standards the following sections will discuss both these standards in detail.

## **2.4. HL7 V2.x messaging standard**

The HL7 V2.x messaging standard was approved in 1988. Since then various release updates of V2 have been published, see Table 3 below for the release dates. The Irish General Practice Messaging standard released in 2010 by the

Health Information Authority (HIQA, 2011) is based on HL7 V2.4 as highlighted in Table 3.

1990	1994	1997	1999	2000	2003	2007	2008
2.1	2.2	2.3	2.3.1	2.4	2.5	2.5.1	2.6

**Table 3: HL7 Version 2 releases**

HL7 V2.x is a protocol for the exchange of clinical data through messages. Messages are encoded as ASCII text strings with delimiters, a specification has also been developed for encoding V2.x messages in XML.

#### **2.4.1. Message Structure**

The HL7 v2.x messages are encoded as ASCII text strings with delimiters. HL7 v2.x has few inherent semantic restrictions with the vocabulary included in the coded segments subject to negotiation between the issuer and recipient of the message.

HL7 V2.x is organised into chapters, each of which has a specific function / domain, see Table 4 below.

Chapter	Domain
<b>01</b>	Introduction
<b>02</b>	Control (Structure of the messages/Conformance)
<b>03</b>	Patient Administration (admission , discharge, transfer)
<b>04</b>	Order Entry (laboratory, pharmacy, etc.)
<b>05</b>	Query
<b>06</b>	Financial Management (Billing / Patient Accounts)
<b>07</b>	Observation Reporting (results sent as identifiable elements - laboratory, imaging, etc.)
<b>08</b>	Master Files

<b>09</b>	Medical Records/Information Management (document management)
<b>10</b>	Scheduling
<b>11</b>	Patient Referral
<b>12</b>	Patient Care
<b>13</b>	Clinical Laboratory Automation
<b>14</b>	Application Management
<b>15</b>	Personnel Management
<b>16</b>	Claims & Reimbursement
<b>17</b>	Materials Management

**Table 4: HL7 v2 Chapters Source:(HL7, 2010)**

Each chapter defines the elements (message types, trigger events, segments, and fields) required to build messages appropriate to a specific domain of the information system. Each of the chapters is developed by a specific Work Group who have expertise and knowledge in that area or domain of healthcare information.

A message is the atomic unit of data transferred between systems which are made up of the following components:

#### **2.4.1.1. Segments**

A HL7 segment is a logical grouping of data fields. Segments of a message may be required or optional and are defined by the chapters as mentioned previously. They may occur only once or they may be allowed to repeat. Each segment is identified by a three character code, known as the Segment ID, and a name. The following table 5 shows the segments for a discharge summary as recommended by the HIQA General Practice messaging standard (Health Information and Quality Authority, 2010).

<b>MSH</b>	Message Header
------------	----------------

<b>PID</b>	Patient Identification
<b>PRD</b>	Provider Data
<b>DG1</b>	Diagnosis
<b>PV1</b>	Patient Visit
<b>NTE</b>	Notes and Comments

**Table 5: Clinical Discharge Summary REF\_I12 Source: (HIQA, 2010)**

### 2.4.1.2. Fields

A field is a string of characters defined by a HL7 data type. A field can have one or more components each of which is assigned a data type. When the data type specifying a component, is itself made up of multiple components, each of its parts is called a subcomponent.

### 2.4.1.3. Delimiter characters

The special characters that can be used in the construction of a message can be seen in Table 6 :

These characters can also be negotiated by parties involved in the implementation of the interfaces.

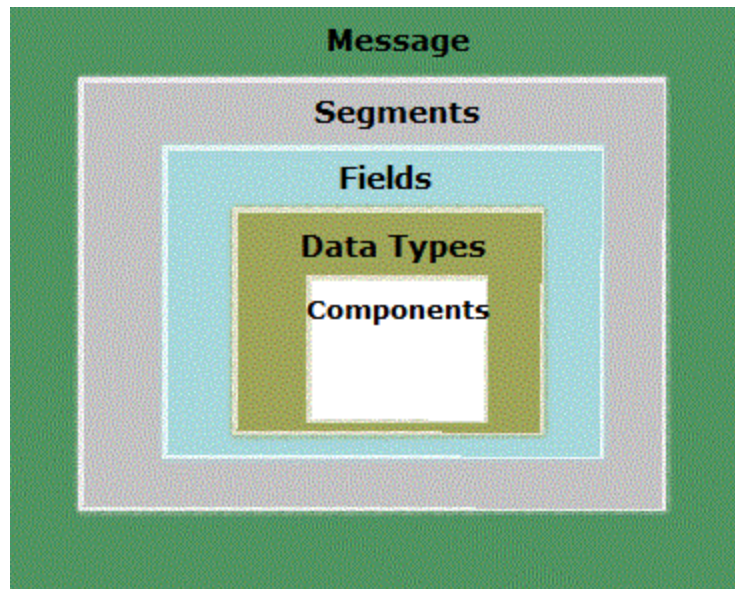
Name	Delimiter	Ascii code
Segment Terminator	<CR>	ASCII 13
Field separator		ASCII 124
Component Separator	^	ASCII 94
Subcomponent Separator	&	ASCII 38
Repetition Separator	~	ASCII 126
Escape Character	\	ASCII 92

**Table 6: HL7 v2.x delimiters Source: (HL7, 2010)**

In conclusion a message consists of segments separated by the segment terminator. Each segment consists of fields separated by the field separator. Each field is composed of one or more components separated by the component separator and each component corresponds to a specific data



type. Depending on its data type, a component can contain one or more subcomponents separated by the subcomponent separator. Figure 2 shows a diagrammatic representation of the message structure.



**Figure 2: Message Structure**

#### **2.4.2. HL7 V2.x Limitations**

The main strength of V2.x messaging is its ability to exchange health information between disparate systems within a single organization, intra organizational versus inter organizational (HL7, 2011a).

HL7 V2.x has few inherent semantic restrictions; the vocabulary to include in the codified elements of the messages is negotiable between the implementing parties.

HL7 V2.x defines the context of each field but may leave the decision of whether field contents should be free text or use a standard terminology up to the implementers. That decision is typically agreed upon between the issuer and the recipient of the message. Herein lies the principal limitation of the HL7 v2.x message, the very fact that each communicating system must agree on what fields to use and ensure each party has the same semantic interpretation of the data elements increases implementation time. Without

this analysis semantic interoperability would not be achievable especially considering the large number of optional segments and fields (Beeler, 1998). This need for agreement for every pair of communicating parties has expensive consequences. As the numbers of systems grow the number of required interfaces increase exponentially according to Equation 1

$$\# \text{ Interfaces required} = n(n-1)/2$$

Where n = the number of systems

#### **Equation 1: Interfaces**

It is evident that eventually the number of interfaces becomes unmanageable and these very issues were realised by attempts to succeed with national and multi-provider installations.

A new standard called HL7 v3 was developed to address these limitations.

## **2.5. HL7 v3 messaging standard**

HL7 V3 was developed to reduce ambiguity in the standard therefore increasing semantic interoperability. The main aim was to provide a standard that serves as the basis for n-information exchanges, with n being as large as possible. The ad hoc development of V2 messages has been replaced with a new and comprehensive development methodology for V3 utilizing formal object orientated design methodology in the development and maintenance of V3 standards.

The Message Development Framework (MDF) is used for most of the V3 with an updated version of the HL7 Development Framework (HDF) being finalised. These frameworks utilise the Unified Modeling Language (UML)

design concepts, the defacto software design methodology used in the industry today.

These substantial enhancements ensure that HL7 is evolving from a communication standard based on messages towards a comprehensive set of interoperability standards and architectural model (Oemig and Blobel, 2005).

### **2.5.1. Reference Information Model (RIM)**

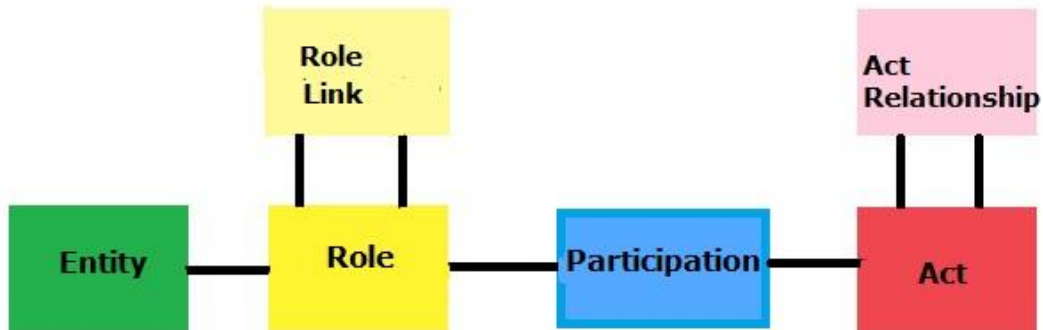
The HL7 RIM is a critical component of the V3 development process. It is the root of all information models and structures developed as part of the V3 development process. The RIM provides a static view of the information needs of HL7 V3 standards (HL7, 2011a).

The RIM consists of six foundation classes:

- Act: A representation of actions that are executed in healthcare domains.
- Participation: The context for an act in terms of who performed it, for whom it was done, where it was done, etc.
- Entity: A Representation of the physical things and beings that are of interest to, and take part in health care.
- Role: The role that each entity plays in its participation.
- ActRelationship: This class represents a relationship or link between acts.
- RoleLink: A connection between two roles expressing dependence between them.

Figure 3 below shows a diagrammatic representation of how the classes interact.

## Reference Information Model (RIM)



**Figure 3: RIM**

In summary all the V3 information models are derived from the Reference Information model (RIM), each functional domain has a specialized subset of the RIM and is referred to as the Domain Message Information Model (DMIM).

Within each domain every message or document can be further refined from the DMIM to the Refined Message Information Model (RMIM).

The structured approach of the development processes means that HL7 V3 can be extended incrementally whenever new healthcare domains are required, ensuring a model that is both scalable and flexible.

### **2.5.2. Data Types**

Datatypes are the fundamental building blocks around which the semantics of a given piece of data are built. Historically, system developers talked about atomic datatypes, such as integer, floating point, character, and string, and more recently about complex datatypes, such as date and time, address, and others.

Healthcare requires several complex datatypes to support concepts, such as physical quantity and time, as well as datatypes describing coded terms within a terminology, such as coding system name, version, primary code, alternate codes, and others.

The effort that is required to be put into defining and agreeing on what exactly goes into each data type should not be underestimated. Even when agreement is reached there are inevitable sections of the standards community who are unhappy with the outcome. For example the ISO 21090 Health informatics - Harmonized data types for information interchange is a joint publication of the three global health informatics SDOs: - ISO TC215, CEN TC251 and HL7 with the aim of having a single, structurally correct, internationally recognised standard for the next generation of abstract data types to be used in healthcare information interchange. ISO 21090 was designed to be compatible with the more generic ISO/IEC 11404 Language independent datatypes standard and also to build on and replace an earlier CEN health datatypes standard and to align with required changes in HL7 abstract datatypes, revision 1 of which are already widely used in HL7v3 messages and CDA documents.

The harmonisation effort also involves an attempt to achieve maximum reconciliation with the *openEHR* data types which are used where the *openEHR* and ISO/EN 13606 EHR communication standard are being applied. Although the project has been underway since 2003, it proved very difficult to get agreement and it was only since the NHS in the UK became involved, 2 years ago, that significant progress has been made.

However the ISO 21090 datatypes have been criticized as being overly complex and this can be as a result of how the standardised datatypes came into being. After more than five years of trying to reach consensus on a global datatypes, a group lead by Graham Grieve put together a combination of documents from ISO, CEN, and HL7. The result was a set of data types which are probably more than will ever be needed. The very fact that the standards are produced in an open process where decisions are made by

many will always result in a standard that is not liked by all. However a common datatypes standard is a major achievement and is beneficial to global health informatics.

## **2.6. Clinical Document Architecture**

The CDA is a HL7 standard that defines the structure of electronic clinical documents: e.g. discharge summaries, referrals, or laboratory reports. CDA specifies the markup of XML documents and standardizes the document semantics and document structure. It is based on the HL7 V3 reference information model (RIM), the HL7 V3 methodology, HL7 V3 datatypes and controlled or local vocabularies (SNOMED, LOINC, etc.).

Before we delve into the details of the CDA it is important to consider when an information exchange scenario should be supported

A. By the exchange of messages?

B. By the exchange of documents?

Messages enable the transmission of events as they occur; they are more transient in nature and generally require closer relationships between systems than documents.

Documents on the other hand are a natural method of exchanging health information, clinicians are used to exchanging discharge reports, referrals etc.

Electronic documents can be structured to be compatible with existing paper forms allowing for a mixture of structured data and also free form text. It has been estimated that about 70% of all medical data is comprised of narrative text. Documents represent a medical episode as a whole and can be incorporated into the patient Electronic Health Record.

When considering these differences, messages appear to be a better solution for the transfer of discharge summaries.

**A brief comparison can be seen in**

Table 7 below.

	Documents	Messages
Life Cycle	Persistent Objects	Transient Objects
Communication	Exchanged between humans	Exchanged between applications
Clinicians	Familiarity with documents	Non intuitive
Legal aspects	Digital signatures associated with persistent documents are recognized by law.	Can be signed electronically but due to transient nature not useful.
Source	Defined by historical consensus	Defined for each domain
Context	Complete article	Rebuilt by each application

**Table 7: Document / Message Comparison Source: (HL7 International, 2010)**

### **2.6.1. Brief History of the CDA**

The initial document standard Patient Record Architecture (PRA) was created in 1998. CDA Release 1 became a HL7 and ANSI standard in 2000. The CDA Release 2 became a HL7 and ANSI standard in 2005 it is this release that is being used for this study. The creation and maintenance of the standard is the responsibility of the Structured Document Committee of HL7 both Liora Alschuler and Robert Dolin co-chair this committee and have provided a wealth of information to support this research activity.

### **2.6.2. CDA Overview**

Dr Kai Heitmann at the Health Informatics Society Ireland (HISI, 2010) described the CDA as the '*most successful kid on the block*' in terms of the HL7 standards to date. The CDA is evolving as the basis for document based EHR's worldwide. The flexibility of the standard and its ability to encompass

all clinical documents are some of the reasons for its success. Other reasons for its success include its incremental semantic interoperability allowing for straight forward implementation initially and providing the ability to incrementally develop and enhance the information exchange process by adding greater markup to clinical documents over time.

The key features of the CDA are:

**Persistence:** A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements.

**Stewardship:** A clinical document is maintained by an organization entrusted with its care.

**Potential for authentication:** A clinical document contains information that is intended to be legally authenticated.

**Context:** A clinical document establishes the context for its contents: who is the patient, who created the document, etc.

**Wholeness:** Authentication of a clinical document applies to the whole and does not apply to portions of the document.

**Human readability:** A clinical document is human readable enabling the document to be viewed using an off-the-shelf web browser without losing clinical meaning.

(Dolin et al., 2006)

### **2.6.3. CDA Structure**

The CDA uses Extensible Markup Language (XML) to encode documents. It derives its machine processable meaning from the HL7 V3 RIM and HL7 V3 data types.

A CDA document is wrapped by the <ClinicalDocument> element and contains a header and a body. The header lies between the, <ClinicalDocument> and the <structuredBody> elements and identifies & classifies the document and provides information on authentication, the encounter, the patient, and the involved providers.



The body contains the clinical report and can be either an unstructured blob or can be comprised of structured markup. Figure 4 below shows an outline of the structure of the CDA with a <structured body> element (HL7(tm) Version 3 Standard, 2005).

```
<ClinicalDocument>
... CDA Header ...
<structuredBody>
  <section>
    <text>...</text>
    <observation>...</observation>
    <substanceAdministration>
      <supply>...</supply>
    </substanceAdministration>
    <observation>
      <externalObservation>...
    </externalObservation>
    </observation>
  </section>
  <section>
    <section>...</section>
  </section>
</structuredBody>
</ClinicalDocument>
```

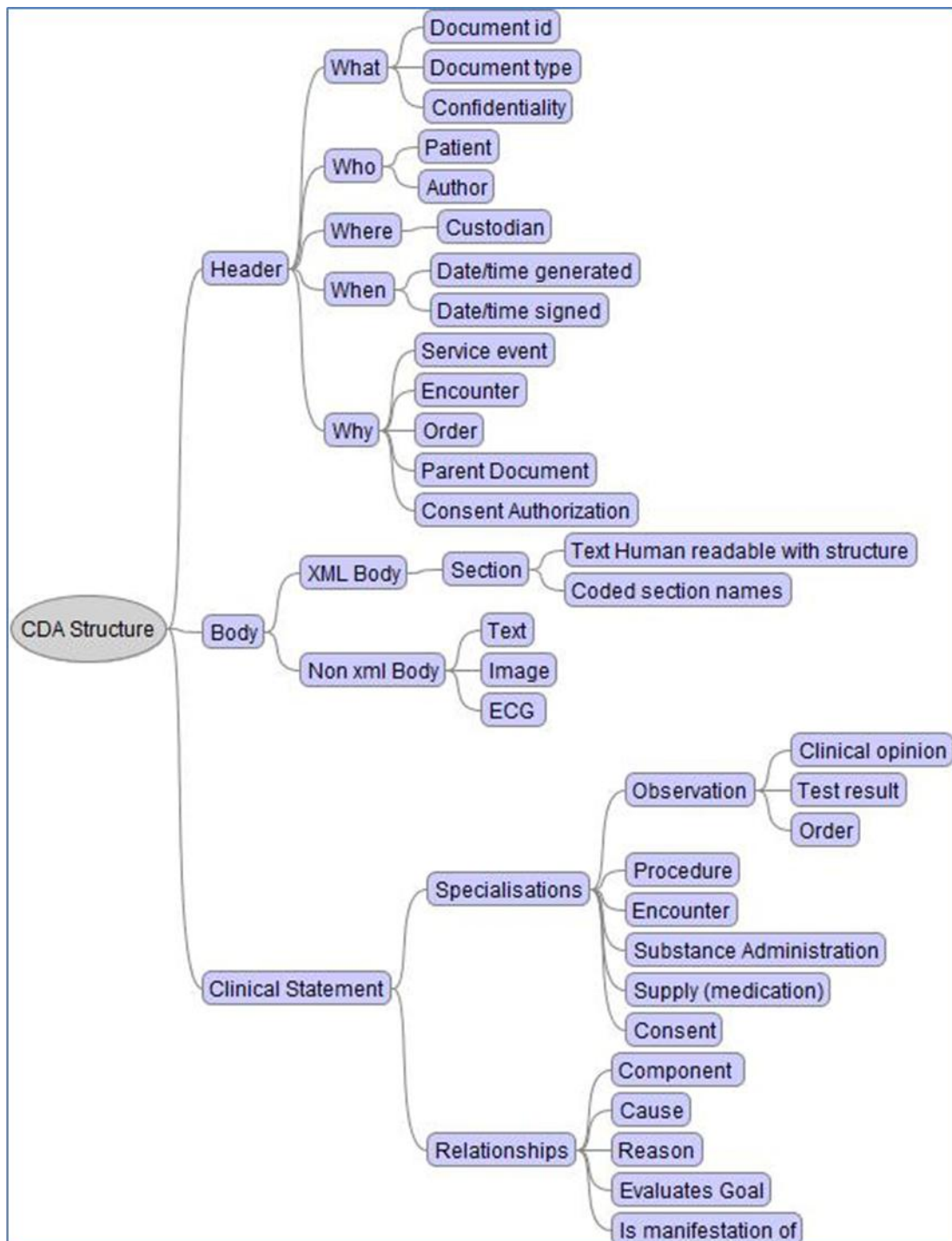
**Figure 4: CDA Structure**

The CDA header, which is required, contains the contextual information. This information is used to identify and classify the document. It contains the identification of the document, the document author, authentication information, the identification of the encounter, the identification of the patient, etc.

A CDA body can take one of two forms:

1. It can be unstructured containing anything and everything. If a document has an unstructured body it will have a <NonStructuredBody> element.
2. It can be structured. A structured body will have a <structuredBody> element. A structured body can have a number of sections each of which may have a title, a code (to classify its content), and text elements. Entries can be optionally included in the narrative text and represent clinical statements, allowing for software processing and reuse of the information examples of entries would include Observation, Procedure, Organizer,

Supply, Encounter, and SubstanceAdministration. Figure 5: CDA Structure  
Figure 5 shows a diagrammatic representation of the structure of the CDA.



**Figure 5: CDA Structure**

**At the outset of this section the CDA's success was explained partly on its incremental semantic interoperability, the different levels of granularity that can be attained in the structured body explain this feature.**

Table 8 below outlines these levels.

<b>Level One</b>	Body is human-readable, no semantic codes.
<b>Level Two</b>	Instances with machine-processable section-level semantics.
<b>Level Three</b>	Instances that have at least some clinical statements/ entries that are machine processable and can be modeled in the RIM.

**Table 8: CDA Levels**

## **2.6.4. CDA Templates**

CDA Templates are used to specify how the CDA can be used for particular purposes. A CDA Template is a set of constraints that can be applied to the CDA in order to further constrain the CDA RMIM. The Template definitions can be generated at the Document Level, Header Level, Section level and entry level.

**A CDA can be constrained by multiple template definitions.**

Figure 6 shows how a template id can be applied to a CDA at document Level.

The template id root shown in red indicates the conformance with the Discharge Summary DSTU so this document must conform to this implementation guide along with the CDA conformance requirements.

```
<ClinicalDocument xmlns="urn:hl7-org:v3">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="2.16.840.1.113883.10.20.16.2"/>
  ....
</ClinicalDocument>
```

### **Figure 6: CDA Template example**

The use of CDA templates provides the ability for specialisation and localisation of the CDA with the template id indicating which template is being used, they also provide a structure to validate the CDA document. The NHS Connecting for Health programme has defined a number of templates for EHR components to be used in CDA messages.

CDA is at the core of most standards based healthcare exchange architecture worldwide. It can be seen that countries that initially adopted a simple CDA level 1 architecture have incrementally improved their information exchange requirements. The CDA architecture is at the core of the NHS strategy for interoperability in England, one of many countries that have chosen this as their architecture of choice. The next chapter will provide a number of case studies of countries utilising the CDA.

An overview of the standards organisations with a more detailed view of the HL7 V2, HL7 V3 standards and CDA has been provided. It is now necessary to refocus on the objectives of these standards, and their main goal in ensuring that health information systems have the ability to provide semantic interoperability thereby supporting seamless care for patients.

## **2.7. Opposition to the Reference Information Model**

The literature review so far has provided a detailed overview of the standards organisations with particular attention paid to the HL7 v2 and v3 standards. It can be seen that HL7 v3 was developed due to the limitations posed by the HL7 v2 standard. The HL7 v3 standard has been developed in a more methodical, extensible and object oriented manner but does it provide the panacea for health data standards?

There are many critiques of the HL7 v3 RIM, as stated previously the RIM is an abstract model developed through an iterative process refinement which defines the grammar of a language for exchanging health care information. A literature review by (Gunther SCHADOW, 2006) found that any technical criticism was mentioned in passing in papers and did not provide concrete information that could be used to improve the RIM. A strong body of criticism has been documented however from (Smith and Ceusters, 2006).

Smith et al (2006) stated that the HL7 provides poor documentation that contains inconsistencies and ambiguities. On this point they are correct and this problem has been noted and is being addressed. The issue occurs due to the standard being developed using a collaborative approach from a wide range of people from different specialty backgrounds. As the standard is amended inconsistencies can occur but as this is a known issue it is being reviewed on a continuous basis.

The second major criticism is that no distinction is made between the RIM information model and the reference ontology (Smith and Ceusters, 2006), they state that the RIM addresses both simultaneously. This may be true but HL7 has followed the OO design by casting real world entities into informational model designs. It is viewed that a complete and integrated ontology of everything would be great however this could potentially cause practicality issues as implementers would expect that the RIM to reflect the other model.

The third criticism relates the HL7 v3's use of speech acts these are a generally accepted linguistic tool for understanding how language is used for achieving certain goals (Vizenor, 2004). Vizenor has many issues with their use by the RIM and claims that not all Act's in the RIM relate to speech acts. These critiques are valid to a point however when trying to develop an implementable standard some boundaries need to be relaxed to ensure the standard is useable. The best results going forward will be based on efforts to harmonise the standards and utilise the qualities of each standard to provide a health information standard that works and can improve patient care and safety which is the ultimate goal of all.

## 2.8. Semantic Interoperability

### 2.8.1. Introduction

To investigate whether systems have the ability to provide semantic interoperability it is important to take a step back and address what is interoperability and how has it been defined in the literature to date?

The Interoperability Work Group of HL7's Electronic Health Record (EHR) Technical Committee was formed in April 2005 in an attempt to define the concept of interoperability. Their analysis identified three principle types of interoperability:

- technical interoperability
- semantic interoperability
- process interoperability

**Technical Interoperability** focuses on the transmission and reception of information that can be used by a person but which cannot be further processed into semantic equivalents by software. This level of interoperability is concerned with the integrity of the data and often checks digits are performed at each end of a transaction and the results compared to assure that the data was successfully transmitted (Patricia Gibbons et al., 2007).

**Semantic Interoperability** has been defined as the ability of information shared by systems to be meaningfully interpreted and incorporated into the receiving system. HL7 international mandates that

*'Health information systems will communicate information in a form that will be understood in exactly the same way by both sender and recipient'.*

(HL7, 2011a)

Two forms of semantic interoperability have been identified in the literature the first is human semantic interoperability which refers to the unambiguous exchange of data between humans. These exchanges usually require an understanding of medical terminologies at clinician level.

The second type is computable semantic interoperability which requires that the meaning of data be unambiguously exchanged from machine to machine(Mead, 2006). As with human language this type of interoperability is only possible if systems use the same vocabulary.

**Process Interoperability** not often mentioned but increasingly important to care delivery refers to the coordination of work processes. It defines the ability of systems to adhere to computable semantic interoperability with the additional ability to filter and summarise the information. It identifies the need to optimise the communication of information to assist work flow processes. Its importance can be seen in emergency situations when critical summary information is required e.g. allergies, medications and diagnosis (Patricia Gibbons et al., 2007).

### **2.8.2. Human Semantic Interoperability - Human Computer Interaction**

Considering the quantity of information available to be exchanged the need for summarizing key information may be even more important. Due to this increased volume of data it may be more difficult for the clinician to read, process, and filter the information. Principles of cognitive research should be incorporated in terms of display information and summarization (Berner and Moss, 2005, Patel and Kushniruk, 1998).

Human semantic interoperability as stated above relates to the idea that exchanged data is understandable among humans involved in an interaction, to discuss this area fully we need to consider the body of research based on human computer interaction (HCI).

Human Computer interaction(HCI) can be described as the interaction between human and computer and involves the intersection of human orientated disciplines and computer related disciplines(Shackel, 2009). The human orientated side of human-computer interaction includes philosophy, physiology, medicine, psychology, and ergonomics. The computer related

disciplines include physics, electrical and electronic engineering, control engineering, information theory, and mathematical logic where a better understanding and design of computer systems is drawn. The discipline can be traced back as far as the 60's where a paper by (Licklider, 1960) discussed the symbiosis of man and computer:

*"Man-computer symbiosis is an expected development in cooperative interaction between men and electronic computers. It will involve very close coupling between the human and the electronic members of the partnership."*

In the 1980's (Norman and Draper, 1986) wrote a book entitled 'User Centered System Design' where the focus on HCI had evolved to the design of computers from the users perspective.

The ISO 9241-11 standard developed in 1998 defines the usability of a product as:

*"The extent to which a product can be used by specific users to achieve specific goals with effectiveness, efficiency and satisfaction in a specific context of use". (ISO, 1998)*

In relation to human semantic interoperability in the context of the electronic exchange of discharge summaries the usability feature of effectiveness, efficiency and satisfaction provide useful heuristics to evaluate the discharge summary structure.

### **2.8.3. Architectural Requirements**

In Ireland as is the trend internationally there is a shift from secondary based care to a focus on primary based care solutions. This shift creates the need for advanced distributed systems that can support this evolving care paradigm. These changes further emphasise the need for a shift in thinking



from message distribution to a more architectural and model driven EHR approach.

Architecture describes how the components of a system are organised, the relationship between these components and the environment and the principles guiding this design (Lopez and Blobel, 2009). As mentioned previously HL7 v3 is based on the HL7 Message Development Framework (MDF), there is a current shift however in the HL7 paradigm from message to architecture as demonstrated by the current move towards the HL7 Development Framework (HDF). Newer HL7 developments such as the EHR-S Functional Model and the Service Oriented Architecture (SOA) Project Group activities have been pushing this move. The CDA encompasses these new ideas and is evolving as the basis for document based EHR's worldwide. The flexibility of the CDA standard has allowed a large number of implementation guides to be created, each describing the use of the standard for a specific document type in a specific context. It is important to recognise that other standards approaches including CEN EN13606 and openEHR as mentioned previously provide different but important EHR architectures with efforts being made to make CEN EN13606 interoperable with HL7 v3 however for the purpose of this study the HL7 CDA standard will be the main area of interest.

CDA documents are richly expressive and can represent a significant breadth of clinical content. As stated before the CDA utilises the HL7 v3 RIM which enables the use of terminologies such as Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT). The HL7 Vocabulary Technical Committee and the Modeling and Methodology Committee manage a formal process for interleaving the RIM with various terminology models, as well as enabling the binding of domain-specific terminologies such as SNOMED, LOINC, ICD 10 and others to message and document specifications (Mead, 2006).

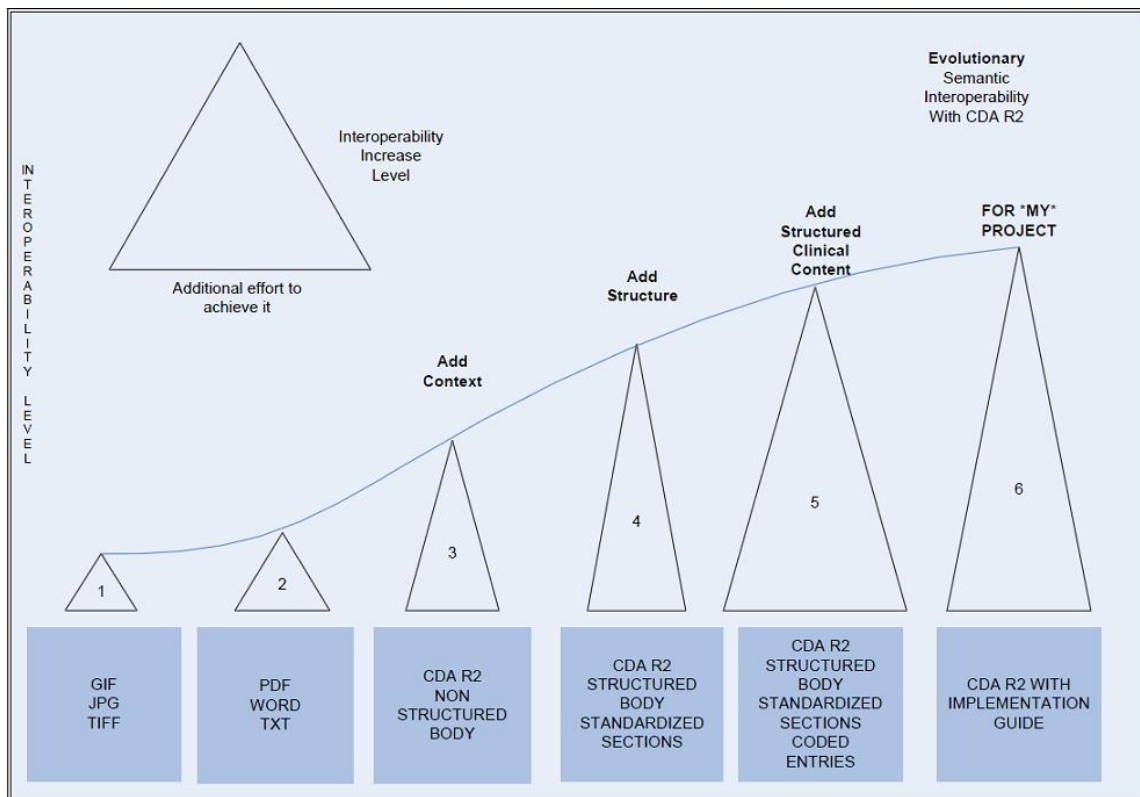
As well as terminologies, certain constraints can be applied to information sets based on a common agreed model. These constraints have been referred to in other models as profiles, archetypes, detailed clinical models,

templates and implementation guides. EHR models need to be sufficiently general to ensure multiple uses in an ever evolving healthcare domain however allowing specificity for new use cases.

HL7 has addressed this issue by developing a strategy referred to as 'template CDA'. CDA supports the use of templates which are constraints on the generic CDA XML specification, a well known template version of the CDA is the HL7 Continuity of Care Document specification, where the standardized data set defined by the American Society for Testing and Materials (ASTM) Continuity of Care Record is used to guide the construction of templates that constrain the CDA specifically for summary documents (Dolin and Alschuler, 2010).

Implementation guides are published and specify constraints on the CDA specification to ensure that the exchanged CDA R2 instances are aligned with the business requirements of a given interoperability scenario.

Therefore making a CDA R2 document compliant with a specific implementation guide is only a minor step as can be seen Figure 7 below.



**Figure 7: CDA R2 Semantic Interoperability Source: (HL7(tm) Version 3 Standard, 2005)**

The Discharge Summary as an integral component of the EHR is a good starting point in developing a model driven approach.

Currently in Ireland we are adopting a message based approach which needs to be addressed to ensure we have the correct system in place whereby we can provide a scalable, semantically interoperable electronic communication system at a national level.

HealthLink(Healthlink, 2011a) as stated in the chapter 1 is a HSE-funded national ICT project was developed to provide a healthcare communications network with specific reference to GPs and acute hospital relationships through data exchange. The service is available to all GPs, the number of GP's using HealthLink is 2057 from 923 practices(Garvin, Novenber 2010). Discharge summary messages are provided by the Healthlink network in Ireland and are based on the General Practice Messaging Standard published by HIQA in 2010 (Health Information and Quality Authority, March 2010)

which is based on HL7 v2.4 message. The clinical information is sent as unstructured text inside the message and therefore the message is not focusing on the data or its level of interoperability.

Data exchange can potentially be divided into four levels of standardisation and sophistication of IT systems as defined by (Walker et al., 2005)

Table 9 provides a description of these four levels

Level	Description
1	Non electronic data—no use of IT to share information (e.g.: mail, telephone).
2	Machine transportable data—transmission of non standardized information via basic IT; information within the document cannot be electronically manipulated (e.g.: fax or PC based exchange of scanned documents).
3	Machine-organisable data—transmission of structured messages containing non standardized data; requires interfaces that can translate incoming data from the sending organization's vocabulary to the receiving organization's vocabulary; usually results in imperfect translations because of vocabularies' incompatible levels of detail (e.g.: e-mail of free text, HL7 v2 messages).
4	Machine-interpretable data—transmission of structured messages containing standardized and coded data; idealized state in which all systems exchange information using the same formats and vocabularies (e.g.: automated exchange of Level 3 CDA discharge summary from secondary care provider into a primary care provider's EMR).

**Table 9: Levels of information sharing Source: (Walker et al., 2005)**

In an electronic discharge summary environment, the ultimate goal is to exchange information such that the systems at each end of the exchange can consistently and reliably interpret the meaning of the exchange and reach Level 4 information sharing refer to Table 9 above. Presently in Ireland we are achieving between level 2 and level 3. The comparative analysis in chapter 6 will detail the differences between HL7 v2 and HL7 v3 CDA and provide technical detail as to how Level 4 could be ultimately accomplished in Ireland by upgrading to HL7 v3 CDA for discharge summaries.

## **2.9. Summary**

This chapter has provided a detailed literature review of the history of discharge summaries and provided an overview of the discharge process and the clinical need for discharge summaries.

The standard organisations including the HL7 standard were reviewed and the motivations for HL7 developing a new standard and the benefits of the new standard.

Interoperability was defined and reviewed with many challenges identified in relation to semantic interoperability.

The need for semantic interoperability and scalability is increasing and the effort required to achieve this functionality is complex. Some of the requirements to achieve semantic interoperability include:

1. A common information model that encompasses the many domains (HL7 V3 RIM).
2. A common datatype specification that provides unambiguous semantics for each data element transferred. Harmonisation efforts over the last 10 years has resulted in the ISO 21090 HL7 Harmonized data types providing a single, structurally correct, internationally recognised datatype standard.

3. The HL7 Vocabulary Technical Committee and Modelling and Methodology Committee manage a formal process enabling the binding of domain-specific terminologies such as SNOMED, LOINC, DICOM and others to message specifications.
4. Human Semantic Interoperability in terms of an easily readable structured document, considering usability issues.

With the above pieces of the semantic interoperability puzzle in place the RIM-compliant CDA specification appears to be a good architectural choice to support computable document exchange especially in the area of discharge summaries.

### **Chapter 3. Case Studies: International use of CDA for electronic data exchange**

### **3.1. Introduction**

This chapter provides an insight into the use of HL7 V3 CDA by detailing five case studies from Irish, European and International implementations of the CDA structure.

The CDA is in use worldwide (HL7, 2011a) and has been said to be at the core of almost every standard based health information exchange worldwide (Benson, 2010).

Support for HL7v3/CDA has been boosted by its utilization in the national programs in the UK and Canada and having been adopted for use across US Government agencies, NATO forces and by the Dutch, German, Mexican and Croatian government health services. It is also the technology of choice for most US Nationwide Health Information Networks (NHIN) prototypes and many Regional Health Information Networks (RHIOs)(NETHA, 2007).

The largest producer of CDA documents worldwide is the Mayo clinic in the United States which produces thousands of CDA's every week. The Mayo clinic sees CDA as a strategic investment in information that will increase in value over time and which can be reused in multiple applications (HL7, 2011a).

### **3.2. NHS Connecting for health**

NHS Connecting for Health is an agency of the Department of Health in the United Kingdom(NHS, 2011). It is responsible for all nationally coordinated major IT programs across the NHS.

The National Programme for IT is connecting more than 8,500 general practices and their respective community health services in England to almost 300 hospitals (R Kavanagh and I Townend, 2008).



The main aims are similar to the aspirations of most other countries:

- Improved and safer care for patients
- Increased efficiency and effectiveness from clinicians
- Provide access to patient information ensuring safety, security and ease of access.

At the start of the NHS connecting for health programme there was a multitude of disparate disconnected systems with some systems having no ability to interoperate and those with information exchange capability, predominately using HL7 v2 and using locally agreed formats further compounding the interoperability issues.

Initially a decision was made to create messages based on the Clinical Statement Pattern (CSP) and after significant effort the UK national profile for CSP, the Clinical Statement Message Pattern (CSMP) was developed. The message pattern was based on the HL7 V3 standard, which posed many issues for both vendors and users. The maturity of the HL7 V3 specification, the CSP approach and the use of terminologies were not widespread within the UK (or internationally) at the time.

The CDA R2 was selected as the standard of choice for document centered clinical exchange. A decision was reached, based on the capabilities of the suppliers and the maturity of the HL7 and SNOMED CT standards that an iterative approach would be used with the CDA whereby early deployments would use minimal coded entries for

- Current Medications
- Allergies and Adverse Reactions

Conformance guides for each CDA implementation was decided on a case by case basis. A number of CDA Conformance Profiles were developed and include:

1. Admissions Reports
2. Ambulance Messaging

3. Diagnostic Image Reporting
4. Discharge Reports
5. Emergency Department Report
6. Health & Social Care Integration
7. Mental Health Report
8. Health Space
9. NHS Direct Report
10. Out of Hours Report
11. Outpatient Report
12. Sealed Envelope Reports

(NHS, 2011)

NHS Connecting for Health have developed a templating approach for the purposes of implementing machine enforceable conformance profiles. The templates are described using R-MIMs, which are authored using the NHS customised HL7 modeling tool. Templates enable further constraints to be applied to the CDA model and are used for validation of the documents. NHS Connecting for Health has made a substantial investment in the development of tools to improve the development; testing and deployment of HL7 based messaging interfaces. A number of the tools have been donated to Open Source communities to assist other groups in HL7 integration projects. The NHS Connecting for Health, plan to continue developing CDA conformance profiles so as to support further clinical information exchanges. They have found from the use of CDA documents, the templates and the machine enforceable conformance profiles that they offer, give the ability to specify and publish high quality interoperability specifications in a timely and efficient manner (R Kavanagh and I Townend, 2008). The UK NHS has a project in train to assess the potential of using openEHR archetypes to model clinical content, but still within the NHS overall national

commitment to HL7 v3, CDA and templates(NHS Connecting for Health, 2006).

### **3.3.NEHTA - National E-Health Transition Authority**

NEHTA was tasked by the Australian government to identify and foster the design and development of technology to deliver Australia's future e-health system (NEHTA, 2011). One of this initial requirements was to propose a standards approach for both the long-term and the short term that would deliver the most effective support for a broad range of e-health information interchange requirements in Australia including referral, discharge, health profiles, prescribing, dispensing, requests and reports for diagnostic tests such as pathology and radiology (NETHA, 2007).

NEHTA commissioned a review to recommend the most appropriate standards for sharing EHR information in the Australian context. The review investigated global developments in e-health standards indicated that successful achievement of longer-term strategy would depend on the ability of its standards to support clinical terminology, constraints (archetypes and templates), structured documents and service-oriented technologies(NETHA, 2007).

The review also took into account the dominance of HL7 version 2 in Australia.HL7 Australia was established in 1998 and Australia was an early adopter of the HL7 V2.x standards, which are now ubiquitously used in Australian public and private healthcare organizations. The localisation of the HL7 standards is undertaken in cooperation with the national standards body, standards Australia (HL7, 2011b).

The findings of the review proposed that a CDA document/services-centric implementation of HL7 v3 was the strongest option from the assessment process. While the report noted that openEHR had some superior strength in its ability to capture and structure detailed clinical content it was believed that at the time archetype proposals addressed only part of the wider

requirement and these approaches still involve considerable difficulty integrating with existing applications.

The Discharge Summary has been specified as a priority clinical domain area ensuring the initial development and provision of specifications for the adoption of a national strategy for discharge summary exchange. The priority as in Ireland and Europe has been driven by the ageing demographic population profile and the increasing prevalence of chronic disease placing an increasing burden on the health sector (NEHTA, 2010a).

NEHTA has specified that its preferred exchange format for the future of discharge summaries is the HL7 CDA and web services infrastructure.

As with the Irish messaging standard Australia's original discharge summaries were developed using HL7 v2.3, 2.4 message type. This standard was found to focus on the exchange of data rather than the structure of the data.

The Australian Medical Association (AMA) defined a number of requirements including the following:

1. The compulsory provision of timely, useful, detailed, legible, accurate and comprehensive discharge information to general practitioners, as a condition of hospital accreditation.
2. The development of an Australian Standard that informs hospitals and GPs of the minimum information sharing required on admission and discharge.
3. Significant and meaningful investment by hospitals in information and communication technology that focuses on the opportunities provided by existing GP connectivity to promote the secure, appropriate and efficient transfer of health information.
4. Change management programs and policy settings that encourage high quality discharge communications.

(NEHTA, 2010b)

The CDA was found to be the most suitable document format for the implementation of a national Discharge Summary that supports reuse and quality structured interoperable data.

### **3.4. Germany – Standardisation of Communication between Information Systems in Physician Offices and Hospitals using XML (SCIPHOX)**

In Germany the use of HL7 V2 commenced in 1993 and was predominately used for the communication of applications within and between hospitals. Originally HL7 messages were not in use for the primary/secondary care interface instead a local proprietary protocol suite was been used called “\*DT”.

It became apparent over time that the “\*DT” approach was not sufficient on semantic level or as an exchange format.

After many years of parallel development between secondary care and primary care it became clear that a more standardised approach to information exchange was required using an XML approach(Heitmann and Dudeck, 2001). The SCIPHOX project was initiated to provide a document oriented solution rather than exchanging messages on demand.

The initial goal of the project was to close the gap between electronic communications between hospital systems and applications for the primary care sector, such as for referral or discharge letters, by providing an XML based method of communication between the two areas(Heitmann and Dudeck, 2001, Kai et al., 2003). Phase I was aimed at the definition of discharge letters and the exchange of referral documents. The CDA was chosen as the ‘backbone’ specification for the SCIPHOX project.

The CDA document content was developed utilising experiences made creating the HL7 and the “\*DT” information models. This was seen as a

process of enriching the already used structures instead of an entire migration from the existing approach where healthcare application communication and data storage were already running smoothly.

It was found that the use of the new standardised approach enabled reuse and shared semantics therefore finding a compromise between local specialisation and global generalisation.

The findings of the SCIPHOX project was that the CDA xml approach provided flexibility however ensuring the enforcement of a global standard for exchange of clinical documents(Kai et al., 2003).

The document approach which enabled electronically available clinical information was seen as one of the “ingredients” for future electronic health record systems (EHR). The CDA was seen as an EHR architectural framework that could have a complementary relationship with other frameworks like ISO EN13606 and openEHR in the future.

### **3.5. Finland**

Finland has a strongly decentralized health care system which has strongly influenced the development and implementation of eHealth solutions. There are 430 municipalities each of which are responsible for providing and developing health services. As in Ireland public health care provision is also supplemented by private health care services. The Ministry of Social Affairs and Health established its first Strategy for the Utilisation of Information and Communication Technologies in Welfare and Health in May 1996, as part of Information Society policies aimed at facilitating information transfer between organisations.

In 2002, as part of the National Program for Securing the Future of Health Care, the government decided that “a national electronic patient record” should be introduced by the end of 2007(eHealth ERA, 2007).

Currently 96% of all primary care health centers use EHR's as the main component of medical documentation and at this stage there should be no

surprise that HL7 CDA R2 was the document standard chosen as part of the national requirements. It was chosen mainly due to its level of semantic interoperability and ability to incorporate object identifiers (OID's) and other standards like Dicom, Snomed CT (Harno et al., 2009).

Navitas is a regional service that was developed to overcome the organizational and interoperability barriers that restricted the use of clinical information between secondary and primary health care. Navitas is provided as a fully hosted ASP (application service provision) service (Harno et al., 2009). The Regional eHealth Network Navitas has facilitated the delivery of improved healthcare information between primary and secondary care. The National Health Information Network NHIN has devised a strategy and communication architecture for health care drawn by the Ministry of Social Affairs and Health which will include the following targets:

- For semantic interoperability all EPR-systems should implement a common core data set for EHR's and use HL7 CDA.
- Communication between EPR-systems and the eArchive shall be based on a standardized message system (e.g. HL7 CDA-messages)
- All patient records will be archived into a logically single national archive

(Harno et al., 2009, Harno et al., 2008)

The success of the HL7 standards and the CDA in particular, can be seen by their inclusion as the standard of choice for eHealth in Finland.

### **3.6. Ireland and the PICNIC project**

A European Commission co-funded research and development project established under the 5<sup>th</sup> Framework of European Research 'Information Societies Technology Programme' called PICNIC (Professionals and Citizens Network for Integrated Care) commenced in 2000 and involved 15 European

partners of which Ireland was one. The main aim of the project was to prepare regional health care providers to implement next generation secure, user-friendly Regional Health Care Networks (RHCN) (Oates and Jensen, 2000) to support their new ways of providing healthcare. Three different groups of services as developed by the Work in Synergy for Europe (WISE) project were required by the RHCN (Saranummi, 2005)

1. Clinical Services and Telemedicine Information Communication

Functionality to provide healthcare professionals with patient-related information relating to patient treatment

2. Health Information Service

Functionality relating to providing health related information services to the general public. The information consisted of general guidelines and procedures and not individual feedback.

3. Administrative Services and Electronic Commerce

Functionality relating to the provision of administrative, financial and management services to professionals.

Clinical messaging which related to group 1 above was seen as the most important functionality in the RHCN as it provided the highly structured patient-related information concerning individual patients. This group concentrated on the exchange of clinical and administrative data between different applications. The HL7V3 CDA standard was selected and document type definitions were developed.

Pilot implementations were developed in co-operation with selected industrial partners within each of the participating regions. These pilots enabled the testing of the PICNIC architecture, messaging structures and functionality in a number of different application domains across Europe.

Ireland was responsible for the piloting of two prototypes by the following bodies:

1. Pharmacy Patient Validation and Reimbursement



## 2. North Western Health Board (NWHB)

The General Medical Services Board (GMS) in 2000 was responsible for all payments to primary care contractors for publically funded health services including consultations, appointments, procedures and prescriptions and was funded by the Department of Health and Children (DoHC). This board has been replaced by the Primary Care Reimbursement Service (PCRS) as part of the creation of the HSE in 2004 (Katehakis, 2005).

At the time the strategies in place by the DoHC supported the piloting of the PICNIC project for the following reasons:

1. The deployment of a unique patient client number PPSN (Personal Public Services Number)
2. The development of a 'government virtual private network' whereby all public bodies would be linked including GP practices and community pharmacies. This infrastructure facilitated the mobilisation of the PICNIC project

The aim of the prototype was to enable the provision of pharmacies and contractors (GP's) access to the GMS back-end system (PIDS database and Payment system). A messaging component was integrated with pharmacy management applications enabling the following functionality:

1. Identify eligible clients and verify the GMS scheme and the cost of prescriptions spent in the current month
2. Update the GMS with the new prescription amount
3. Upload prescription reimbursement files to GMS

(Katehakis, 2005)

The prescription reimbursement files were developed using HL7 Clinical Document Architecture (CDA). The CDA was selected due to its content, structure with the goal of creating a virtual electronic prescribing record.

This pilot proved very successful and HL7 CDA is presently still in use by the PCRS for prescription reimbursement files as well as the deployment of the fully operational pharmacy system including an extension to GP's.

The testing and validation of all the prototypes at all sites in the PICNIC project demonstrated that no major operational problems were found and all sites were able to implement the prototypes.

### **3.7. Summary**

This chapter detailed five case studies on HL7 v3 CDA implementations from an Irish, European and International perspective.

The evidence suggests that the CDA has been successfully implemented worldwide and as a result, has caused a network effect, as demonstrated by these case studies. As NEHTA stated (NETHA, 2007) by adopting an HL7 v3 CDA approach this would enable Australia to work closely with and share tools, expertise and methods with the UK, Canada Health Infoway and US Government health agencies.

As the CDA implementations increase then so too does the community of support.

## **Chapter 4. Research Methodology**

## **4.1. Introduction**

This chapter outlines the research methodology taken by the author to address the research question(s) and illustrates the reasons for utilising a qualitative methodology for this dissertation.

As outlined in the introduction the main research question that this study is addressing is whether the HL7 v3 Clinical Document Architecture can provide a more semantically interoperable and scalable solution for discharge summaries than the current HL7 v2.4 standard for discharge summaries.

### **4.1.1. Qualitative Methodology**

Qualitative research is typically based on narrative data, whereas quantitative research relies on numeric data (Creswell, 2009). For the purpose of this study, narrative data as opposed to numeric data is required as the data sources are mainly comprised of documents, case studies and a detailed descriptive comparative analysis. One of the characteristics of this methodology is its interpretive nature whereby the author must assimilate the multiple data sources and make an interpretation of what they see and understand.

The main intention throughout this study was to adopt a researcher's perspective, and review and assimilate all information gathered as objectively and impartially as possible.

One of the reasons for the design of the storyboard narrative was to ensure that both the message and document are created from the same information data source further reducing any bias to the results.

The storyboard narrative will be described in detail in the section on the comparative analysis methodology.

#### **4.1.2. Literature Review**

##### **4.1.2.1. Literature requirements and goals**

As stated by Creswell (2009) an initial requirement in the research process is to thoroughly review the literature in order to reduce and refine the scope of a proposed study.

To focus on specific literature required to address the research question a list of literature requirements and research goals were developed as seen in Table 10 below.

<b>Literature Review Requirements</b>	<b>Research Goals</b>
To obtain an overview of the discharge process and the clinical need for discharge summaries.	To develop a clear understanding of the history and importance of the discharge summary process and the relevance the discharge summary has in relation to the longitudinal patient electronic health record.
Identify a minimum data set applicable for a discharge summary.	To define the minimum data set that is required for a discharge summary to enable the construction of the HL7 v2 message and HL7 v3 Clinical Document Architecture for the comparative analysis.
To understand the role that interoperability plays in health information systems with specific focus on semantic interoperability.	To identify what are the principle requirements for an electronic discharge summary with specific focus on the issues related to interoperability.
To understand the role of HL7 and standards as part of the development process of the Electronic Health Record.	To identify the importance of standards in the area of health informatics and assess how HL7 international standards perform and their level of maturity in relation to other standards.
Identify key case studies of countries	Identify any lessons that may be learned

adopting the Clinical Document Architecture.	from its adoption in other countries
Identify technical documents and tutorials on the HL7 international standards.	Develop a working knowledge of the HL7 v2 and v3 message structure to enable the development of example discharge summaries in the v2, v3 format to enable a technical analysis of both structures.

**Table 10: Literature Review requirements and research goals**

#### **4.1.2.2. Literature Search Strategy**

The literature search strategy was developed in adherence to the specified requirements as stated above in Table 10.

The electronic database, 'Pubmed' was the initial database searched.

It contains more than 20 million citations for biomedical literature from MEDLINE, life science journals, and online books.

Some of the mesh terms and search strings used can be seen in Table 11 below.

The initial Pubmed search performed produced 1033 records, after reviewing titles 165 records were reviewed of which 27 were retained. Searches using a variety of other criteria were equally unsuccessful as substantial numbers of irrelevant articles were retrieved.

It became apparent at an early stage that the specificity of the available mesh terms was low so string searches were compiled some of which are shown in Table 11 resulting in more specific results.

Other electronic resources included IEEE, ACM, Scopus, Science direct and Springerlink were also used along with Google scholar for accessing document titles referenced by relevant selected articles.

Database	Search String	Results	Saved
Pubmed	<i>Electronic Health Records"[Mesh] OR ("Electronic Health Records/history"[Mesh] OR "Electronic Health Records/standards"[Mesh])</i>	1033	27
Pubmed	<i>electronic discharge summaries</i>	76	21
Pubmed	<i>hl7 clinical document architecture</i>	40	12
Pubmed	<i>hl7</i>	99	33
IEEE	<i>hl7 + clinical document architecture</i>	69	54
IEEE	<i>hl7 + interoperability + cda</i>	53	53
Google Scholar	<i>hl7 + interoperability + cda</i>	1010	342

**Table 11: Database literature search strategy**

This combined research was reviewed using the titles and abstracts, and 253 articles that were deemed relevant to the literature requirements and goals were selected. All reference information was recorded using 'EndNote X3' and full text articles were stored for review.

A review of 'grey literature' was required to access government articles, international standards organisations and European and international working groups relevant to the research.

There was a considerable lack of detailed tutorials on HL7 so the author contacted HL7.org and completed a 14 week online course in HL7 v2, v3 and CDA provided by leading figures from the HL7 international standards organisation. This practical online course provided all the necessary knowledge and expertise required for developing the HL7 v2 message and v3 CDA, the attained certificate can be viewed in Appendix 1.

#### **4.1.3. Comparative Analysis**

As defined by (Eldredge, 2004) a comparative study consists of a systematic effort to find similarities and differences between two or more observed entities.

Comparison has been described by (Collier, 1993) as a fundamental tool for analysis. Collier states that it sharpens our power of description and focuses the mind on similarities and differences between cases. (Lijphart, 1975) defines the comparative method as a systematic analysis of a small number of cases, he highlighted that the use of comparison can emphasise the differences that exist between two cases. For the purpose of this study there are two cases to compare, the HL7 v2 message structure and the HL7 v3 Clinical Document Architecture.

The method of comparative analysis has been used in many fields including database schema methodologies (Batini et al., 1986), politics (Collier, 1993), social science (Ragin, 1987, Ragin and Zaret, 1983), and strategic management (Greckhamer et al., 2008). Research with a comparative dimension has also been used on many occasions in the field of health informatics (Murphy, 2007).

Comparison has enabled authors to investigate how technology is being used in different countries some of whom include (Protti et al., 2008a, Protti et al., 2008b, Protti et al., 2008c, Protti et al., 2009, Protti et al., 2006, Schoen et al., 2006, Detmer and Steen, 2006).

Comparative analysis will enable the systematic analysis of the similarities and differences that exist between the HL7 v2 message structure and the HL7 v3 Clinical Document Architecture.

An evaluation and interpretation of the results will enable further testing of the hypothesis that HL7 v3 Clinical Document Architecture could potentially provide a more semantically interoperable and scalable solution for discharge summaries than the current HL7 v2.4 standard for discharge summaries and also to highlight where the benefits could be achieved by upgrading from the



current HL7 v2 messaging standard for discharge summaries to the HL7 v3 CDA.

#### **4.1.3.1. Storyboard Narrative**

The use of storyboards was introduced at the analysis stage of design for the HL7 Version 3 Standard. The concept of storyboards came from the cinematography industry and is similar to narrative script. The storyboard describes a domain of interest and relates a series of events for a patient encounter, including actors (doctors, nurses, pharmacists etc.) playing roles to achieve interoperability.

The author will develop a storyboard detailing a patient's discharge scenario that will contain the information required to develop the HL7 v 2, HL7 v3 discharge summaries. The common information source will ensure the messages are developed in an objective and unbiased manner.

#### **4.1.3.2. Discharge data set**

The HSE National Discharge Planning report in 2008 (HSE National Integrated Discharge Planning Steering Committee, 2008) stated that integrated discharge planning systems should include transfer and discharge communication including information on medications and administration details. From this dataset the following headings will be used to provide the required content for the discharge summaries for this study:

1. Organisation Name.
2. Patient identification information.
3. Responsible clinician name and contact details.
4. Patient's registered GP details.
5. Diagnoses on discharge (including problem list).
6. Patient alerts/allergies.
7. Presenting problem/complaint (include current diagnoses).
8. Procedures and investigations.
9. Medications and relevant information on administration of medicines.

The storyboard will be created to encompass this information and give the information context in relation to the patient's discharge.

#### **4.1.3.3. HL7 message and document creation**

The HL7 v2.4 discharge summary message will be created as a REF\_I12 message type in accordance with the General Practice messaging standard as the recommended discharge summary type (Health Information and Quality Authority, 2010).

The HL7 v3 CDA discharge summary document will be created in accordance with the HL7 Clinical Document Architecture, Release 2.0.

Chapter 5 will provide a detailed account of the document creation techniques used.

## **Chapter 5.    Research**

## 5.1. Introduction

This chapter describes the process of developing the HL7 v2 REF\_I12 message and the HL7 v3 CDA.

In order to achieve this, a number of processes were required each of which will be described in detail.

Firstly the use case for the research study will be defined and the storyboard will be described. The storyboard details the contextual information which will provide the required data for the HL7 v2 REF\_I12 message and the HL7 v3 CDA creation.

Finally the creation and validation of both the HL7 v2 REF\_I12 message and the HL7 v3 CDA will be described.

## 5.2. Use Case Domain

The domain of interest for the comparative analysis is a standard inpatient discharge from an acute hospital to home.

**Use case:** A patient is discharged after an inpatient stay from a healthcare institution, a clinical discharge is recorded on the hospital system and this clinical discharge is sent to other systems including primary care.

## 5.3. Storyboard

As stated in the previous chapter the storyboard describes a domain of interest and relates a series of events for a patient encounter in this case a routine in-patient discharge home.

The storyboard narrative developed here is a description of a real-life event that provides the necessary context and information required to develop the HL7 version 2, HL7 v3 CDA discharge summary. The storyboard depicts a patient's routine discharge using a series of events, each of which represent key pieces of recordable information that are significant to the routine patient discharge encounter. The reader is given snapshots of information to enable them to understand the sequence of events that occurred, for example during a patient's stay in hospital. The storyboard also provides a coherent description of the activity illustrating the key participants and the roles they played in the encounter.

The names of persons, places and organizations that are used in the storyboard for this study are fictional.

### 5.3.1. Discharge Summary

#### Demographic Information

<b>Patient</b>	Mrs Mary Kate Shamrock
<b>Sex</b>	Female
<b>MRN(Hospital Number) +OID</b>	1233445-2.16.840.1.113883.2.27.5
<b>Address</b>	34 Irish Town Road, Blackrock, Co Dublin
<b>DOB</b>	22-01-1961
<b>Age</b>	50 yrs
<b>Phone No</b>	01 4223355
<b>Next of Kin</b>	Mr Denis Shamrock
<b>NOK Address</b>	34 Irish Town Road, Blackrock, Con Dublin
<b>Admission Date</b>	10-04-2011
<b>Admission Time</b>	13:01:46

<b>Ward</b>	Good Ireland Hospital Ward 1
<b>Room</b>	21
<b>Bed</b>	5
<b>Hospital</b>	Good Ireland Hospital
<b>Hospital OID</b>	2.16.840.1.113883.2.27.5
<b>Hospital Address</b>	32 All Sick Street, Dublin 2
<b>Hospital Phone</b>	01 3456677
<b>GP Practice</b>	Blackrock GP Clinic
<b>GP Name</b>	Dr Tony JR Medic
<b>GP Address</b>	3 Seatown Crescent, Seatown Place, Blackrock, Dublin.
<b>GP Telephone</b>	01 3223347
<b>Hospital Consultant</b>	Mr Alan TK BetterHeart: Cardiologist
<b>Hospital Consultant ID</b>	KP00099-2.16.840.1.113883.2.27.5
<b>Author</b>	Dr Terry Sample MD
<b>Author ID</b>	KC00017-2.16.840.1.113883.2.27.5
<b>Telephone no</b>	01 3452277
<b>Discharge Date</b>	16-04-2011
<b>Discharge Time</b>	13:01:52

### **Admission History**

Mrs. Mary Shamrock a 50 year old female was admitted to the Good Irish Hospital for cardiac evaluation following a 6 month history of sleep problems associated with breathing difficulties.

One month ago Mrs. Shamrock symptoms became worse where she gradually started having significant symptoms of heart failure, including episodes of nocturnal dyspnoea, palpitations, racing heartbeat, and occasional dizziness.

### **Hospital Course**

Mrs. Mary Shamrock was admitted to the Good Irish Hospital Ward 1 on the 04 April 2011 for a 6 day period. On admission an electrocardiogram was performed and was consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant STT abnormalities, suggestive of ischemia. A chest X-ray was consistent with cardiomegaly.

Mr Alan BetterHeart the cardiac consultant reviewed the patient and commenced her on the following medication Aspirin 325mg / day, Spirinolactone 50 mg p.o. daily, Lisinopril 20 mg p.o. daily, which has been well tolerated. He has discussed the need to perform an electrophysiology study, and depending on the results, may proceed with ICD implantation. The patient has agreed to perform an electrophysiology study, and will return to outpatients in 2 weeks.

### **Allergies and Reactions**

Penicillin – Hives were the reaction to this drug

Codeine - Itching and nausea

### **Medications**

Spirinolactone 25 mg p.o. daily

Aspirin 81 mg p.o. daily

Lisinopril 20 mg p.o. daily

Tylenol 500 mg p.r.n. for pain

### **Observations**

#### **Electrocardiogram (ECG)**

Mrs. Shamrock's ECG at the time of admission is consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST abnormalities, suggestive of ischemia.

**Chest X-ray**

Mrs. Shamrock is consistent with cardiomegaly.

**Laboratory**

1. RBC: 4.15 10<sup>12</sup>/L,
2. Hemoglobin: 12.2 g/dl,
3. Serum glucose: 5.00mmol/L
4. Serum creatinine: 68umol/L

**Primary Diagnosis**

1. Congestive heart failure, with severe Left Ventricular systolic dysfunction

**Secondary Diagnosis**

1. Paroxysmal Nocturnal Dyspnoea caused by Congestive heart failure
2. Cardiomegaly

**Family History**

1. Father had fatal MI in his early 50's.

**Treatment Plan**

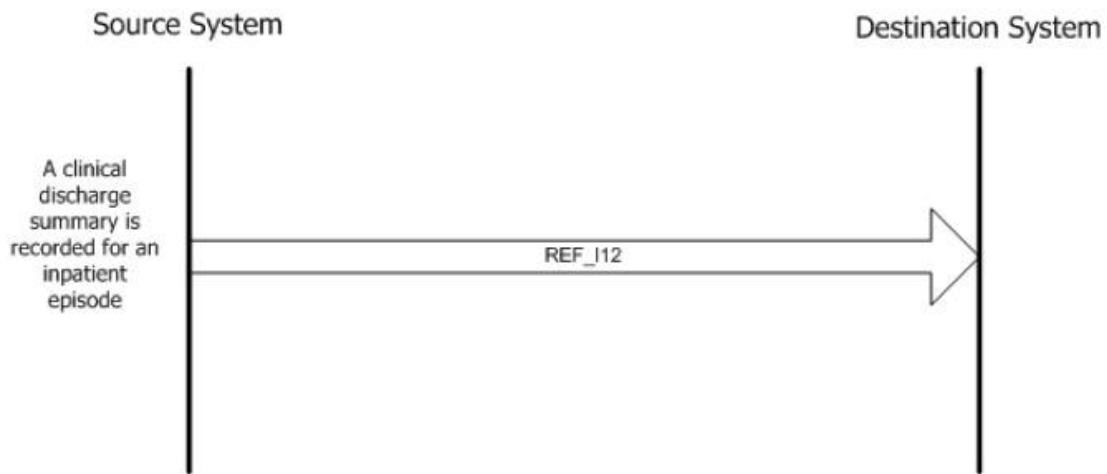
1. Continue on medications
2. Outpatients visit organised for Mrs. Shamrock to attend for electrophysiology study in 2 weeks.

**5.4. HL7 2.4xml message creation**

The Health Information and Quality Authority (HIQA) in 2010 developed the General Practice Messaging Standard (GPMS) which is a messaging standard to standardise the electronic transmission of messages between the primary care and secondary care interfaces in Ireland. This standard focuses on the



structure and content of electronic messages used to communicate between practice management systems of general practitioners and secondary care and out of hours care systems and is based on the HL7international 2.4xml message structure. The message type recommended and used in Ireland for discharge summary messages is the HL7 v2.4 referral message (REF\_I12 message) type.



**Figure 8: GPMS Discharge Summary**

Figure 8 above shows a representation of the GPMS discharge summary (HL7 v2.4 REF\_I12 message).

For the purpose of this standard the minimum clinical discharge summary message contains the following segments:

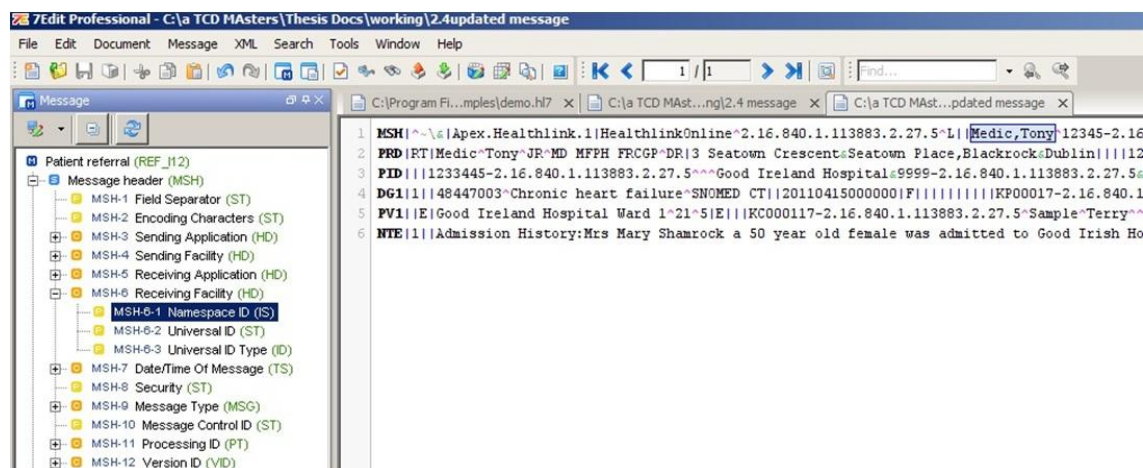
- MSH Message Header
- PID Patient Identification
- PRD Provider Data
- DG1 Diagnosis
- PV1 Patient Visit
- NTE Notes and Comments

The GPMS set out the following conditions to apply when generating a clinical discharge summary message

- PV1.36 (Discharge Disposition). This element is required
- PV1.37 (Discharge to Location). This element is optional in this context but if known it is strongly recommended that it is populated
- PV1.45 (Discharge Date/Time). This element is required
- NTE.3 (Comment). It is strongly recommended that the clinical information is included in this element.

The HL7 v2.4 message was developed in accordance to this standard and the content was based on the storyboard outlined in section 5.3.1 above.

7Edit Professional V2.5.2 was the tool selected to create, view, edit, validate the V2.4 message and export the 2.4 xml version of the message.



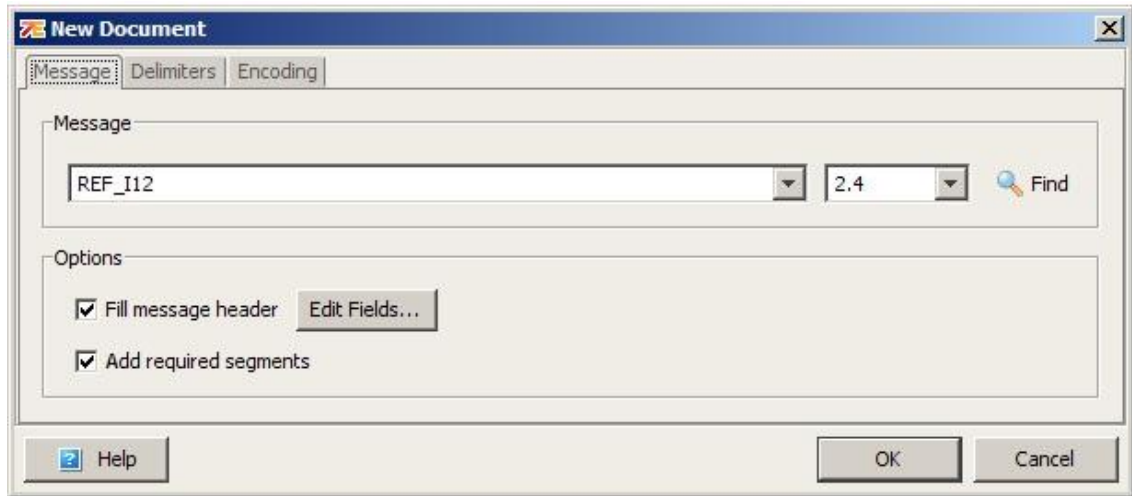
**Figure 9: 7Edit Professional**

The tool provided a user-friendly interface for developing the message.

The message was created as follows

1. Select File: New

Figure 10 below shows the dialogue provided where the message type and version required were selected.



**Figure 10: 7Edit Professional Message Creation**

The new empty message is displayed in the message viewer;

2. Figure 9 above shows the message in the viewer.

**The message explorer as seen in**

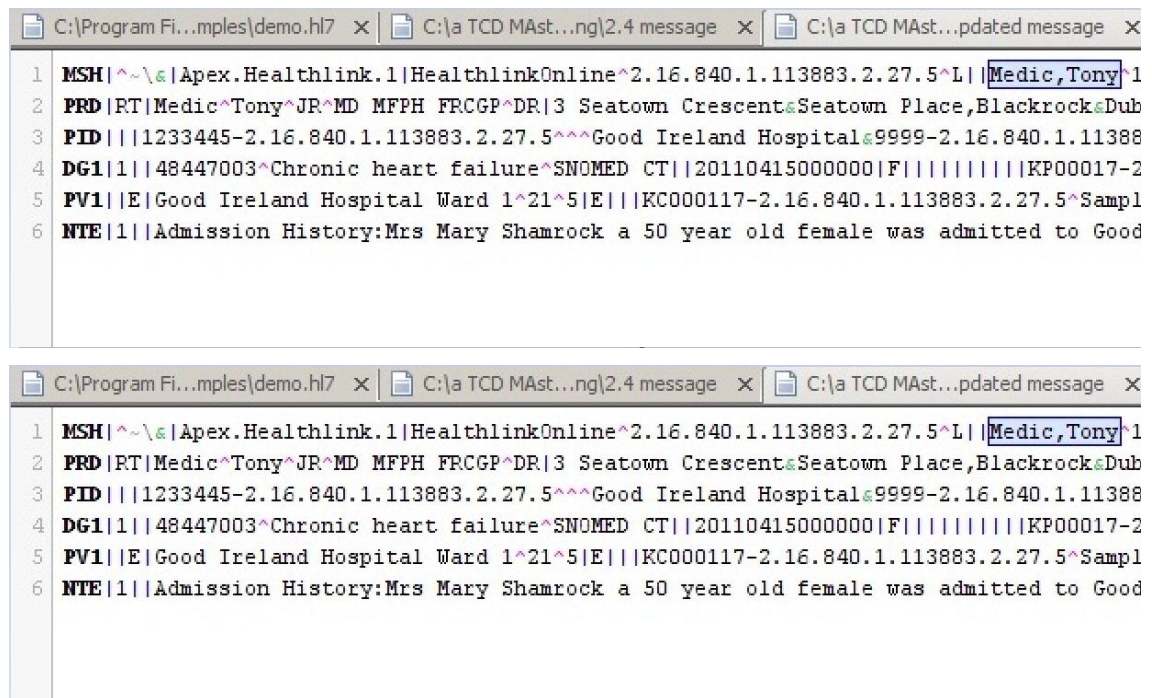
3. Figure 11 provides a list of segments and fields required for the REF\_I12 message. The GPMS was used in conjunction with the tool as extra segments and fields are required as part of the Irish standard.



**Figure 11: Message Explorer**

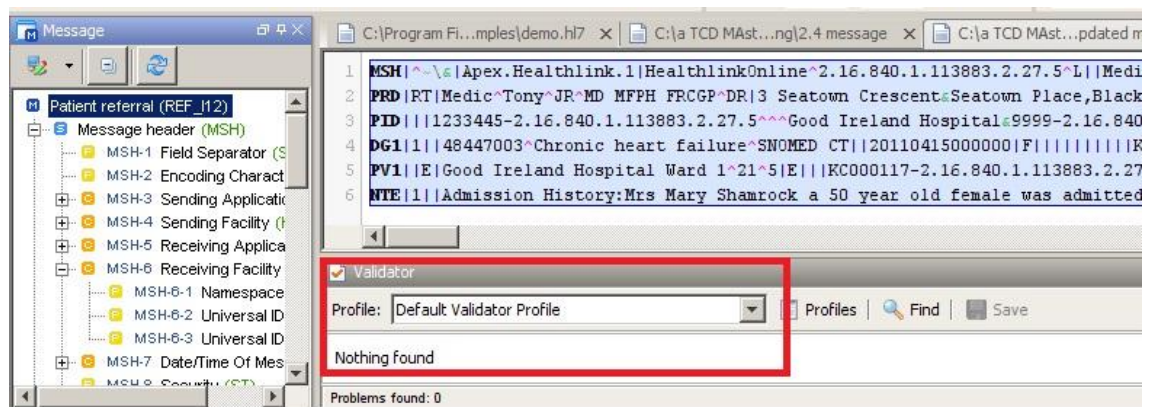
**The fields were filled with the required patient and contextual information information as provided by the storyboard in section 5.3.1 above. The message viewer can be seen in**

4. Figure 12 below.



**Figure 12: Message Viewer**

- When the message was created the 7Edit tool validated the message to ensure the correct structure was adhered to Figure 13 below shows the validation results i.e. no problems found.



**Figure 13: Message Validation**

5. The final stage of the message creation process involved exporting the message structure to 2.4xml format.

The completed HL7 2.4xml message can be viewed in Appendix 2

## **5.5. HL7 v3 CDA Document**

The CDA document was created using a text editor and the following documentation:

1. HL7 Clinical Document Architecture, Release 2 HL7(tm) Version 3 Standard (HL7, 2005).
2. Implementation Guide for CDA Release 2.0 Care Record Summary Release 2 Discharge Summary,(U.S. Realm)Draft Standard for Trial Use Levels 1, 2 and 3 (HL7, December 2009).
3. HL7® Version 3 Standard (HL7(tm) Version 3 Standard, 2005).
4. Reference Material: XML schema
  - a. POCD\_MT000040.xsd
  - b. NarrativeBlock.xsd
  - c. infrastructureRoot.xsd
  - d. datatypes-base.xsd
  - e. datatypes.xsd
  - f. voc.xsd
5. CDA (POCD\_HD000040) Hierarchical Description(HL7, 2005).

As stated previously the CDA document was created and validated in accordance with the HL7 Clinical Document Architecture, Release 2.0. The Implementation guide for CDA Release 2.0 Care Record Summary Release 2 Discharge Summary was also used as a cross referencing guide. This implementation guide is a draft standard for trial use after a 24 month period a normative ballot will be submitted for approval by ANSI as an American National Standard. This implementation guide specifically addresses areas required for a patient discharge summary record and is why the guide was referenced.

The POCD\_MT000040.xsd contains the xml schema definitions and this was referenced for document creation and validation.

### **5.5.1. Use of ID's and codes for the CDA document**

#### **5.5.1.1. ID usage**

Before the CDA document creation commenced it was necessary to define the identifier scheme to be used for this document. ISO Object Identifiers (OID's) were used to uniquely specify the value of a person, organization, or other entity.

The identifier consists of 2 parts:

1. Root: a globally unique identifier composed of an OID whose root is obtained from HL7.
2. Extension: The value of this attribute is the responsibility of the organization, system, and/or application where the document is created and stored.

Together, the root and extension when concatenated result in a universally unique string for identification of the document, person, or organization.

For the purpose of this study The root OID selected is as follows:

- **"2.16.840.1.113883.2.27.xxx"** which is the OID for HL7 Registered models in Ireland
  - 'xxx' will be replaced by the number '5' representing the 'Good Ireland Hospital' domain
    - e.g. **'2.16.840.1.113883.2.27.5'**

The extension value has been made up following no explicit pattern and is only for representation purposes.

There is one exception and that is in the typeID the root and extension are fixed

```
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
```

- root = "2.16.840.1.113883.1.3" the OID for HL7 Registered models
- extension = "POCD\_HD000040" the unique identifier for the CDA, Release Two Hierarchical Description.

Identifiers that were created for the CDA document are:

- document ID: unique identifier for each CDA instance  
**<id root="2.16.840.1.113883.2.27" extension=" GIH-12345789"/>**
- patient (record target)  
**<id extension="1233445" root="2.16.840.1.113883.2.27.5"/>**
- provider organization associated with the patient  
**<id root="2.16.840.1.113883.2.27.5"/>**
- author and author's organization  
**<id extension="KC00017" root="2.16.840.1.113883.2.27.5"/>**
- document custodian  
**<id extension="M345" root="2.16.840.1.113883.2.27.5"/>**
- Legal Authenticator (Cardiac Consultant)  
**<id extension="KP00099" root="2.16.840.1.113883.2.27.5"/>**

### 5.5.1.2. Code usage

The CDA also makes extensive use of code sets for document types, document sections, clinical procedures, and clinical findings. In this CDA discharge document, Logical Observation Identifier Names and Codes (LOINC®) have been used which are the recommended codes for classification of document types.

```
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5" displayName="DISCHARGE SUMMARIZATION NOTE"/>
```



### Figure 14: Code element using LOINC

Figure 14 above shows the code element at the root of the document which is required to specify the document type that is being created in this case the 'Discharge Summarization note'. The required attributes are

- Code = 18842-5 (Discharge Summarization note)
- CodeSystem = 2.16.840.1.113883.6.1 (LOINC OID)

For Human readability the 'codeSystemName' and 'displayName' were also added to the document but these are optional elements and were not required for validation purposes.

LOINC codes are available for commercial use without charge, subject to the terms of a license that assures the integrity and ownership of the codes.

LOINC coded values were selected and verified via the official LOINC website <http://loinc.org/> and also the National Cancer Institute Enterprise Vocabulary Services (EVS) <http://evs.nci.nih.gov/>. The NCI EVS provides very useful resources for controlled terminology.

The CDA entry level clinical statements are the level 3 entries that provide computable semantics for the discharge summary document. These CDA entries are optional and are placed after the required narrative block in the structured body. To demonstrate the semantic ability of the CDA level 3 these entries are important for the purpose of this study, SNOMED CT has been selected to code entries at level 3. It must be noted at this stage that SNOMED CT is not the only coding system that can be used at an entry level as an example International Classification of Diseases (ICD 10) codes could be used, in the US Rx Norm is one of their coding standards for medication coding.

Figure 15 shows the use of SNOMED CT in the discharge document to code the value for a follow-up visit. The National Cancer Institute Enterprise Vocabulary Services (EVS) <http://evs.nci.nih.gov/> was used to reference SNOMED CT codes.

```
<entry> <encounter classCode="ENC" moodCode="RQO">

<code code="185389009" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Follow-up visit"/>

<effectiveTime>

    <low value="20110430"/>

    <high value="20110505"/>

</effectiveTime></encounter></entry>
```

**Figure 15: SNOMED CT at entry level**

### **5.5.2. Document creation**

The CDA document was firstly divided into two parts the header and the body.

#### **5.5.2.1. CDA Header**

**The CDA header contains the contextual information as defined from the R\_MIM.**

Figure 16 shows the attributes from the CDA R\_MIM the highlighted attributes are fixed, required and structural attributes.

ClinicalDocument
classCode*: <= DOCCLIN
moodCode*: <= EVN
id*: II [1..1]
code*: CE CWE [1..1] <= <i>DocumentType</i>
title: ST [0..1]
effectiveTime*: TS [1..1]
confidentialityCode*: CE CWE [1..1] <= <i>x_BasicConfidentialityKind</i>
languageCode: CS CNE [0..1] <= <i>HumanLanguage</i>
setId: II [0..1]
versionNumber: INT [0..1]
copyTime: TS [0..1] (Deprecated)

**Figure 16: CDA R2 R-MIM attributes**

### Attributes Included in the CDA Discharge Document

1. The id element is required and contains a root and extension attributes which universally distinguishes a document from all other documents.

```
<id root="2.16.840.1.113883.2.27" extension="GIH-12345789"/>
```

2. Figure 14) is required and specifies the particular kind of document that is being created.
3. The title element is optional but renders in the browser as the page caption.

```
<title>Discharge Summary</title>
```

4. The `effectiveTime` element is required and shows the time of the document creation in the format 'year/month/day/hour/min/sec'.

```
<effectiveTime value="20110416113026"/>
```

5. The `confidentialityCode` element is required where 'N' code provides the document with the normal access rights level.

```
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
```

### **Participants Included in the CDA Discharge Document**

Figure 17 shows the participants that can participate in a Clinical Document encounter. The cardinality on the participants depicts whether the participant is required or optional as per the CDA R\_MIM.



Figure 17: CDA R2 R-MIM participants

The recordTarget element represents the patient that this discharge document refers to. The recordTarget contains a nested patientRole with classType 'PAT'. The id as before represents the unique patient within the provider organisation. Patient demographic information is detailed and also the associated provider organisation.

6. Figure 18 below shows the recordTarget created from the provided Storyboard in section 5.3.1 above.

```
<recordTarget>
  <patientRole classCode="PAT">
    <id extension="1233445" root="2.16.840.1.113883.2.27.5"/>
    <addr>
      <streetAddressLine>34 Irish Town Road</streetAddressLine>
      <streetAddressLine>Blackrock</streetAddressLine>
      <city>Dublin</city>
      <county>Dublin</county>
      <country>Ireland</country>
    </addr>
    <telecom value="tel:(01) 4223355"/>
    <patient>
      <name>
        <given>Mary</given>
        <given>Kate</given>
        <family>Shamrock</family>
        <suffix>Mrs</suffix>
      </name>
      <administrativeGenderCode code="F"
        codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19610122"/>
    </patient>
    <providerOrganization>
      <id root="2.16.840.1.113883.2.27.5"/>
      <name>Good Ireland Hospital</name>
    </providerOrganization>
  </patientRole>
</recordTarget>
```

**Figure 18: Participant: recordTarget**

**The author element is required and represents the person that created the document. From the storyboard the author in this case is Dr Terry Sample who is a MD in The Good Irish Hospital see**

7. Figure 19 below.

```

<author>
  <time value="2000040714"/>
  <assignedAuthor>
    <id extension="KC00017" root="2.16.840.1.113883.2.27.5"/>
    <assignedPerson>
      <name>
        <given>Terry</given>
        <family>Sample</family>
        <suffix>MD</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.2.27.5"/>
      <name>Good Ireland Hospital</name>
    </representedOrganization>
  </assignedAuthor>
</author>

```

**Figure 19: Participant Author**

8. The custodian element is required and represents the organisation where the document originated and that is responsible for maintaining the document.

```

<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.2.27.5"/>
      <name>Good Ireland Hospital</name>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>

```

**The legalAuthenticator element is optional and represents the person legally responsible for the document. There is only one allowed per document and in this case it is the Cardiac Consultant Mr. Alan BetterHeart see**

9. Figure 20 below.

```

<legalAuthenticator>
  <time value="20110416113026"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="KP00099" root="2.16.840.1.113883.2.27.5"/>
    <assignedPerson>
      <name>
        <prefix>Mr</prefix>
        <given>Alan</given>
        <family>BetterHeart</family>
        <suffix>MD</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.2.27.5"/>
      <name>Good Ireland Hospital</name>
    </representedOrganization>
  </assignedEntity>
</legalAuthenticator>

```

**Figure 20: legalAuthenticator**

10. The participant element identifies other supporting participants, in this case the patients next of kin (classCode='NOK') whose association with the patient is 'Husband'.



```

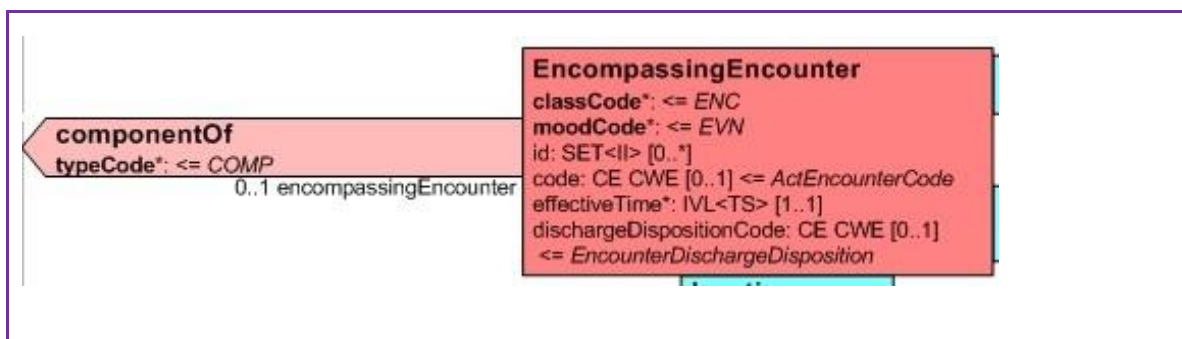
<participant typeCode="IND">
  <associatedEntity classCode="NOK">
    <code code="HUSB" codeSystem="2.16.840.1.113883.5.111" codeSystemName="HL7 RoleCode"
      displayName="husband"/>
    <addr>
      <streetAddressLine>34 Irish Town Road</streetAddressLine>
      <streetAddressLine>Blackrock</streetAddressLine>
      <city>Dublin</city>
      <county>Dublin</county>
      <country>Ireland</country>
    </addr>
    <telecom value="tel:(01) 4223355"/>
    <associatedPerson>
      <name>
        <given>Denis</given>
        <family>Shamrock</family>
        <suffix>Mr</suffix>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>

```

**Figure 21: participant element**

The **componentOf** element is a related act element and represents the setting and documentation of events that occurred during the **EncapsulatingEncounter**. As a routine discharge is always associated with a hospital encounter this element was included. The 'dischargeDispositionCode' records the disposition of the patient at time of discharge the code '01' in

11. Figure 22 represents patient discharged to home or self care (routine discharge).



```

<componentOf>
  <encompassingEncounter>
    <id extension="9937012" root="2.16.840.1.113883.2.27"/>
    <effectiveTime>
      <low value="20110410"/>
      <high value="20110416"/>
    </effectiveTime>
    <dischargeDispositionCode code="01" codeSystem="2.16.840.1.113883.12.112"
      displayName="Routine Discharge" codeSystemName="HL7 Discharge Disposition"/>
    </encompassingEncounter>
  </componentOf>

```

**Figure 22: componentOf element**

### 5.5.2.2. CDA Structured Body

The structured body type was selected for the CDA discharge document. The body consists of a number of component/section elements **Table 12** below shows the seven sections used to incorporate the information required from the storyboard narrative.

LOINC Code	Component Name
<b>10164-2</b>	HISTORY OF PRESENT ILLNESS
<b>8648-8</b>	HOSPITAL COURSE
<b>11535-2</b>	HOSPITAL DISCHARGE DIAGNOSIS
<b>10155-0</b>	ALLERGIES AND ADVERSE REACTIONS
<b>10160-0</b>	HOSPITAL DISCHARGE MEDICATIONS
<b>11493-4</b>	HOSPITAL DISCHARGE STUDIES SUMMARY
<b>10157-2</b>	FAMILY HISTORY
<b>18776-5</b>	PLAN OF CARE

**Table 12: LOINC Section codes**

Each of the sections was developed in two phases as follows

**The human readable section:** - This consists of

- The code element to classify the section
- The title element
- The text element

**Both the title and the text element are required and are the sections that the LegalAuthenticator are responsible for. The code element has been developed using LOINC codes as described in section 5.5.1.2 above. The text element contains all the human readable content from the storyboard narrative with the addition of allowed structural elements for rendering purposes.**

Figure 23 shows the first section 'History of present illness' as an example.

```
<component>
  <section>
    <code code="10164-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>HISTORY OF PRESENT ILLNESS</title>
    <text><paragraph>
      <content styleCode="Bold">Mrs Mary Shamrock </content>
      is a 50 year old female was admitted to Good Irish
      Hospital Ward 1 on the 04 April 2011 </paragraph>
      <paragraph>
        for cardiac evaluation following a 6 month history of sleep
        problems associated with breathing difficulties.</paragraph>
      <paragraph>
        One month ago Mrs Shamrock symptoms became worse where she
        gradually started having significant symptoms of heart failure, </paragraph>
      <paragraph>
        including episodes of nocturnal dyspnoea, palpitations, racing heartbeat,
        and occasional dizziness.</paragraph>
    </text>
  </section>
</component>
```

**Figure 23: Present Illness Section**

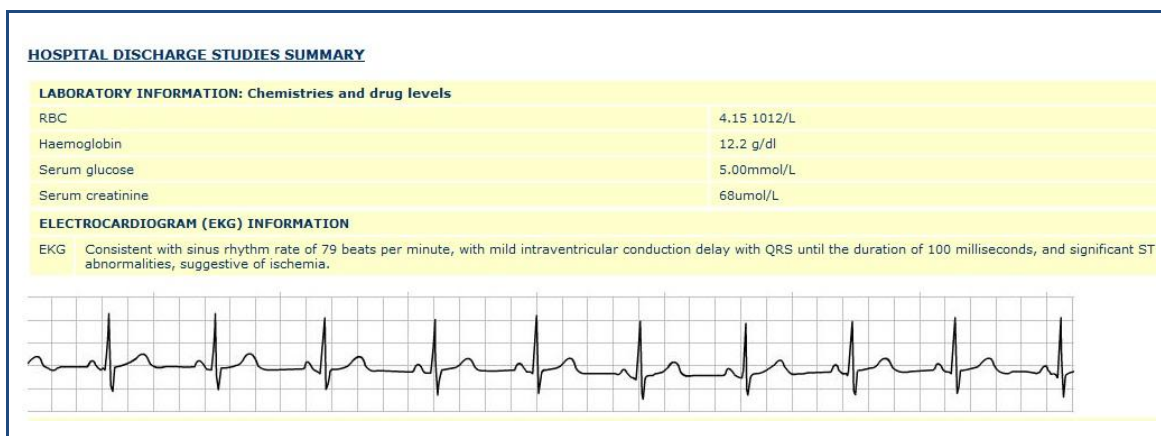
There are advanced features that can be used in this section to enable the document to render multimedia objects. The following was added to the 'HOSPITAL DISCHARGE STUDIES SUMMARY' section and referenced an ECG reading on the patient, Figure 24 shows the reference used.

```
<text>...<renderMultiMedia referencedObject="MM1"/>...</text>
```

```
<entry>
  <observationMedia classCode="OBS" moodCode="EVN" ID="MM1">
    <value mediaType="image/jpeg">
      <reference value="ekg.jpg"/>
    </value>
  </observationMedia>
</entry>
```

**Figure 24: multimedia reference**

A portion of the document rendered with a stylesheet is shown in Figure 25 showing the multimedia ECG picture in the CDA Discharge Documentation.



**Figure 25: CDA rendered Document**

### **The semantically computable section:**

The CDA Entries are RIM based structures used to convey software processable information in CDA documents with a structured body. Entries are based on the concept of "Clinical Statements" and are completely optional.

### **The entry types used can be seen in**

Figure 26 below and a description of their use.

Entry Type	Entry Use
<b>Act</b>	Contains information about generic/other clinical activities
<b>Observation</b>	Contains information related to an observation (e.g. a laboratory, radiology observation) or diagnoses.
<b>ObservationMedia</b>	Contains a multi-media observation (e.g. image) as seen above.
<b>SubstanceAdministration</b>	Contains information related to the substance administration activity. (e.g. prescription and administration data related to pharmaceutical products)
<b>Encounter</b>	Identifies a patient encounter related to a particular item/set of clinical data.

**Figure 26: Entry Types Used**

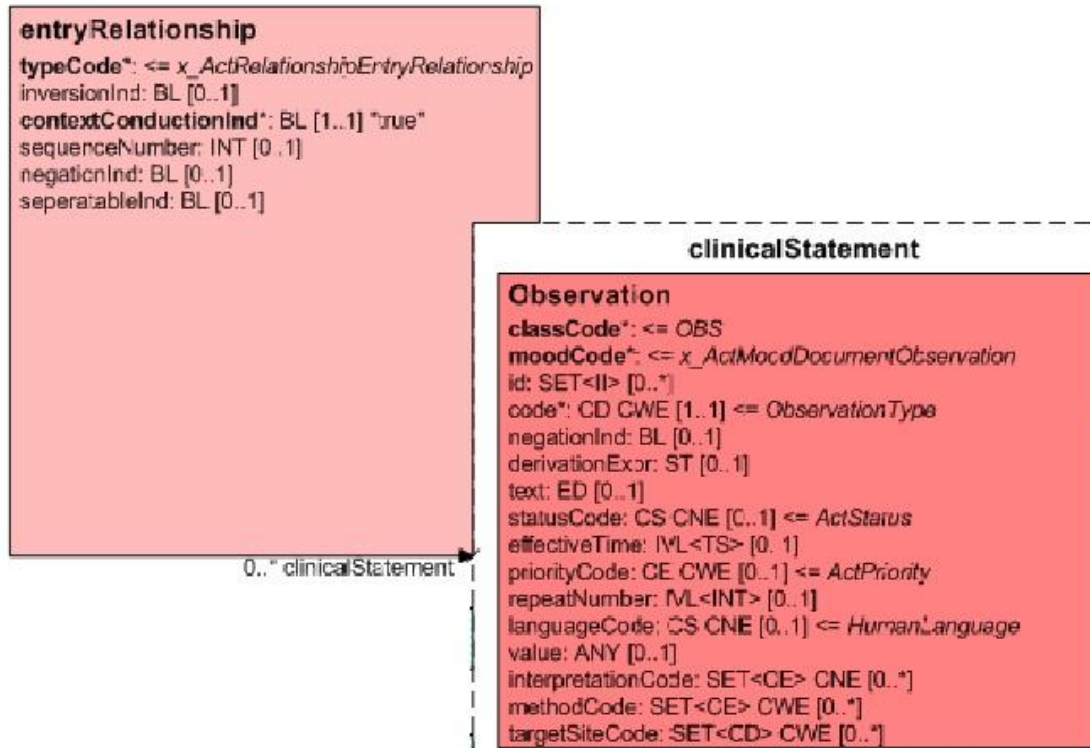
Table 13 below shows the sections developed with RIM based entries.

Section	Entry Type
<b>HOSPITAL DISCHARGE DIAGNOSIS</b>	Act
<b>ALLERGIES AND ADVERSE REACTIONS</b>	Observation
<b>HOSPITAL DISCHARGE MEDICATIONS</b>	SubstanceAdministration
<b>HOSPITAL DISCHARGE STUDIES SUMMARY</b>	ObservationMedia
<b>FAMILY HISTORY</b>	Observation
<b>PLAN OF CARE</b>	Encounter

**Table 13: Sections using entries**

**The development of each entry involved referencing the RIM**

Figure 27 below gives a diagrammatic representation of the Observation class which was used to create the 'Family History' and 'Allergies and Adverse Reactions' entries.



**Figure 27: CDA R\_MIM Observation**

**The following**

Figure 28 shows the entry as per the R\_MIM definition above.

```

<entry>
  <observation classCode="OBS" moodCode="EVN">
    <code code="22298006" codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT" displayName="MI"/>

    <statusCode code="completed"/>
    <effectiveTime value="1970"/>
    <subject>
      <relatedSubject classCode="PRS">
        <code code="FTH" codeSystem="2.16.840.1.113883.5.111"/>
      </relatedSubject>
    </subject>
    <entryRelationship typeCode="CAUS">
      <observation classCode="OBS" moodCode="EVN">
        <code code="399347008" codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED CT" displayName="death"/>
        <statusCode code="completed"/>
        <effectiveTime value="1970"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>

```

**Figure 28: Observation Entry**

Each Observation requires a fixed classCode 'OBS' and the moodCode in this instance is 'EVN' relating to observation produced. The following code '22298006' represents the SNOMED CT coding of 'MI' which represents a myocardial infarction. The <statusCode> is 'completed' and <effectiveTime> refer to the diagnosis being a final diagnosis and the diagnosis was made in 1970.

The <subject> entry contains a nested <relatedSubject> which states the subject in question is of type person and is the father of the patient.

The following <entryRelationship> describes in coded form that the patients father died in 1970 from the above mentioned myocardial infarction.

Each section was developed in accordance with the storyboard narrative to demonstrate the extendable nature of the CDA architecture. The entire CDA document can be seen in Appendix 3.



#### **5.5.2.3. CDA Validation**

The NIST ( National Institute of Standards and Technology ) provides a series of testing tools for promoting the adoption of standards-based interoperability by vendors and users of healthcare information systems (<http://xreg2.nist.gov/cda-validation/validation.html>).

The tools are designed to be used by developers and implementers during the development of software that implements CDA/CCD-based specifications. The CDA tool was used in this project to validate that the CDA document instance created was correct with respect to the specifications.

### **5.6. Summary**

In this chapter the use case and storyboard for the research study were developed, which provided the contextual information for the HL7 v2 REF\_I12 message and the HL7 v3 CDA.

This was followed by a detailed description of the process of creating and validating the HL7 v2 REF\_I12 message and the HL7 v3 CDA.

The resulting HL7 v2 REF\_I12 message and the HL7 v3 CDA will be used in the following chapter to complete the comparative analysis and evaluation of each structure in relation to interoperability.



## **Chapter 6. HL7 message and document analysis**

## **6.1. Introduction**

The previous chapter provided a detailed explanation of the creation and validation of the HL7 2.4 message and the HL7 CDA document.

The aim of this chapter is to examine these two data structures and technically compare and contrast each attribute and develop an understanding into the levels of semantic interoperability that each structure can potentially provide.

The chapter will initially concentrate on the technical differences between the HL7 v2.x message and the HL7 v3 CDA and then conclude with an evaluation of the findings from the analysis.

## **6.2. Comparison method**

### **6.2.1. Overview**

An important aspect of any comparison study is to develop themes on which the structures in question can be compared. Before developing themes that are similar to both message and document it is important to review some overall comparisons that can be drawn between the use of messages and documents for a given information scenario.

#### **1. Readability:**

- a. Messages were designed entirely for the transmission of events between machines. The newer version of HL7 2.4 XML however can be rendered using style sheets in a browser.
- b. Documents were designed with the intention to provide an electronic version of the paper form of written documents that medical personnel are used to. The main benefit was to ensure that documents could be rendered in any browser and viewed.

## 2. Model:

- a. Messages use a dynamic model based on trigger events that manage the status of business-objects and are capable of providing real time transient information.
- b. Documents on the other hand are persistent in nature, their purpose is to capture a particular domain of interest at a certain snapshot in time e.g. discharge summaries, referral letters.

## 3. Communication

- a. Messages are generally used to support real time processing by conveying status information and updates to related business objects. This lends messages to a more interactive and tightly coupled communication process specifically with the intention of exchange between machines. The use of messages is more applicable to intra organizational structures.
- b. Documents contain a snapshot of data as it was at document creation time. For discharge summaries and referral letters this is more appropriate as for each consecutive patient episode the patient information will be updated and amended therefore losing the original snapshot of information of a previous episode. Documents are therefore passive and do not drive any activity, their purpose is to capture information and enable the sharing of that information. This in turn lends documents to a more loosely coupled communication process as that which occurs between organisations with heterogeneous systems.

## 4. Legal aspects

- a. Messages can contain digital signatures however their use is questionable due to the transient nature of the message.

- b. Documents can also contain digital signatures and due to their persistent nature these signatures are recognized by law in certain countries.

## 5. Methodology

- a. Messages (V2.x) has very few semantic restrictions, the context of each field is defined but it is up to the implementers as to whether the field contents should be free text or use a standard terminology. Messages (V2.x) do not have a semantic framework therefore have no specification regarding the meaning and content of a message. Because of this, interchange of clinical data in V2 requires what has been termed "bilateral negotiation" of the semantics of messages. This refers to a process whereby, every time a V2 interface is built, the systems on both ends are programmed to interpret correctly all the possible values in each field of the V2 messages they might receive over the interface.
- b. Documents (CDA) were developed from formal object orientated design methodology. Documents are derived from HL7 V3 Reference Information model (RIM) and use HL7 V3 datatypes. The RIM and the V3 data types provide a powerful mechanism for enabling documents to incorporate concepts from standard coding systems such as Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC) (Dolin et al., 2006).

Table 14: Comparative OverviewTable 14 provides a tabular representation of differences between documents and messages.

CDA Document		HL7 Message
Readability	Human-readability and	Machine processable

	machine processable	
Model	Static Model – Snapshots at a particular time. Persistent by nature.	Temporary – developed to transmit events as they occur. Dynamic model (trigger based).
Communication	Passive and loosely coupled communication. Exchange between humans and machines	Tightly coupled communication process. Exchange between machines
Legal aspects	Digital signatures are recognized by law in some countries	Digital signatures are temporary in nature as the message is short lived
Methodology	Formal Object Orientated design methodology	Ad hoc development methodology defined for each domain

**Table 14: Comparative Overview**  
**(Modified version of (HL7 International, 2010)as seen in chapter 2)**

### 6.2.2. Detailed Analysis

To perform an effective comparison it was necessary to analyze the HL7 v2 message and the HL7 V3 CDA and divide the structures into thematic areas that enabled further evaluation in terms of

1. Human semantic interoperability
2. Computer semantic interoperability

The following thematic areas were identified:

1. Header Elements

## 2. Participant Elements

## 3. Medical Information Elements

Each of these areas will be investigated and evaluated in relation to human semantic interoperability and computer semantic interoperability.

The heuristics used for the evaluation in terms of human semantic interoperability are based on the usability features of effectiveness and efficiency based on the ISO definition on usability (ISO, 1998).

Effectiveness relates to the accuracy and completeness with which specified users can achieve specified goals in particular environments.

Efficiency relates to the time spent in comparison with the accuracy and completeness of the goals achieved.

The heuristics used in terms of computer semantic interoperability are based on Mead's four pillars of computable semantic interoperability (Mead, 2006):

1. A common model across domains of interest
2. Model based on robust data type specification
3. Methodology for binding terms from concept based terminologies to elements of the model
4. A formal process for defining specific structures to be exchanged between machines.

### **6.2.2.1. Header Elements**

The header elements can be described as the entries that relate to the message/document metadata.

The HL7 V2 message consists of the 'MSH' segment which defines the intent, source, destination, and some specifics of the syntax of a message (Health Information and Quality Authority, 2010).

The HL7 CDA header identifies and classifies the document and sets the context for the document as a whole to enable document exchange. The header also contains patient, provider information but this will be covered in the section on participant elements to follow.

The MSH.3/HD.1 element describe the sending application, the field structure is 'System.Middleware.MessageNumber' as recommended HIQA (Health

Information and Quality Authority, 2010). The use of local codes can become unwieldy and unmanageable if the network and the number of interfaces increase especially if there is no formal methodology with respect to the creation of these codes.

The CDA document uses ISO object identifiers (OID's) to uniquely specify the domain of a coded data value or an identifier for a person, organisation, or other entity. The idea of using OID's is that they provide a globally unique namespace (Dubuisson, 2001) and with the ultimate goal of European interoperability between systems this seems like a more robust starting point.

**The identification of the message and document can be seen in**

Figure 29 below. The MSH.10 contains the identifier that uniquely identifies the message the datatype of this element is a string value. The CDA uses the OID to uniquely identify the document source along with the extension value to uniquely identify the document.

- |  |
|--|
| <ol style="list-style-type: none"><li>1. &lt;MSH.10&gt;MSG00001&lt;/MSH.10&gt;</li><li>2. &lt;id root="2.16.840.1.113883.2.27.4" extension="GIH-12345789"/&gt;</li></ol> |
|--|

**Figure 29: 1.Message id, 2.CDA id**

**The MSH.9 segment defines the message type code 'REF' and the trigger event code 'I12' as seen below in**

**Figure 30. The CDA uses LOINC as the code sets for document types as described in the previous chapter.**

Figure 30 shows the LOINC coding of the Discharge summarization note.

- |  |
|--|
| <ol style="list-style-type: none"><li>1. &lt;MSH.9&gt;<br/>    &lt;MSG.1&gt;REF&lt;/MSG.1&gt;<br/>    &lt;MSG.2&gt;I12&lt;/MSG.2&gt;<br/>  &lt;/MSH.9&gt;</li><li>2. &lt;code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"</li></ol> |
|--|

```
displayName="DISCHARGE SUMMARIZATION NOTE"/>
```

**Figure 30: 1. MSH.9: message type, trigger event code, 2. CDA document spec code**

**The MSH.12 specifies the version id of the V2 message being transported whereas the CDA specifies the document 'typeID' which consists of the document root id '2.16.840.1.113883.1.3' which is the Object Identifier for the HL7 registered models and the extension 'POCD\_HD000040' which uniquely identifies the CDA Release Two Hierarchical Description see Figure 31 below.**

```
1. <MSH.12>  
    <VID.1>2.4</VID.1>  
</MSH.12>  
  
2. <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
```

**Figure 31: 1. MSH.12 message version id 2.CDA Header type id**

On investigation of some of the header elements there are a few consistent areas whereby the 2 standards differ. The use of identifiers is more standardised in the HL7 v3 standard with the use of object identifiers whereas the v2 standard uses more proprietary local coded values. Considering computable semantic interoperability however the use of a standard object identifier scheme would provide a more extensible solution reducing the need to update each interface in the communication network. The identification strategy further shows the reason why HL7 v2 messages were initially developed for transmission of dynamic messages within an organisational structure i.e. tightly coupled systems. Human semantic interoperability will not be discussed in relation to the header information as these elements are not rendered for view by the HL7



v3 CDA or HL7 v2 message and even with the use of stylesheets the values are not rendered.

#### **6.2.2.2. Participant Elements**

The participant entries refer to all people who participate in the encounter these would include patient, information recipient, custodian, author and legal authenticator.

##### **6.2.2.2.1 Patient**

**The HL7 V2 message consists of the PID segment which is used by all applications as the primary means of communicating patient identification information see**

Figure 33.

**In the CDA document this information is documented in the record target element see**

Figure 32. The Record target is referred to as one of the CDA participants and represents the person who this document refers to. The record target is defined by the CDA R2 R-MIM and is associated with a patient entity by the role type patientRole.

The HL7 v2 message PID.3 segment contains the patient identifier. The patient identification is achieved by a combination of the CX.1 field which specifies the patient's hospital MRN (Medical record number), the CX.4/HD.1-HD.3 fields which consist of

HD.1: The name of the hospital that assigned the MRN

HD.2: The HIPE code of the assigning hospital

HD.3: The coding system used.

And the CX.5 field which defines the type of identifier used in CX.1.

```

<recordTarget>
  <patientRole classCode="PAT">
    <id extension="1233445" root="2.16.840.1.113883.2.27.5"/>
    <addr>
      <streetAddressLine>34 Irish Town Road</streetAddressLine>
      <streetAddressLine>Blackrock</streetAddressLine>
      <city>Dublin</city>
      <county>Dublin</county>
      <country>Ireland</country>
    </addr>
    <telecom value="tel: (01) 4223355"/>
    <patient>
      <name>
        <given>Mary</given>
        <given>Kate</given>
        <family>Shamrock</family>
        <suffix>Mrs</suffix>
      </name>
      <administrativeGenderCode code="F"
        codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19610122"/>
    </patient>
    <providerOrganization>
      <id root="2.16.840.1.113883.2.27.5"/>
      <name>Good Ireland Hospital</name>
    </providerOrganization>
    </patientRole>
  </recordTarget>

```

**Figure 32: CDA Record Target**

The patient identifier is an attribute of patientRole and is specified by an OID and an extension to uniquely identify the patient. The use of object identifiers greatly reduces the information required for locally derived codes.

The patient name and address are recorded in both structures. The gender is recorded in the message by a character the cda uses the HL7 terminology set for administrative gender code. The information in the message is flat in structure with little contextual information. The CDA structure provides both the role as patient and also the associated provider organization associated with the patient role.

```

<PID>
  <PID.3>
    <CX.1>1233445</CX.1>
    <CX.4>
      <HD.1>Good Ireland Hospital</HD.1>
      <HD.2>9999</HD.2>
      <HD.3>HIPE</HD.3>
    </CX.4>
    <CX.5>MRN</CX.5>
  </PID.3>
  <PID.5>
    <XPN.1>
      <FN.1>Shamrock</FN.1>
    </XPN.1>
    <XPN.2>Mary</XPN.2>
    <XPN.3>Kate</XPN.3>
    <XPN.5>Mrs</XPN.5>
  </PID.5>
  <PID.7>
    <TS.1>19610122</TS.1>
  </PID.7>
  <PID.8>F</PID.8>
  <PID.11>
    <XAD.1>
      <SAD.1>34 Irish Town Road</SAD.1>
    </XAD.1>
    <XAD.2>Blackrock</XAD.2>
    <XAD.3>Dublin</XAD.3>
    <XAD.4>Ireland</XAD.4>
  </PID.11>
</PID>

```

**Figure 33: HL7 V2 PID Segment**

#### 6.2.2.2.2 Information Recipient

The information recipient is a term used by the CDA to represent the person or organization that shall receive the discharge summary. This information is represented in the PRD (provider data) segment of the message. This element is optional in the CDA document due to the fact that the document is actually the payload of a message. Interestingly in the message structure the only field that is required is the PRD.1/CE.1 which is a string representation of the provider role. This field contains the contact role that defines the relationship of the person described in this segment to the patient being referred. The provider identifier is declared in the PRD.7/PI.1 and for

discharge referrals in Ireland the identifier used is either the practice id or the medical council number and is an optional element. The optionality of elements especially identifiers reduces the level of semantic interoperability, further emphasizing the need for each interface to require "bilateral negotiation" of the semantics of messages.

The CDA information recipient is also optional however once used in the document certain elements are required including received organisation identifier, name and address. The CDA can also be further restrained with the use of templates. The document therefore complies and is validated initially with the CDA and each section can in turn be constrained and validated with the applied templates schema.

#### **6.2.2.2.3 Author**

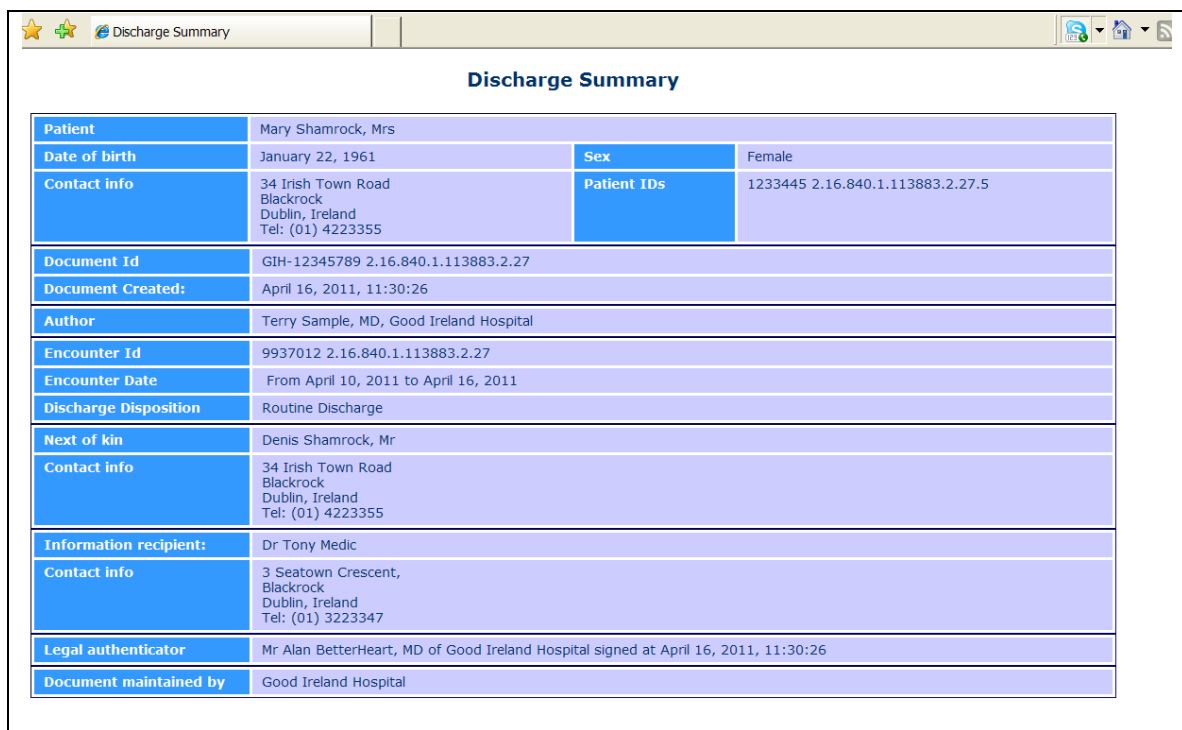
The author element in the CDA document represents the person or devices that created the contents of the document. The author represents an action with the assigned author as the participant in the action; in turn each assigned author has an assigned person and a represented organisation. This mapping of information to a standard structure HL7 Reference Information Model further enhances the ability to achieve semantic interoperability, enabling the mapping of data structures to the model. There is no equivalent author entity in the HL7 V2 message.

The RIM enables the messaging paradigm to move from functional interoperability that exists with HL7 v2 messaging and closer to the ultimate goal of semantic interoperability.

There are other participant entries in the header of the CDA document that had no corresponding information in the HL7 v2 message. Two of these elements are the custodian and the legal authenticator, the custodian represents the organisation where the document originated and the legal authenticator represents the person legally responsible for the document. These elements can be seen in Appendix 3: CDA discharge summary.

The number of participant entries is greater in the CDA document with more emphasis on document ownership and responsibility which further emphasise some of the key features including persistence, stewardship and authentication.

When considering human semantic interoperability the CDA will always be superior as it can be viewed in any browser as it has a pointer to a stylesheet to render the document. Figure 34 below shows the view of the discharge summary as seen in Windows Internet Explorer browser version 7, the format and style can be changed to suit any user view.



Discharge Summary			
Patient	Mary Shamrock, Mrs		
Date of birth	January 22, 1961	Sex	Female
Contact info	34 Irish Town Road Blackrock Dublin, Ireland Tel: (01) 4223355	Patient IDs	1233445 2.16.840.1.113883.2.27.5
Document Id	GIH-12345789 2.16.840.1.113883.2.27		
Document Created:	April 16, 2011, 11:30:26		
Author	Terry Sample, MD, Good Ireland Hospital		
Encounter Id	9937012 2.16.840.1.113883.2.27		
Encounter Date	From April 10, 2011 to April 16, 2011		
Discharge Disposition	Routine Discharge		
Next of kin	Denis Shamrock, Mr		
Contact info	34 Irish Town Road Blackrock Dublin, Ireland Tel: (01) 4223355		
Information recipient:	Dr Tony Medic		
Contact info	3 Seatown Crescent, Blackrock Dublin, Ireland Tel: (01) 3223347		
Legal authenticator	Mr Alan BetterHeart, MD of Good Ireland Hospital signed at April 16, 2011, 11:30:26		
Document maintained by	Good Ireland Hospital		

**Figure 34: Rendered CDA Header**

The HL7 V2 message in xml format can also be rendered but the limitation is that an application is required to render the message as there is no inbuilt reference to standard stylesheets.

### 6.2.2.3. Medical Information Elements

The CDA body consists of the medical information elements which include the following sections:

1. History of present illness
2. Hospital course
3. Discharge diagnosis
4. Allergies and adverse reactions
5. Discharge medication
6. Discharge studies summary
7. Family history
8. Plan of care

The CDA body can be either structured or non-structured in the case of the discharge summary for this study the body consists of a structured body element which includes the above mentioned sections.

Each section requires structured textual information and optional entries.

Entries are RIM based structures based on the concept of 'Clinical Statements' allowing the coding of such entries providing machine processable information.

The entries which will be analyzed in detail are the most critical difference in relation to semantic interoperability between the CDA and the V2 message.

**The DG1 segment of the V2 message consists of the patient's primary diagnosis information. The DG1 segment and the NTE segment are the two segments that transfer clinical data in relation to the discharge summary. As repeating segments are not supported by HealthLink(Healthlink, 2011) the primary diagnosis is recorded in the DG1 segment and all other clinical data is recorded as a text blob in the NTE.3 field.**

Figure 35 below shows the data captured, DG1.1 indicated the set id numbering in this case one as there are no repeating segments supported. The DG1.3 segment contains the code for the diagnosis, the text for the diagnosis and the coding system. I have used the Snomed CT coding system

here as an example but it is more usual to provide either an ICD10 code if available or just the text in the DG1.4 segment.

The general practice messaging standard recommends the use of the optional date and time of the diagnosis as seen in DG1.5 below and also the stage of diagnosis DG1.6 in this instance F for final diagnosis. The consultant responsible for the diagnosis is also recorded.

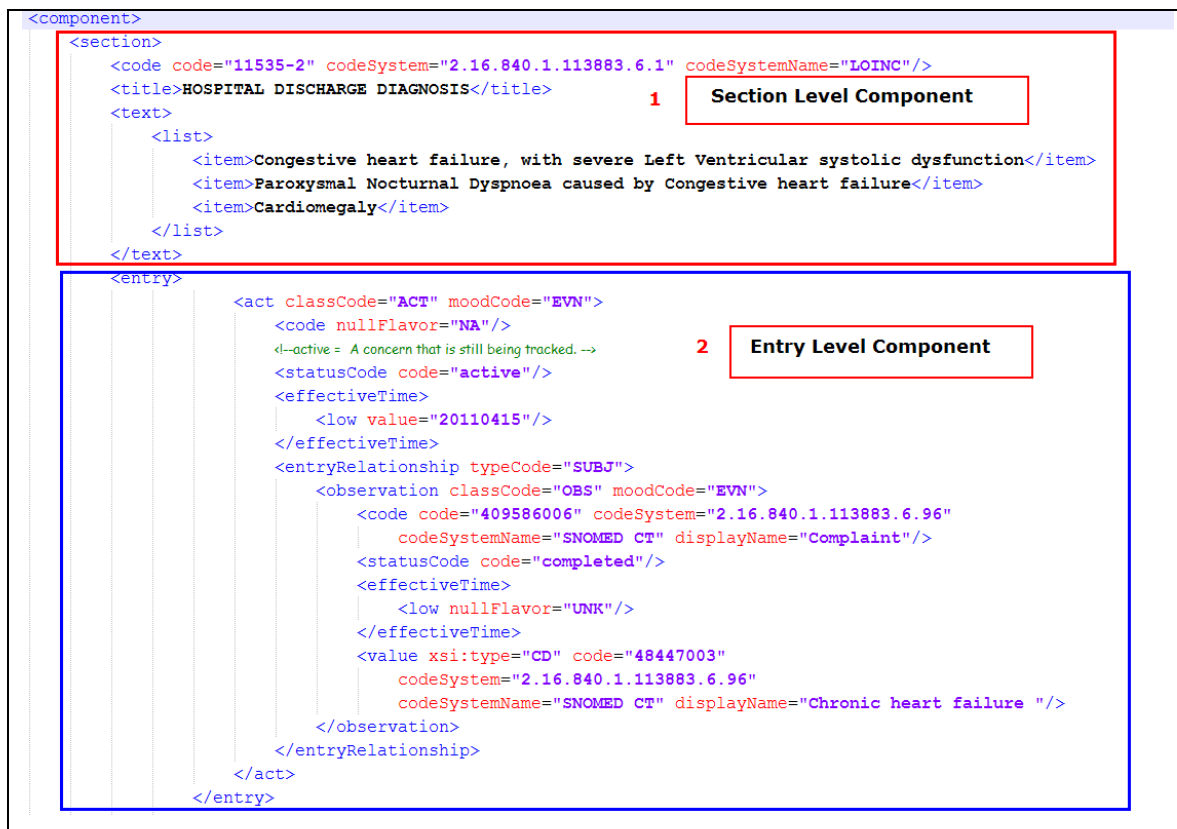
```
<DG1>
  <DG1.1>1</DG1.1>
  <DG1.3>
    <CE.1>48447003</CE.1>
    <CE.2>Chronic heart failure</CE.2>
    <CE.3>SNOMED CT</CE.3>
  </DG1.3>
  <DG1.5>
    <TS.1>20110415000000</TS.1>
  </DG1.5>
  <DG1.6>F</DG1.6>
  <DG1.16>
    <XCN.1>KP00017</XCN.1>
    <XCN.2>
      <FN.1>BetterHeart</FN.1>
    </XCN.2>
    <XCN.3>Alan</XCN.3>
    <XCN.4>TK</XCN.4>
    <XCN.5>MD</XCN.5>
    <XCN.6>Mr</XCN.6>
  </DG1.16>
</DG1>
```

**Figure 35: DG1 Segment**

**The body of the CDA is composed of components; each component consists of a section and optional entries,**

**Figure 36 shows the hospital discharge diagnosis component. The red outlined section represents the component section which represents the textual information that will be rendered in a browser, the human readable portion consisting of the title and text see**

Figure 37 below for the rendered view.



**Figure 36: CDA body component**

The blue outlined section represents the entry which is based on the Reference Information Model and represents the software processable equivalent to the textual section. In chapter 2 the CDA's incremental semantic interoperability was discussed, it is these entry level components that were being referred to. As these entries are optional it is possible for an implementation to ignore these initially, then over time by adding these entries incrementally enhancing semantic interoperability and the information exchange process.

### **The entry section in**

Figure 36 above is based on the concept of clinical statements which describe clinical information relevant to the care of the patient. The entry type is Act which is intended to contain information about generic clinical activities and has a moodCode 'EVN' which relates that this statement is about an actual



event that occurred. The status code is active indicating that this condition is still being tracked. The effectiveTime indicates the time this condition was observed. This clinical statement is linked to an observation entry by means of the ActRelationship class; in this case the ActRelationship type is 'SUBJ' used to relate this act with the observation event. Note that the code and value that specify the condition are coded in Snomed CT, other clinical concept codes or local codes can also be used here.

### HOSPITAL COURSE

**Mrs Mary Shamrock** was admitted to the Good Irish Hospital Ward 1 on the 04 April 2011 for a 6 day period

On admission an electrocardiogram was preformed and was consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST T abnormalities, suggestive of ischemia. A chest X-ray was consistent with cardiomegaly.

Mr Alan Betterheart the cardiac consultant reviewed the patient and commenced her on the following medication

Aspirin 325mg / day, Spirinolactone 50 mg p.o. daily, Lisinopril 20 mg p.o. daily , which has been well tolerated.

He has discussed the need to perform an electrophysiology study, and depending on the results, may proceed with ICD implantation.

the patient has agreed to an electrophysiology study, and will return to outpatients in 2 weeks.

### HOSPITAL DISCHARGE DIAGNOSIS

- Congestive heart failure, with severe Left Ventricular systolic dysfunction
- Paroxysmal Nocturnal Dyspnoea caused by Congestive heart failure
- Cardiomegaly

### ALLERGIES AND ADVERSE REACTIONS

Substance	Reaction
Penicillin	Hives
Codeine	Itching and nausea

**Figure 37: CDA body component rendered in browser**

**The model of the clinical data in the entries along with terminology models like Snomed CT defining the meaning of the data enhances semantic interoperability as compared to the flat V2 message structure which provides more functional interoperability.**

Figure 37 above shows the information view as rendered in a browser with no intervention therefore enabling human semantic interoperability without the need for a specific application.

**As mention previously the message consists of the DG1 segment that has just been reviewed and NTE segment which is the recommended segment for the clinical data.**

Figure 38 below shows the NTE.3 segment consists of the patient's clinical data.

<p>&lt;NTE.3&gt;Admission History:Mrs Mary Shamrock a 50 year old female was admitted to Good Irish Hospital Ward 1 on the 04 April 2011 for cardiac evaluation following a 6 month history of sleep problems associated with breathing difficulties.One month ago Mrs Shamrock symptoms became worse where she gradually started having significant symptoms of heart failure, including episodes of nocturnal dyspnoea, palpitations, racing heartbeat, and occasional dizziness.</p> <p>Hospital Course:Mrs Mary Shamrock was admitted to the Good Irish Hospital Ward 1 on the 04 April 2011 for a 6 day period. On admission an electrocardiogram was preformed and was consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST T abnormalities, suggestive of ischemia.</p> <p>A chest X-ray was consistent with cardiomegaly.Mr Alan BetterHeart the cardiac consultant reviewed the patient and commenced her on the following medication Aspirin 325mg / day, Spirinolactone 50 mg p.o. daily, Lisinopril 20 mg p.o. daily , which has been well tolerated. He has discussed the need to perform an electrophysiology study, and depending on the results, may proceed with ICD implantation. The patient has agreed to perform an electrophysiology study, and will return to outpatients in 2 weeks.</p>	
<p>Allergies and Reactions:Penicillin - Hives were the reaction to this drug</p> <p>Allergies and Reactions:Codeine - Itching and nausea</p>	Allergies and Reactions
<p>Medications:Spirinolactone 25 mg p.o. daily</p> <p>Medications:Aspirin 81 mg p.o. daily</p> <p>Medications:Lisinopril 20 mg p.o. daily</p> <p>Medications:Tylenol 500 mg p.r.n. for pain</p>	Medications
<p>Electrocardiogram (ECG):Mrs Shamrock ECG at the time of admission is consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST abnormalities, suggestive of ischemia.</p> <p>Chest X-ray:Consistent with cardiomegaly.</p> <p>Laboratory:RBC: 4.15 10<sup>12</sup>/L</p> <p>Laboratory:Haemoglobin: 12.2 g/dl</p> <p>Laboratory:Serum glucose: 5.00mmol/L</p> <p>Laboratory:Serum creatinine: 68umol/L</p>	Laboratory Information
<p>Secondary Diagnosis:Paroxysmal Nocturnal Dyspnoea caused by Congestive heart failure</p> <p>Secondary Diagnosis:Cardiomegaly</p> <p>Family History:Father had fatal MI in his early 50's.</p> <p>Treatment Plan:Continue on medications and outpatients visit organised for Mrs Shamrock to attend for electrophysiology study in 2 weeks to determine the next course of action.</p>	
</NTE.3>	

**Figure 38: NTE Segment**

The clinical data is stored as a text blob of data which consists of patient hospital course, allergy and reaction information, medications, secondary diagnosis and family history information. This information is unable to be formatted in any suitable fashion as it is contained within one XML tag and it is these tags that are used to design stylesheets to enable formatting. Given the fact that that most general practitioner consultations are approximately 10 minutes the data provided here is not easily deciphered. Another issue is the inability to reuse this data or integrate this data automatically with the

general practice software systems. Presently medication information is being manually transcribed into the general practice systems by general practitioners on a weekly basis which is both time consuming, expensive and prone to transcription errors (Callen et al., 2010).

**Three areas of information have been highlighted in**

Figure 38 above, these include:

- Allergies and Reactions
- Medications
- Laboratory information

With regard to laboratory information it can be seen that this data requires more contextual information to accurately interpret this data however as there are different message types that transfer laboratory information presently this area will not be included in the evaluation.

**Information regarding patient allergies and reactions are critical in relation to patient safety. The textual information provided see Figure 38 above not only states the allergen substances but also the reactions produced. Regarding human semantic interoperability it can be seen that the lack of formatting reduces the user's ability to read this information, even for this study it was deemed necessary to highlight these areas to the reader.**

Figure 37 above shows the same information as rendered by the CDA in a browser window, the information is clearly visible at a glance and links are also provided to each section by a menu.

**The CDA clinical statement entry can be seen in**

**Figure 39 below, which consists of two observation entries representing the allergies and reactions. The entry type is observation and the actRelationship is of type 'MFST' which is used in this case to relate that hives were a manifestation of having an allergy to penicillin. The second example as seen in**

Figure 38 in green shows the use of qualifiers for a value where the value is 'allergic reaction to drug' and the qualifier specifies the causative agent to be codeine. These examples provide an insight to the level of complexity that

can potentially be provided by employing the CDA as a model for discharge summaries.

```

<entry>
  <observation classCode="OBS" moodCode="EVN">
    <code code="84100007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="history taking (procedure)"/>
    <value xsi:type="CD" code="247472004" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Hives"/>
    <entryRelationship typeCode="MFST">
      <observation classCode="OBS" moodCode="EVN">
        <code code="84100007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="history taking (procedure)"/>
        <value xsi:type="CD" code="91936005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Allergy to penicillin"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <code code="84100007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="history taking (procedure)"/>
    <value xsi:type="CD" code="32738000" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Pruritis"/>
    <entryRelationship typeCode="MFST">
      <observation classCode="OBS" moodCode="EVN">
        <id root="2.16.840.1.113883.19.25.47"/>
        <code code="84100007" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="history taking (procedure)"/>
        <value xsi:type="CD" code="62014003" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Adverse reaction to drug">
          <qualifier>
            <name code="246075003" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="causative agent"/>
            <value code="1476002" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="codeine"/>
          </qualifier>
        </value>
      </observation>
    </entryRelationship>
  </observation>
</entry>

```

**Figure 39: CDA Allergies entry**

**The NTE.3 segment contains the medication information see highlighted section in**

Figure 38 above. The medication information consists of the drug name, dose, route and frequency. The level of semantic interoperability on either a human or computable level is limited due to both the lack of structure to enable rendering the message and a semantic model to ensure the unambiguous exchange of information at a system level.

Figure 40 below shows the substance administration entry section of the CDA body.

The substance administration statement captures medication-related information based on administration of medication. The supply class represents dispensing and can be related to the substance administration

class if required. Coded entries are used to specify the medication and route of administration. The effectiveTime attribute specifies the timing of administration and uses the data type 'GTS' general timing specification, the 'PIVL\_TS' represents a periodically recurring time interval in this case every twenty four hours or once daily. Clinical statements can have participations in this case the consumable participation is used to describe the administered substance. The Snomed CT terminology set has been used here but local sets can be used e.g. RxNorm which is a standardized nomenclature for clinical drugs and drug delivery devices used especially in the USA.

```
<entry>
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <code code="225426007" codeSystem="2.16.840.1.113883.6.96" displayName="Administration of therapeutic substance">
      <qualifier>
        <name code="410675002" displayName="Route of administration"/>
        <value code="26643006" displayName="Oral route"/>
      </qualifier>
    </code>
    <effectiveTime xsi:type="PIVL_TS">
      <period value="24" unit="h"/>
    </effectiveTime>
    <doseQuantity value="1"/>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="370166004" codeSystemName="SNOMED CT" codeSystem="2.16.840.1.113883.6.96" displayName="Aspirin 325mg tablet"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

**Figure 40: CDA medications section**

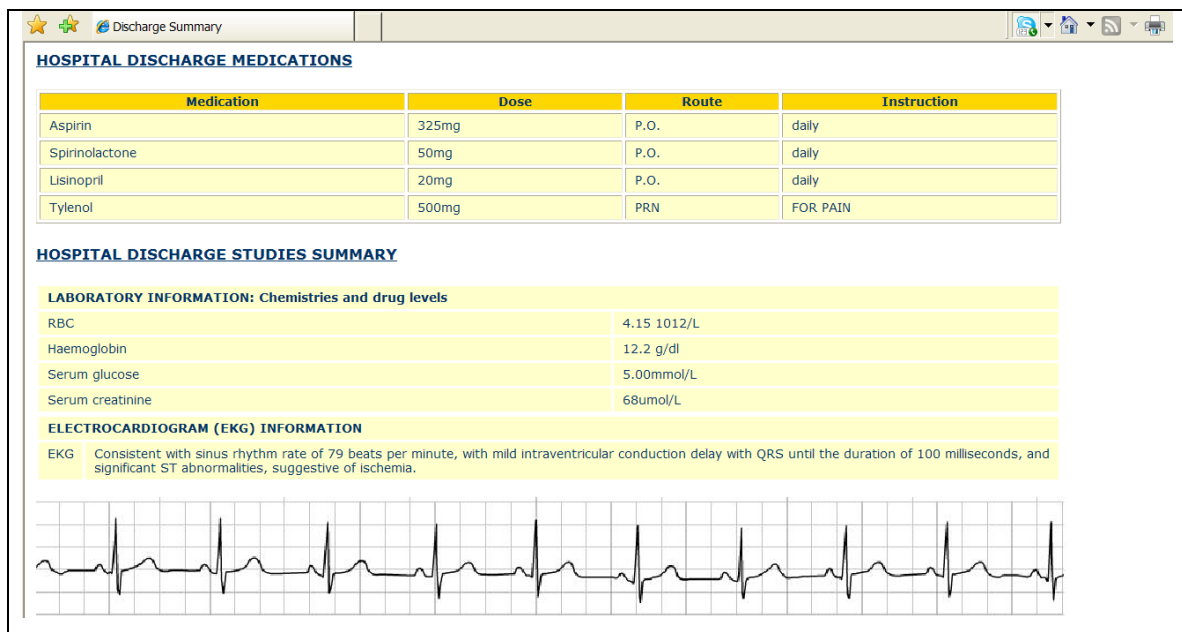
The entries consist of a terminology model Snomed CT and information model R-MIM and datatypes which together provide the semantic structure to enable the computer processable information to be exchanged between systems.

**The medications section narrative block can be seen in Figure 41 below. These narrative blocks are one of the key components of CDA and contains the human readable content of the section. The Section.text includes xml markup in this case table data to enable the rendering of the medication data in tabular form.**

Figure 42 below shows the medication information as rendered by the CDA in a browser window in tabular format.

```
<component>
  <section>
    <code code="10160-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>HOSPITAL DISCHARGE MEDICATIONS</title>
    <text>
      <table border="1" width="100%">
        <thead>
          <tr><th>Medication</th>
            <th>Dose</th>
            <th>Route</th>
            <th>Instruction</th></tr>
          <tr><td>Aspirin</td>
            <td>325mg</td>
            <td>P.O.</td>
            <td>daily</td></tr>
          <tr><td>Spirinolactone</td>
            <td>50mg</td>
            <td>P.O.</td>
            <td>daily</td></tr>
          <tr><td>Lisinopril</td>
            <td>20mg</td>
            <td>P.O.</td>
            <td>daily</td></tr>
          <tr><td>Tylenol</td>
            <td>500mg</td>
            <td>PRN</td>
            <td>FOR PAIN</td></tr>
        </thead>
      </table>
    </text>
  </section>
</component>
```

**Figure 41: CDA Medication Text section**



**Figure 42: CDA Medications rendered**

## 6.3. Study Evaluation

### 6.3.1. Study evaluation criteria

In order to properly evaluate this comparative study it is important to restate the goals that were defined at the outset.

The primary goal of this study was to assess whether the current HL7 v2.4 message (REF\_I12) as recommended by the general practice messaging standard (Health Information and Quality Authority, 2010) provided a semantically interoperable structure to exchange patient information for discharge summaries.

The secondary goal was to investigate whether the HL7 v3 Clinical Document Architecture could potentially provide a more scalable and semantically interoperable structure to exchange patient information for discharge summaries.

### **6.3.2. Human semantic interoperability**

As stated previously human semantic interoperability guarantees that the meaning and structure of the data can be exchanged unambiguously between humans.

#### **6.3.2.1. Suitability of the HL7 V2.4 xml (REF\_I12) message to provide human semantic interoperability**

Before considering human semantic interoperability it must be stated an assumption is made that the human viewers of the discharge summary information should have the required medical knowledge to understand and interpret the information. Based on that assumption the visual appearance and visual structure of the data is important for the usability of this information. As stated by the ISO usability standard for products (ISO, 1998) the important features of any user interaction with a product are effectiveness, efficiency and satisfaction.

These heuristics provide important criteria to evaluate the suitability of the HL7 v2 (REF\_I12) message in terms of human semantic interoperability. Consider efficiency which relates to the time spent by a skilled user to complete a task and achieve a specified goal. The discharge summary contains summary information required by the general practitioner to enable continuity of care for the patient post hospital discharge. As each general practitioner consultation is constrained by time the task for the general practitioner is to assimilate the information provided by the discharge summary to enable the correct and safe care of the patient. The electronic transmission of the v2 message ensures that the information is available, but is it readable?

**In the context of the consultation the data provided in an unstructured text blob would hinder readability. Constantine and Lockwood (Constantine et al., 2000) provided a set of five rules of usability which included the access rule, efficacy rule, progression rule, support rule and the context rule. In**



**this case 'the context rule' would relate to the need for the message to be easily readable in the operational context of the surgery which is definitely questionable. The support rule refers to the fact that the system should support real work by making it simpler, faster, easier and more fun. These attributes cannot be achieved by the discharge message in this format. Microsoft Word, PDF and HTML to name but a few were developed to enable data to be formatted in specific ways to ensure the above rules could be attained. As**

Figure 38 showed above the entire clinical content is contained within one segment and therefore one xml tag. It is possible to develop an application to render the header and patient demographic information using style sheets however it is not possible for the clinical data as there is only one tag. Currently information is being pre pended with textual visual cues e.g. Medications, Allergies etc. to improve the readability of the data. Imagine a patient with comorbidity on multiple medications and complex history, as the amount of clinical information required in the transfer increased there would be a subsequent decrease in the ability to render the information guaranteeing readability. It can then be seen that in the case of high risk patients with comorbidity there is a potential reduction in the level of human semantic interoperability that can be achieved by this standard in this format. The reduction in the effectiveness of this standard especially for at risk patients considerably reduces its level of usability, suitability and in turn user satisfaction.

From the analysis performed in this study it would appear that the HL7 v2 message (REF\_I12) in use for discharge summaries is not an entirely suitable structure to be used for discharge summaries in relation to human semantic interoperability.

An initial recommendation would be to utilise the repeating segments for each section of clinical information so that formatting could be achieved using style sheets by the receiving application.

#### **6.3.2.2. Suitability of the HL7 v3 CDA to provide human semantic interoperability**

The secondary goal of this study was to evaluate the suitability of the HL7 v3 CDA to provide semantic interoperability for discharge summaries.

As both computer and human semantic interoperability are being evaluated we will firstly evaluate human semantic interoperability.

The evaluation like above will be based on the usability heuristics namely ISO usability features of effectiveness, efficiency and satisfaction(ISO, 1998).

In relation to effectiveness the CDA has been shown to be very effective as a document structure. Given the same goal as above where a clinician needs to review a patient within certain time constraints the layout of the CDA provides a more usable structure. The clinical data is divided into headed sections and each section can be directly referenced by the use of html links. This level of formatting would greatly increase the efficiency in which the clinician could review the patient discharge information. In the case of at risk patients with comorbidity where there is a significant increased in the quantity of information the CDA document structure would provide more visually structured information and therefore consistently providing human semantic interoperability.

As the CDA information can be easily filtered using a HTML menu system human semantic interoperability can be guaranteed in this case. The CDA document was designed to be a standalone artifact whose initial purpose was to convey human understanding. The meaning as perceived by the reader is paramount even when the information is backed with computable processable information. One of the main motivations behind the creation of XML was to enable the human readable persistence of information.

It is clear from the analysis of the document structure that the HL7 v3 CDA is a suitable structure to be used for discharge summaries in relation to human semantic interoperability.

### **6.3.3. Semantic interoperability**

Semantic interoperability has been defined as the ability of information shared by systems to be meaningfully interpreted and incorporated into the receiving system. The heuristics that were used for this evaluation in terms of computer semantic interoperability as stated above were based on Mead's four pillars of computable semantic interoperability (Mead, 2006):

1. A common model across domains of interest
2. Model based on robust data type specification
3. Methodology for binding terms from concept based terminologies to elements of the model
4. A formal process for defining specific structures to be exchanged between machines.

#### **6.3.3.1. Suitability of the HL7 V2.4 xml (REF\_I12) message to provide computable semantic interoperability**

The main reasoning behind the development of HL7 v3 was the growing awareness that v2 could not meet the growing requirements of computable semantic interoperability. As the number of systems and the scope of the message in an exchange increase so to does the number of interfaces and the scalability of such systems became costly and unmanageable.

Firstly v2 lacks a common information model that spans the domains of interest. In this instance the domain of interest is clinical information regarding patient discharge information. This is the most critically important requirement to achieve the goal of computable semantic interoperability.

The lack of an information model causes inconsistencies within the standard and difficulties understanding how message elements relate to each other. At an inter-organizational level the use of locally defined data semantics exposes conflicts and weaknesses also. When considering the challenges and complexity of the data that is required to be exchanged in the discharge

summary the HL7 v2 message format is unable to achieve computable semantic interoperability.

As the discharge summary involves data exchanges at an inter-organizational level the message format is not suited to these types of data exchange.

The HL7 V2 message lacks a robust datatype specification the data model is only implied but not enforced by the standard.

It must be noted that there is an ability to restrict specific message sets especially those containing quantitative data e.g. laboratory data, to achieve a level of bounded computable semantic interoperability. It is for this reason that the laboratory data was not evaluated as part of the discharge summary message.

**The v2 message has the ability to use controlled vocabularies however it lacks a robust infrastructure for binding these concept-based terminology values to any of the specific message elements.**

Figure 35 above shows the DG1 segment for patient primary diagnosis, this is a good example of the ability of the message to use terminology sets however the information is not bound to any message elements and there is a lack of information regarding whether the diagnosis is final or still in progress.

The V2 message was developed in an ad-hoc manner with no explicit model, or development process.

Overall based on the applied heuristics it can be seen that the HL7 v2 REF\_I12 message is not designed for inter-organizational exchange and therefore is not the most suitable standard to provide computable semantic interoperability on any scale.

#### **6.3.3.2. Suitability of the HL7 v3 CDA to provide computable semantic interoperability**

The HL7 v3 CDA from the analysis has demonstrated the four heuristics in relation to computable semantic interoperability. The CDA is based on a refined version of the RIM (R-MIM) providing a common information model which defines the semantics of different clinical domains. An example of this from the analysis is the transfer of allergy and reaction information across inter-organisational boundaries. The information is declared by the Act class and further specialized by the Observation class enabling relationships to be drawn from the information by the actRelationship class. The information represented the fact that the patient was allergic to penicillin and that the manifestation of this reaction was hives. The RIM with the help of terminology sets provided the semantic structures to enable this exchange which would not be possible in V2. The use of terminology sets therefore can be seen to play an important part in achieving semantic interoperability. From the literature review it was seen that the transfer of accurate medication information is critical to the safety of patients. A number of studies have investigated medication discrepancies at transition points in care and have found that inaccuracy in medication information can compromise quality of care (Grimes et al., 2008, Moore et al., 2003, Coleman et al., 2005).

The provision of the substanceAdministration clinical statement as described above enables the capture and transfer of medication information involving interrelationships between other classes. Prescription information can also be represented by using the administration statement and the supply statement. The attributes of the clinical statements are bound to specific datatypes providing unambiguous semantics for each data element transferred. The HSE National Discharge Planning report in 2008 (HSE National Integrated Discharge Planning Steering Committee, 2008) included information on medications as a requirement for patient discharge. This requirement can be achieved on both a human and computer semantic interoperable level with the HL7 v3 CDA.

The HL7 v3 CDA has shown to be a suitable standard for discharge summaries and provides a suitable standard for inter-organisational clinical data exchange as required by the discharge summary.

#### **6.3.4. Summary**

This chapter has conducted a comparative analysis and evaluation on the HL7 v2 REF\_I12 message and the HL7 v3 CDA in relation to their ability to transfer discharge summary information.

It was seen that at a functional level both standards could transfer data however using the heuristics on usability and semantic interoperability it became apparent that the HL7 v2 CDA provided a more robust and scalable solution for discharge summaries.

It must be noted however that this analysis only considered the HL7 v2 REF\_I12 as specified by the general practice messaging standard. The author is aware that other implementations of this message type by other bodies would differ and are not being referred to by this analysis.

## **Chapter 7. Conclusion**

The aim of this research study was to investigate the HL7 V2 REF I12 message based on the General Practice Messaging Standard (GPMS) and establish if the standard provided a semantically interoperable solution for the transfer of discharge summaries from secondary care to primary care. An alternate standard the HL7 V3 CDA was analysed and evaluated to establish if it could provide a more scalable and semantically interoperable solution.

The research question queried:

*Is the current HL7 v2.4 discharge summary message a semantically interoperable solution or would the HL7 v3 Clinical Document Architecture provide a more scalable and semantically interoperable solution for discharge summaries in the Irish context?*

## **7.1. Summary of research**

Initially the importance of the discharge summary document was identified in relation to the overall longitudinal electronic health record of a patient. Specific challenges were identified in relation to the electronic discharge summary in relation to semantic interoperability at transition points in the care pathway. Key research questions were highlighted and addressed as part of this study.

The literature review highlighted the history of the discharge summary document over the past three decades and its progression from an illegible hand written letter that could take anything up to 180 days to reach the primary care providers to the electronic discharge summaries of today that can be electronically transferred in seconds.

Research highlighted that transition points in relation to continuity of patient care required extra attention in relation to the quality of information.



Continuity of care was seen as playing a major role in the safety of the patient.

To ensure the timely and accurate transfer of healthcare data it was recognised that standards were required to enable communication and sharing of quality data with other systems and the end user.

The HL7 international standards were investigated in detail including HL7 v2 and HL7 v3 and the HL7 v3 CDA. The HL7 v3 standard was created out of limitations found with the v2 standard. The main limitation was in relation to the flexibility of the standard and the inherent issues with semantic interoperability.

The study detailed the types of interoperability and the importance of semantic interoperability to enable semantically accurate communication of healthcare data.

HL7 v2 remains a popular standard with the uptake of HL7 v3 slower but gaining momentum. The HL7 v3 CDA has proved to be a very popular starting point in the upgrading from v2 to v3 and is being used worldwide. Five case studies' of countries that implemented the HL7 v3 CDA were detailed providing reasons and experiences of the implementation.

A case study and storyboard detailing a patient's hospital episode were developed, which provided the content for the HL7 v2 REF I12 message and HL7 v3 CDA creation, hence providing the basis for the technical comparative analysis. The study concluded with a technical comparison analysing the similarities and differences between the two discharge summary structures.

## **7.2. Conclusion of research**

Further to the conclusions drawn from the comparative evaluation in chapter 6 the main conclusions of this research are as follows.

The discharge summary is an important document in the patient's journey through the healthcare system and is considered to be the most comprehensive document in the health record. The evidence states that there are substantial implications for the continuity of care, patient safety, patient and clinician satisfaction, were there was inaccuracies in the information transferred or delays in the communication transfer. The discharge summary data needs to be available and utilised for research, as it contains vital information that may enable the identification of at-risk populations.

The HL7 v2.4xml REF I12 message does not provide a semantically scalable interoperable solution for discharge summary clinical data. The HL7 v2 messaging standard was initially developed for the exchange of messages within an organisation. It was found that the design of the discharge summary message was not suited to the loosely coupled nature of inter-organizational exchange and going forward could not provide a suitably scalable solution.

HL7 v2.4 is still an important standard for the exchange of data within an organisation. As message sets can be restricted the HL7 v2 message is particularly suited to exchanging quantitative data for example laboratory data. Laboratory data is being successfully exchanged in Ireland using a bounded level of semantic interoperability.

There is compelling evidence both from the comparative analysis in chapter 6 and also the worldwide acceptance and use of the HL7 v3 Clinical Document Architecture as documented in chapter 3 that the HL7 v3 Clinical Document Architecture R2 provides the architectural capabilities to enable semantic interoperability. The HL7 v3 Clinical Document Architecture provides a scalable interoperable solution to enable the exchange of discharge summary data.

As the HL7 v3 Clinical Document Architecture can be transported as the payload of a HL7 v2 message this could provide a cost effective solution in an Irish context. The HL7 v2 infrastructure could remain in place and the HL7 v3 Clinical Document Architecture initially could be transported as a multimedia object in the OBX segment of the HL7 v2 message.

There is a requirement for formal models to represent the complexity of clinical data. The greater the expressivity of these models, the more a computer can understand the data and act on that data. Formal models are the basis for the HL7 v3 messaging standards and the HL7 v3 Clinical Document Architecture standards and are derived from the HL7 Reference Information Model (RIM). HL7 version 3 messages and Clinical Document Architecture documents are richly expressive, in that they can formally represent the significant depth and breadth of the clinical content.

Semantic interoperability is not a binary state, that is either present or absent, but rather something that can incrementally improve over time given the correct models. This incremental approach can be achieved with the HL7 v3 Clinical Document Architecture. The exchange of health information can start with the minimum required for useful exchange, and then as systems develop the exchange can be improved. Communication is never perfect and semantic interoperability is the ultimate goal on this journey.

The adoption and consistent use of standards is particularly important, to facilitate the national interoperability of healthcare IT systems. The following categories of standards are required:

1. Data content standards e.g. Snomed CT, ICD 10, ICPC 2
2. Information content standards e.g. HL7 v3 RIM
3. Information exchange standards e.g. HL7 messaging
4. Identifier standards e.g. OID, National identifier
5. Privacy and security standards

The overall conclusion of this study is the significant need to address the structure of the discharge summary message. The HL7 v3 CDA provides a solution that is both scalable and semantically interoperable. It also provides a framework that enables a cost effective initial implementation followed by incremental improvements overtime.

### **7.3. Limitations of the study**

The main limitation of this study was that it focused primarily on HL7 as a solution for Ireland. The other standards were reviewed but a detailed comparative analysis using HL7, OpenEHR or ISO EN13606 would have been out of the scope of this study.

The HL7 v3 CDA was deemed the best solution initially due to the fact that the HL7 standards are the standard of choice currently in use in Ireland and also due to the current budgetary limitations on the Irish health sector a cost effective solution was required.

Ideally it would have been interesting to investigate the harmonisation efforts in relation to the embedding of archetypes into the CDA structure. This was however deemed out of the scope of this study but could pose some interesting work for the future.

### **7.4. Recommendations and future work**

Considering that the adoption and consistent use of standards is particularly important, to facilitate the national interoperability of healthcare IT systems. To fully utilise these standards a number of key requirements need to be addressed:

There is a need for the adoption of a national data content standard for use within all healthcare systems.

There is a need for further research into countries that provide incentives for general practices to improve the coding of diseases in their patient records. The compulsory auditing of these practices may provide an initial answer.

There is an urgent need for the introduction of a unique health identifier the importance of which can be seen especially when considering national interoperability.

A unique identification strategy to identify healthcare professionals as part of a nationwide should be introduced. A further identification strategy is also required for healthcare institutions. Object Identifiers could be one potential solution that would need further research.

There is a need for a national strategy for the creation or implementation of a dictionary containing unique identifiers and associated textual descriptions for medicines and medical devices. The dictionary of medicines and devices that has been developed for use throughout the NHS may be a good starting point for this research.

Further work is required in relation to the development of CDA templates; this would include the creation of templates to restrict the discharge summary for use within Ireland.

Document repositories are being used to store the CDA, as they are persistent records that can overtime provide a representation of the electronic patient record. It may be beneficial to investigate the use of these repositories in relation to the identification of at risk populations.

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## Appendix 1: HL7 International Certificate



## Appendix 2: HL7 2.4xml message

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      <XPN.3>JR</XPN.3>
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        <SAD.2>Seatown Place, Blackrock</SAD.2>
        <SAD.3>Dublin</SAD.3>
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</XCN.2>
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    <XCN.5>MD</XCN.5>
    <XCN.6>Dr</XCN.6>
  </PV1.7>
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    <XCN.4>TK</XCN.4>
  </PV1.9>

```



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 <XCN.6>Mr</XCN.6>  
 </PV1.9>  
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 </PV1.45>  
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 </PV1>  
 </REF\_I12.PATIENT\_VISIT>  
 <NTE>  
 <NTE.1>1</NTE.1>  
 <NTE.3>Admission History: Mrs Mary Shamrock a 50 year old female was admitted to Good Irish Hospital Ward 1 on the 04 April 2011 for cardiac evaluation following a 6 month history of sleep problems associated with breathing difficulties. One month ago Mrs Shamrock symptoms became worse where she gradually started having significant symptoms of heart failure, including episodes of nocturnal dyspnoea, palpitations, racing heartbeat, and occasional dizziness.  
 Hospital Course: Mrs Mary Shamrock was admitted to the Good Irish Hospital Ward 1 on the 04 April 2011 for a 6 day period. On admission an electrocardiogram was preformed and was consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST T abnormalities, suggestive of ischemia. A chest X-ray was consistent with cardiomegaly. Mr Alan BetterHeart the cardiac consultant reviewed the patient and commenced her on the following medication Aspirin 325mg / day, Spirinolactone 50 mg p.o. daily, Lisinopril 20 mg p.o. daily , which has been well tolerated. He has discussed the need to perform an electrophysiology study, and depending on the results, may proceed with ICD implantation. The patient has agreed to perform an electrophysiology study, and will return to outpatients in 2 weeks. Allergies and Reactions: Penicillin – Hives were the reaction to this drug

Allergies and Reactions: Codeine - Itching and nausea

Medications: Spironolactone 25 mg p.o. daily

Medications: Aspirin 81 mg p.o. daily

Medications: Lisinopril 20 mg p.o. daily

Medications: Tylenol 500 mg p.r.n. for pain

Electrocardiogram (ECG): Mrs Shamrock ECG at the time of admission is consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST abnormalities, suggestive of ischemia.

Chest X-ray: Consistent with cardiomegaly.

Laboratory: RBC: 4.15 10<sup>12</sup>/L

Laboratory: Haemoglobin: 12.2 g/dl

Laboratory: Serum glucose: 5.00mmol/L

Laboratory: Serum creatinine: 68umol/L

Secondary Diagnosis: Paroxysmal Nocturnal Dyspnoea caused by Congestive heart failure

Secondary Diagnosis: Cardiomegaly

Family History: Father had fatal MI in his early 50's.

Treatment Plan: Continue on medications and outpatients visit organised for Mrs Shamrock to attend for electrophysiology study in 2 weeks to determine the next course of action.

</NTE.3>

</NTE>

</REF\_I12>

### Appendix 3: CDA document

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hl7-org: v3 CDA.xsd">

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5" displayName="DISCHARGE SUMMARIZATION NOTE"/>

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      <streetAddressLine>Blackrock</streetAddressLine>

      <city>Dublin</city>

      <county>Dublin</county>

      <country>Ireland</country>
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        </addr>

        <telecom value="tel:(01) 4223355"/>

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            <given>Kate</given>

            <family>Shamrock</family>

            <suffix>Mrs</suffix>

        </name>

        <administrativeGenderCode code="F"

            codeSystem="2.16.840.1.113883.5.1"/>

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    </patient>

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    </providerOrganization>

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    <time value="2000040714"/>

    <assignedAuthor>

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    <family>Sample</family>

    <suffix>MD</suffix>

  </name>

</assignedPerson>

<representedOrganization>

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  <name>Good Ireland Hospital</name>

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</assignedAuthor>

</author>

<custodian>

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            <given>Alan</given>

            <family>BetterHeart</family>

            <suffix>MD</suffix>

        </name>

    </assignedPerson>

    <representedOrganization>

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    </representedOrganization>

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    codeSystemName="HL7 RoleCode" displayName="husband"/>

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</addr>

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<suffix>Mr</suffix>

</name>

</associatedPerson>

</associatedEntity>

</participant>

<componentOf>

<encompassingEncounter>

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</effectiveTime>

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</encompassingEncounter>

</componentOf>

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CDA Body

\*\*\*\*\*

-->

<component>

<structuredBody>

<!--

\*\*\*\*\*

History of Present Illness section

\*\*\*\*\*

-->

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<title>HISTORY OF PRESENT ILLNESS</title>

<text><paragraph>

<content styleCode="Bold">Mrs Mary Shamrock </content>is a 50 year old female was  
admitted to Good Irish Hospital Ward 1 on the 04 April 2011 </paragraph>

<paragraph>for cardiac evaluation following a 6 month history of sleep problems  
associated with breathing difficulties.</paragraph>

<paragraph>One month ago Mrs Shamrock symptoms became worse where she  
gradually started having significant symptoms of heart failure, </paragraph>



<paragraph>including episodes of nocturnal dyspnoea, palpitations, racing heartbeat, and occasional dizziness.</paragraph>

</text>

</section>

</component>

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\*\*\*\*\*

## HOSPITAL COURSE

\*\*\*\*\*

-->

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<section>

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codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<title>HOSPITAL COURSE</title>

<text>

<paragraph><content styleCode="Bold">Mrs Mary Shamrock </content> was admitted to the Good Irish Hospital Ward 1 on the 04 April 2011 for a 6 day period</paragraph>

<paragraph>On admission an electrocardiogram was preformed and was consistent with sinus rhythm rate of 79 beats per minute,</paragraph>

<paragraph>with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds,</paragraph>

<paragraph>and significant ST T abnormalities, suggestive of ischemia. A chest X-ray was consistent with cardiomegaly.</paragraph>

<paragraph>Mr Alan Betterheart the cardiac consultant reviewed the patient and commenced her on the following medication </paragraph>

<paragraph>Aspirin 325mg / day,Spirinolactone 50 mg p.o. daily,Lisinopril 20 mg p.o. daily , which has been well tolerated.</paragraph>

<paragraph>He has discussed the need to perform an electrophysiology study, and depending on the results, may proceed with ICD implantation.</paragraph>

<paragraph>the patient has agreed to an electrophysiology study, and will return to outpatients in 2 weeks.</paragraph>

</text>

</section>

</component>

<!--

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#### Hospital Discharge Diagnosis

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<component>

<section>

<code code="11535-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<title>HOSPITAL DISCHARGE DIAGNOSIS</title>

<text><list>

<item>Congestive heart failure, with severe Left Ventricular systolic dysfunction</item>

<item>Paroxysmal Nocturnal Dyspnoea caused by Congestive heart failure</item>

<item>Cardiomegaly</item>

</list></text>

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    <effectiveTime>

        <low nullFlavor="UNK"/>

    </effectiveTime>

    <value xsi:type="CD" code="48447003"
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displayName="Chronic heart failure "/>

</observation>

</entryRelationship></act></entry><entry>

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        </effectiveTime>

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<code code="409586006"
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Allergies & Adverse Reactions section

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<title>ALLERGIES AND ADVERSE REACTIONS</title>

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        <item>Codeine - Itching and nausea</item>

</list></text>

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*****

HOSPITAL DISCHARGE MEDICATIONS section

*****

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<item>Aspirin 325mg / day</item>

<item>Spirinolactone 50 mg p.o. daily</item>

<item>Lisinopril 20 mg p.o. daily</item>

<item>Tylenol 500 mg p.r.n. for pain</item>

</list></text>

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<value code="26643006" displayName="Oral route"/>

</qualifier>

</code>

<effectiveTime xsi:type="PIVL\_TS">



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    </effectiveTime>

    <doseQuantity value="1"/>

    <consumable><manufacturedProduct><manufacturedLabeledDrug>

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</substanceAdministration></entry>

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<text>Spirinolactone 50 mg p.o. daily</text>

<code code="225426007" codeSystem="2.16.840.1.113883.6.96"
displayName="Administration of therapeutic substance">

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    <doseQuantity value="1"/>

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    </substanceAdministration>

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    <substanceAdministration classCode="SBADM" moodCode="EVN">

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        displayName="Administration of therapeutic substance">
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        </qualifier>

        </code>

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        <doseQuantity value="1"/>

        <consumable><manufacturedProduct><manufacturedLabeledDrug>

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</entry>

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<text>Tylenol 500 mg p.r.n. for pain</text>

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displayName="Administration of therapeutic substance">

<qualifier>

<name code="410675002" displayName="Route of administration"/>

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</substanceAdministration>

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</component>

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## Hospital Discharge Studies Summary

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<title>HOSPITAL DISCHARGE STUDIES SUMMARY</title>

<text>

<table>

<tbody>

<tr><td colspan="2"><content styleCode="Bold">LABORATORY INFORMATION:  
Chemistries and drug levels</content></td></tr>

<tr><td>RBC</td><td>4.15 1012/L</td></tr>

<tr><td>Haemoglobin</td><td>12.2 g/dl</td></tr>

<tr><td>Serum glucose</td><td>5.00mmol/L</td></tr>

<tr><td>Serum creatinine</td><td>68umol/L </td></tr>

</tbody>

</table>

<table><tbody><tr><td colspan="2"><content styleCode="Bold">ELECTROCARDIOGRAM (EKG) INFORMATION</content></td></tr>

<tr><td>EKG</td><td>Consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST abnormalities, suggestive of ischemia.

</td></tr></tbody>

</table><renderMultiMedia referencedObject="MM1"/>

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<tbody>tr><td colspan="2"><content styleCode="Bold">CHEST XRAY INFORMATION</content></td></tr>

<tr><td>X-RAY</td><td>Consistent with cardiomegaly.</td></tr>

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<reference value="chest.jpg"/>

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        </observationMedia>

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*****

FAMILY HISTORY section

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    <section>

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codeSystemName="LOINC"/>

        <title>FAMILY HISTORY</title>

        <text><list>

            <item>Father had fatal MI in his early 50's.</item>

        </list></text>

    <entry>

        <observation classCode="OBS" moodCode="EVN">

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            <statusCode code="completed"/>

            <effectiveTime value="1970"/>

            <subject>

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    <relatedSubject classCode="PRS">

    <code code="FTH" codeSystem="2.16.840.1.113883.5.111"/>

    </relatedSubject>

  </subject>

  <entryRelationship typeCode="CAUS">

    <observation classCode="OBS" moodCode="EVN">

      <code code="399347008" codeSystem="2.16.840.1.113883.6.96"
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  </entryRelationship>

</observation>

</entry>

</section>

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*****

Plan section

*****

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<component>

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<title>PLAN OF CARE</title>

<text><list>

<item>Continue on medications</item>

<item>Outpatients visit for electrophysiology study in 2 weeks.</item>

</list></text>

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</section></component>

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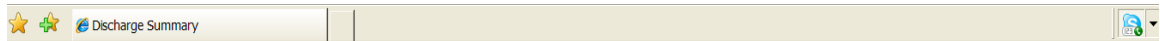
</component>

</ClinicalDocument>

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## Appendix 4: CDA rendered in Windows Internet Explorer 7



### Discharge Summary

<b>Patient</b>	Mary Shamrock, Mrs		
<b>Date of birth</b>	January 22, 1961	<b>Sex</b>	Female
<b>Contact info</b>	34 Irish Town Road Blackrock Dublin, Ireland Tel: (01) 4223355	<b>Patient IDs</b>	1233445 2.16.840.1.113883.2.27.5
<b>Document Id</b>	GIH-12345789 2.16.840.1.113883.2.27		
<b>Document Created:</b>	April 16, 2011, 11:30:26		
<b>Author</b>	Terry Sample, MD, Good Ireland Hospital		
<b>Encounter Id</b>	9937012 2.16.840.1.113883.2.27		
<b>Encounter Date</b>	From April 10, 2011 to April 16, 2011		
<b>Discharge Disposition</b>	Routine Discharge		
<b>Next of kin</b>	Denis Shamrock, Mr		
<b>Contact info</b>	34 Irish Town Road Blackrock Dublin, Ireland Tel: (01) 4223355		
<b>Information recipient:</b>	Dr Tony Medic		
<b>Contact info</b>	3 Seatown Crescent, Blackrock Dublin, Ireland Tel: (01) 3223347		
<b>Legal authenticator</b>	Mr Alan BetterHeart, MD of Good Ireland Hospital signed at April 16, 2011, 11:30:26		
<b>Document maintained by</b>	Good Ireland Hospital		



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- [HOSPITAL COURSE](#)
- [HOSPITAL DISCHARGE DIAGNOSIS](#)
- [ALLERGIES AND ADVERSE REACTIONS](#)
- [HOSPITAL DISCHARGE MEDICATIONS](#)
- [HOSPITAL DISCHARGE STUDIES SUMMARY](#)
- [FAMILY HISTORY](#)
- [PLAN OF CARE](#)

### HISTORY OF PRESENT ILLNESS

**Mrs Mary Shamrock** is a 50 year old female was admitted to Good Irish Hospital Ward 1 on the 04 April 2011

for cardiac evaluation following a 6 month history of sleep problems associated with breathing difficulties.

One month ago Mrs Shamrock symptoms became worse where she gradually started having significant symptoms of heart failure,

including episodes of nocturnal dyspnoea, palpitations, racing heartbeat, and occasional dizziness.

### HOSPITAL COURSE

**Mrs Mary Shamrock** was admitted to the Good Irish Hospital Ward 1 on the 04 April 2011 for a 6 day period

On admission an electrocardiogram was preformed and was consistent with sinus rhythm rate of 79 beats per minute,

with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds,

and significant ST T abnormalities, suggestive of ischemia. A chest X-ray was consistent with cardiomegaly.

Mr Alan Betterheart the cardiac consultant reviewed the patient and commenced her on the following medication

Aspirin 325mg / day, Spirinolactone 50 mg p.o. daily, Lisinopril 20 mg p.o. daily , which has been well tolerated.

He has discussed the need to perform an electrophysiology study, and depending on the results, may proceed with ICD implantation.

Done

HOSPITAL DISCHARGE DIAGNOSIS

- Congestive heart failure, with severe Left Ventricular systolic dysfunction
- Paroxysmal Nocturnal Dyspnoea caused by Congestive heart failure
- Cardiomegaly

ALLERGIES AND ADVERSE REACTIONS

Substance	Reaction
Penicillin	Hives
Codeine	Itching and nausea

HOSPITAL DISCHARGE MEDICATIONS

Medication	Dose	Route	Instruction
Aspirin	325mg	P.O.	daily
Spirinolactone	50mg	P.O.	daily
Lisinopril	20mg	P.O.	daily
Tylenol	500mg	PRN	FOR PAIN

HOSPITAL DISCHARGE STUDIES SUMMARY

LABORATORY INFORMATION: Chemistries and drug levels	
RBC	4.15 1012/L
Haemoglobin	12.2 g/dl
Serum glucose	5.00mmol/L
Serum creatinine	68umol/L
ELECTROCARDIOGRAM (EKG) INFORMATION	
EKG	Consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST abnormalities, suggestive of ischemia.

ELECTROCARDIOGRAM (EKG) INFORMATION

EKG	Consistent with sinus rhythm rate of 79 beats per minute, with mild intraventricular conduction delay with QRS until the duration of 100 milliseconds, and significant ST abnormalities, suggestive of ischemia.
-----	--



CHEST XRAY INFORMATION

X-RAY	Consistent with cardiomegaly.
-------	-------------------------------



FAMILY HISTORY

- Father had fatal MI in his early 50's.

PLAN OF CARE

- Continue on medications
- Outpatients visit for electrophysiology study in 2 weeks.