In search of good health messages: *An investigation of the properties of a messaging standard that makes it useable but generally applicable*

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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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Abstract

The majority of health informatics standards are developed by the International Standards Organization's Technical Committee 215 (TC215) and Comité Européen de Normalisation's Technical Committee 251 (TC251), who have currently published 87 (ISO, 2010c) and 74 (CEN, 2010) standards respectively. In view of this large number of standards it is important to be able to determine which are likely to be successful. The "good" aspects of a standard need to be fully utilised, while the "bad" aspects are clearly identified and used with caution.

This study goes in search of those properties of a messaging standard that make it successful in terms of its usability and applicability (specifically that it's implementable by anyone who wishes to use it for the purpose for which it was intended).

A study was undertaken of 30 ASTM E1394-97 implementations in order to identify the "good" and "bad" features of the standard by assessing the compliance and non-compliance of the chosen implementations. Furthermore these implementations were assessed in terms of compliance with the ISO 18812 that profiles the use of ASTM E1394-97.

An analysis of these findings found that the following features were central to the success of ASTM E1394-97 standard:

- Simplicity
- Use of Language
- Optionality

Furthermore it was found that use of the following improved the quality of the messages and would also help to bring about semantic interoperability:

- Standardised Codes/ Code Sets
- Data Standards
- Data Typing

From the study it was also found that it is important to ensure that messaging standards meet the required functionality demanded of them by systems/devices.

Abbreviations

AI	Analytical Instrument
ASTM	American Society for Testing and Materials
CALM	Clinical Analyser interfaces to Laboratory inforMation systems (project team of CEN TC251)
CCM	Critical Care Medicine
CEN	Comité Européen de Normalisation (European Committee for Standardisation)
CLSI	Clinical and Laboratory Standards Institute
DICOM	Digital Imaging and Communications in Medicine
DMS	Data Management System
EDI	Electronic Data Interchange
GP	General Practitioner
HIQA	Health Information and Quality Authority
HL7	Health Level Seven
HSE	Health Service Executive
IBM	International Business Machines
ICT	Information and Communications Technologies
ISO	International Organisation for Standardisation
IVD	'In Vitro Diagnostic'
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
MRN	Medical Record Number
NCCLS	National Committee for Clinical Laboratory Standards
OSI	Open Systems Interconnection
PAS	Patient Administration System
POCT	Point Of Care Testing
PPSN	Public Personal Service Number
QC	Quality Control
SCSS	School of Computer Science and Statistics

SDO	Standards Development Organisation
SNA	Systems Network Architecture
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms
TC	Technical Committee
TCD	Trinity College Dublin
TCP/IP	Transmission Control Protocol/Internet Protocol
TTP	Trusted Third Party
UCUM	Unified Code for Units of Measure
XML	eXtended Markup Language

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Chapter 1 Introduction

1.1 Background Information

It is estimated that 77 million laboratory investigations are carried out annually in Ireland on various types of human biological specimens, at a cost to the Irish exchequer of €469 million euros (McDonald, 2009). Given that the Irish population according to the 'Population and Migration Estimates April 2009' (Central Statistics Office, 2009) is approximately 4.5 million people, that represents an annual average of almost 20 tests for every man, woman and child. It is also clear that laboratory testing is a key instrument for patient diagnosis and treatment, (Harrison and McDowell, 2008), (Plebani, 2009).

Orders for laboratory investigations (henceforth called tests), originate from a variety of sources including general practices, outpatient clinics and hospital inpatient services. The majority of the tests are processed onsite in one of the 44 HSE hospital laboratories located throughout the country. There are also third party laboratories, such as Claymon Bionmis, who are contracted by the HSE to process a significant portion of these tests in so called 'cold lab' facilities. The majority of this work originates from primary care (Mitchell, 2009).

There has been a significant increase in laboratory testing in recent years. Between 2000 and 2004, laboratories in the UK saw an 83% increase in the number of tests submitted by primary care practitioners (Plebani, 2009). The same study noted that similar international trends were having an impact on the delivery of laboratory services in other countries. The modern automated laboratory environment enables laboratories to efficiently and effectively process this ever increasing volume of laboratory tests (Harrison and McDowell, 2008).

Electronic messaging is central to the laboratory automation process. Each laboratory test result, whether processed by the HSE or by a contracted laboratory, is the main subject of electronic communication between the

Laboratory Information System (LIS) and the Analytical Instrument (AI). Electronic laboratory messaging technology enables this communication; thus making it possible for all the test orders, test queries and test results to be communicated between the devices and the information system(s) to which they are connected.

Lab results have a major impact on the decisions that health professionals make. So the quality of laboratory messaging is literally a matter of life and death. According to some sources, the information obtained from laboratory results accounts for between sixty and seventy percent of all information that is used in the clinical decision making process (Harrison and McDowell, 2008). Furthermore, almost two-thirds of acute care decisions relating to admission, discharge and administering of medication to patients is based upon these test results (Plebani, 2009).

The quality of laboratory messaging also impacts on the number of potential errors in laboratory medicine. Such errors were highlighted in the influential 'To Err is Human' report (Kohn, Corrigan and Donaldson, 2000). Due to the enormous volume of laboratory tests performed worldwide on a daily basis, possibly billions, even a very low incidence of laboratory testing errors can have a significant negative impact with resulting implications for both public health and patient safety (Plebani, 2009).

Electronic messaging standards play a central role in ensuring the quality of laboratory messages. But they are not limited solely to usage within the laboratory environment. They enable the messaging and recording of information pertaining to patients between many different information systems through the use of such standards as HL7 and DICOM. The usage of messaging standards is continually increasing as many other areas of healthcare are beginning to use electronic standards based messaging to improve the service they are providing to patients (Rajeev et al, 2010).

The linking of laboratory systems to other systems using standardised messages can also improve the quality of laboratory messaging. For example, a laboratory system may be connected to an order communications system that maintains records for all patient medications. In this instance it could be possible for the LIS to automatically highlight the impact of a patient's medications on their laboratory test results (Kaplan, 2009). This type of interoperability between systems is called semantic interoperability. Achieving semantic interoperability is not a trivial matter, but it can have a major impact on the healthcare decision-making process.

1.2 Motivation for Study

There is currently a drive internationally to improve the quality of healthcare messages. This work feeds into that initiative by examining characteristics of a good messaging standard. If a messaging standard is of high quality and suitable for a particular purpose, those who adopt the standard can be sure that messages conforming to it will also be of high quality and fit for purpose.

The drive for quality messaging is also happening within the Irish health system. There are currently a number of initiatives between the HSE and the Health Information and Quality Authority (HIQA) who are together embracing the use of messaging standards and technologies to enable interoperability. One such initiative is the National GP Messaging Standard. This standard uses a subset of the HL7 messaging standard to enable messaging of results to GPs and electronic referrals by GPs to secondary care via the national messaging portal, Healthlink, (Health Information and Quality Authority, 2010a). The Authority see such standards as "an essential way of improving how we use technology to enable safe and effective information exchange, including the exchange of clinical, administrative and patient information, for the benefit of the quality and safety of patient care", (Health Information and Quality Authority, 2010b).

So given the current interest in adopting and adapting messaging standards, it is important to know what makes a good standard. It is equally important to be able to identify the elements or aspects of a standard that are weak, so that authors of national profiles can actually caution at a national level about possible misuse of any vague parts, concepts or sections that could be misinterpreted.

1.3 Aims and Objectives of this Work

1.3.1 Aims of this Work

This dissertation attempts to identify those properties of a messaging standard that make it successful in terms of its usability and applicability (specifically that it's implementable by anyone who wishes to use it for the purpose for which it was intended). More specifically in relation to health messaging standards, the aim is to consider:

- The positive and negative features of a standard
- What makes a "good" standard
- What makes a standard successful
- What makes a standard usable by system/instrument vendors
- What properties of a messaging standard aid system interoperability

In order to accomplish these aims, it is first necessary to identify a successful messaging standard that has been widely implemented by vendors/manufacturers. The ASTM E1394-97* (ASTM, 1998b) specification is well suited to this requirement. It has been widely used by Analytical Instrument (AI) manufacturers as the de facto messaging standard between analysers and Laboratory Information Systems (LISs) for almost two decades, with a majority of vendors still choosing to use it in preference to their own proprietary protocols. ASTM E1394 is also apparently a successful standard.

* It should be noted that the ASTM E1394-97 standard was approved on Dec. 10, 1997. However it was not published until March 1998.

So what are the features of ASTM E1394 that has made it so successful and do these features also make a “good” standard? This work will attempt to answer this question through a number of different routes.

1.3.2 Objectives of this Work

- Firstly, implementations of a number of ASTM E1394-97 interfaces by different Analytical Instrument (AI) vendors will be studied to gain an insight into how the standard is implemented, by different vendors. In this manner it is hoped to identify the “good” and “bad” features of the standard by assessing the compliance and non-compliance of the chosen implementations.
- Specifically, the work will show how good features have enabled the wide spread and effective use of the standard.
- The use of language in the standard will also be assessed, by correlating the language used in clauses with compliance to those clauses. Does the use of strong language and mandatory/optional flags prompt compliance?
- Next the unexpected (mis)use of the standard, points to features that are missing from the standard or other weaknesses.

This work attempts to identify and document these shortcomings in order to provide feedback to standards developers.

1.4 Laboratory Messaging and ASTM E1394-97

Before embarking on a detailed examination of the ASTM E1394-97 standard it is helpful to review the following background information:

- The key Standard Development Organisations (SDOs) that have been involved in the development of messaging standards that have impacted on electronic healthcare messaging.

- The evolution of laboratory messaging that brought about the need for ASTM E1394-97

The next few sections will cover these topics.

1.4.1 Standards Development Organisations (SDOs) who develop Laboratory Messaging Standards

There are a number of organisations that have been involved with the development of messaging standards; many that are still in use today. These originate from EDIFACT in the 1970s through to organisations such as HL7 that continue to play a major role in the development and oversight of messaging standards within the laboratory and general healthcare sector. This section will briefly discuss these.

EDIFACT

As mentioned earlier, EDIFACT was the first standard for Electronic Data Interchange (EDI). In 1960 the United Nations identified a need for such a standard to facilitate the electronic interchange of information among businesses. This resulted in the establishment of a working party (WP.4); which subsequently published the first EDI standard in 1975.

ASTM

In 1970, the American Society for Testing and Materials (ASTM) identified a need for a committee with responsibility for development of medical information standards, (Hammond and Cimino, 2000). So that same year the E31 committee was formed. It was responsible for the development of laboratory messaging standards until 2001, when responsibility was transferred to the National Committee on Clinical Laboratory Standards (NCCLS); which later changed its name to the Clinical Laboratory and Standards Institute (CLSI) in January 2005 (CLSI, 2010a). This committee continues to work on health informatics standards, with a focus on issues such as privacy, security and the electronic health record, (NCCLS, 2004).

CEN TC 251

CEN (Comité Européen de Normalisation / 'European Committee for Standardization') established the Technical Committee 251 (TC 251) with responsibility for health informatics in 1990 (Klein, 2002). Its directive was "to develop standards that enable compatibility and interoperability between independent systems in healthcare" (Huff, 1998). Its primary function is to "facilitate a European market for products and services" by establishment of agreed European standards, so to eliminate any differing national standards that may exist, (Klein, 2002). TC 251 Working Group 4 is responsible for health informatics issues affecting medical devices. It developed the specification that became the ISO 18812 standard that provides a framework, based on message profiles, for the development of ASTM E1394-97 interfaces. This specification will be reviewed in more detail in section 3.3.

CEN TC140

This committee has primary responsibility for the development of 'In Vitro Diagnostic' (IVD) medical devices and quality management within the medical laboratory. As such it manages the quality standards associated with laboratory analysers; primarily standards that fall under the European IVD directive (CENELEC, 2010).

ISO TC215

ISO (International Standards Organisation) established the Technical Committee 215 (TC 215) in 1998, (ISO, 2010e). It too has responsibility for the development of standards to enable compatibility and interoperability between systems in a healthcare environment. It has published a number of standards pertaining to electronic health records and communication/messaging between systems in the health domain.

ISO TC212

ISO established TC 212 in 1994, prior to TC 251, (ISO, 2010d). It has responsibility for the development of standards and guidelines pertaining to the field of laboratory medicine and in vitro diagnostic test systems. Because of their area of responsibility, the CLSI (formerly NCCLS) have worked closely with TC

212 on a number of laboratory related standards. During the course of this research it was found that responsibility for ISO 18812 seemed to fall between the two committees (TC 212 and TC 215). This may be as a result of the more dominant role held by TC 212, with regards to laboratory standards development. This would account for the fact that there has been no revision of the standard since its publication in 2003.

HL7

Health Level Seven (HL7) refers to both a family of health messaging standards and the organisation that developed them (HL7, 2010). The HL7 organisation was founded in 1987. It developed the HL7 protocol which has since become an international standard for the exchange of electronic data between healthcare applications (Coiera, 2003). As the name suggests, the protocol operates at the seventh (application) layer of the Open Systems Interconnection (OSI) reference model and is concerned only with the information being passed between the applications. It doesn't define how the message is transmitted between healthcare systems; this is left to other transport protocols, such as TCP/IP, that operate at lower levels of the OSI reference model.

The first version of the protocol (version 1.0) was released in March 1987 (Huff, 1998),. Version 2.0 of HL7 was released the following year in 1988, with the protocol being extended to include the reporting of treatment and tests along with order exchanges; which was based closely on the ASTM E1238[*] standard (Benson, 2010). It wasn't till 1991 when version 2.1 of the standard was released that it began to gain widespread acceptability and use. Version 3.0 of the standard was subsequently published in 2007, (HL7, 2007); as shown in figure 1.

[*] It should be noted that the ASTM E1238 standard was approved on Aug. 10, 1997. However it was not published until March 1998.

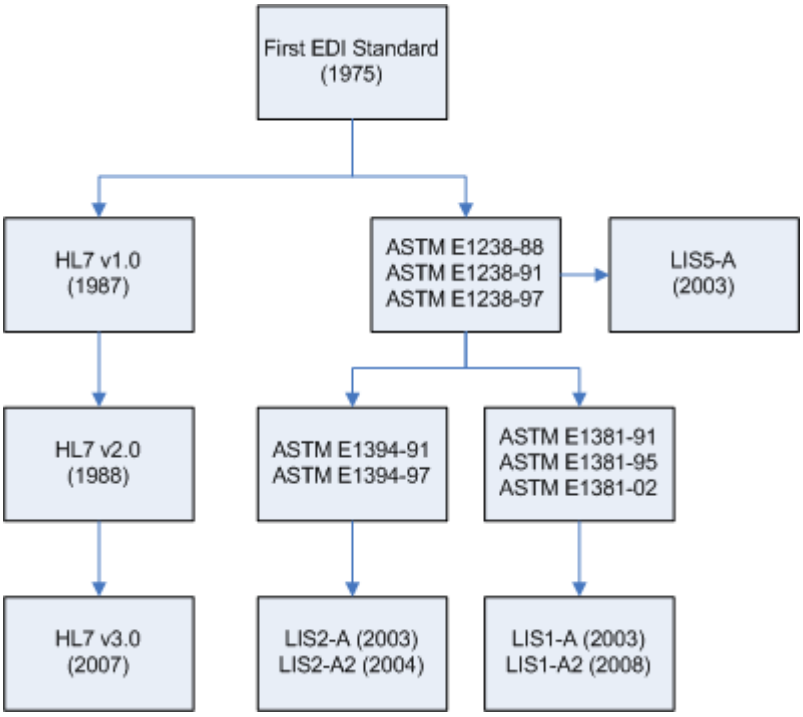

Figure 1 - Evolution of the ASTM and HL7 Messaging Standards

1.4.2 The Evolution of Laboratory Messaging

Central to successful operation of any laboratory is the Laboratory Information System (LIS). It performs both the *analytical* and *peri-analytical* processes that are required of it. '*Peri-analytical*' processes "includes both *preanalytical* processes, such as the processing of physicians' orders and specimen accessioning, and *postanalytical* processes, such as result verification and report generation" (Young, 2000). It also manages the transfer of patient information and test orders to analysers/data management systems, while retrieving and storing results from them.

The key devices that communicate with the LIS are:

- **Analytical Instruments (AIs)** – These are analytical devices that are located in the central laboratory. Their functionality varies depending on functional, operational and other requirements. While they are most often

to be found in the areas with the highest volume of tests, such as chemistry and haematology, they are generally used in all areas of the clinical laboratory (Selmyer and Cloutier, 1996). The test orders are usually transported from the LIS to AIs in the form of electronic messages. The operator usually loads a number of bar-coded specimens into a tray, which in turn is loaded into the analyser. The AI will then automatically identify the specimen by the barcode and perform the required test(s). It may request additional patient information and will subsequently send the test result(s) for the given specimen(s) back to the LIS.

- **Data Management System (DMS)** (sometimes also called a host system) – This is a system that manages one or more analytical instruments or POCT devices. As part of its role, it will manage all aspects of communication that are required between the LIS and analysers under its control.

- **Patient Information System (PAS)** – also referred to as the Hospital Information System (HIS), this holds both the demographics and administrative information pertaining to patients. In some instances it also holds the central electronic patient record. Information may be passed between the systems for the purpose of:
    - Obtaining patient information pertaining to laboratory orders or laboratory results, such as a medical record number.
    - Updating the patient's electronic health record with laboratory results

- **Point of Care (POCT) Devices** – which are analytical instruments positioned outside of the central laboratory that normally carry out only a limited number of specific tests; such as a blood-gas analyser. They are usually handheld or small bench units and they may communicate directly with the LIS, but are usually managed and transmit results back via a DMS. They are highly effective in Critical Care Medicine (CCM) where they are "advantageous, by decreasing Therapeutic Turnaround Time, number of

errors, and by reduction of blood-volume lost for analyses. Though not much evidence exists to prove beneficial effects with respect to early diagnostic accuracy, decrease in length of stay in Intensive Care Unit (ICU), reduced costs, or decreased morbidity or mortality, clinicians in general agree that POCT technology is a prerequisite for early recognition of life-threatening conditions, and for titration of commonly applied therapies", (Drenck, 2001).

The evolution of the Laboratory Information System (LIS) gives an interesting insight into the evolution of health ICT and of the associated standardisation over the last four decades. During this time, the LIS has been central to enabling laboratory automation. According to Lincoln, (Lincoln, 1987), this is driven by the need to:

- Increase the speed of testing (i.e. reduction in time required for testing)
- Reduce costs (i.e. primarily labour time/costs)
- Increase the accuracy of testing
- Increase the productivity of diagnostic testing

Laboratory Information Systems were first introduced in laboratories during the early 1970s as part of this process (Sarkozi, Simson and Ramanathan, 2003). These were usually large mainframe or minicomputer systems that often required a massive capital investment to procure, install and commission. They also required specialised knowledge to operate them, where individual instructions had often to be issued by an operator in order to perform the simplest of tasks. This could be both a difficult and cumbersome task, which often required lines of programming/code to enable the processing of a single test. As a result these devices were often inaccessible to a large proportion of laboratory staff.

Until the introduction of communications interfaces for analytical instruments, most laboratory results were manually transcribed. However with the advent of unidirectional interfaces between the LIS and Analytical Instruments, it became

possible for laboratory results to be uploaded and recorded electronically (Streitberg et al, 2009).

Heterogeneity was an issue with these early systems. Most communication was proprietary, with vendors only facilitating communication between their own systems, using their own protocols; such as IBM's Systems Network Architecture (SNA), (Zatti and Janson, 1988). Mainframe or minicomputer systems would use a standardised serial connection(s) to link the system to the user terminal(s) or analyser(s) within the laboratory environment (Kataoka, 2010). However, vendors tended to use their own variations on the implementation of this standard with (for instance) non-standard physical connectors. This obviously meant that each implementation could differ with such differences (Huff, 1998).

To further complicate the situation, it was often the case that more than one LIS would be employed within a single laboratory, as some departments had a dedicated LIS for each function/area. These separate computer systems would often be developed in different languages, using different hardware, different operating systems and interfaces. This resulted in expensive and unnecessary heterogeneity. This heterogeneity was not confined to the laboratory. Many other systems throughout the healthcare environment had limited or no interoperability.

The United Nations were one of the first to address problems surrounding data exchange. In 1960 they set up a 'Working Party' (WP.4) to look at the development of a set of international rules for exchange of information around businesses. This culminated in the publication of the first EDI (Electronic Data Interchange) standard in 1975 by the Transport Data Coordinating Committee (Salminen, 1995); see Appendix A - Laboratory Standards - Organisations & Standards Timeline.

By 1978, the International Organisation for Standardisation (ISO) created a subcommittee SC16 with responsibility for "Open Systems Interconnection" (OSI); with the term "open" referring to the ability of any system conforming to OSI

standards being able to communicate with any other conforming network, (Day and Zimmermann, 1983). This was closely followed by the arrival of the microcomputer in the 1980s, which brought about powerful and inexpensive computing (Moravec, 1998).

This exponential growth in computing further drove the need for standardisation of messaging between applications. By 1983, Day and Zimmerman proposed the Open Systems Interconnection (OSI) model (Day and Zimmermann, 1983) which was published as an international standard the following year, (ISO, 1984). This offered a framework to support computer interoperability.

The arrival of Microsoft Windows in 1983 (Microsoft Corporation, 2010) meant that computers were becoming much easier to use (Rai University, 2010). Users would no longer require the technical expertise associated with complex command driven systems. Also the increasingly powerful and cost effective format of the desktop PC now made it possible to develop more powerful computing solutions throughout different areas of laboratories, thus expanding laboratory automation even further.

Four years after the OSI reference model was published, the American Society for Testing and Materials (ASTM) published the E1238-88 standard in May 1988, (McDonald and Hripcsak, 1992); which “became a basis for HL7’s message formats through agreements between ASTM and HL7”, (AACC, 2010). It was “the first balloted standard in the area of medical information exchange” and it addressed the issue of “transferring clinical observations between independent computer systems”, (Huff, 1998).

That same year the HL7 (Health Level Seven) organisation was formed to develop a set of protocols to support messaging in the healthcare sector; with the publication of the first version of HL7 in 1988 (Huff, 1998), followed by its second revision the following year. Since then, both standards have gone through a number of iterations in the intervening years; as described in figure 1.

By 1991 the need to have a standardised messaging format over the point-to-point serial connections employed in laboratories was addressed by ASTM with the publication of E1381-91 and E1394-91 (Blick, 2001). E1381-91 operated at the transport level of the OSI model (Nova Biomedical, 2003), while E1394-91 operated at the higher level, (Hawker and Schlank, 2000). These two complimentary standards worked together to facilitate the communication of the LIS to the laboratory analysers. These were based upon the previously published E1238-88 standard, (AACC, 2010).

Thus by the 1990s more powerful LIS applications were becoming the norm, as computing power increased exponentially and computing costs decreased in a similar manner. This further aided the move of laboratories towards a totally automated solution. Interoperability between the LIS, Analytical Instruments (AIs) and other hospital systems, such as the Patient Administration Systems (PAS) was now becoming a reality. Hospitals were now gradually moving towards an all-encompassing 'Electronic Health Record'.

Over the last 10 years interoperability has increased to allow laboratory results to be electronically messaged to GPs in a primary care setting and subsequently to be fully integrated into their clinical systems. This originated within the former Health Boards, where extranet services were developed and agreed with Trusted Third Parties (TTPs). In the last couple of years there has been a concerted effort to move this to a more national level with the advent of Healthlink as the perceived national messaging portal for GP messaging (Healthlink, 2010).

1.5 Conclusion

This chapter has provided a general description of the SDOs involved in messaging standards development and how these standards have evolved. Before embarking on a description of the ASTM E1394-97 and ISO 18812 standards in chapter 3, we are going to briefly look at what necessitates such messaging standards in chapter 2.

Chapter 2 The Need for Messaging Standards

2.1 The Need for Messaging Standards

In order to fully understand a standard it is important to understand the context in which it has been introduced. As outlined in chapter 1, many organisations have been involved in the development of health messaging; that date back as far as the 1960s. This chapter will examine what have been the driving factors, issues and relationships between these organisations and standards.

As far back as 1996, the NCCLS (National Committee on Clinical Laboratory Standards), as outlined by Hawker, (Hawker and Schlank, 2000), indicated that messaging standards were required to:

- Help reduce the costs to manufacturers, implementers and customers.
- Ensure integrity/quality of information being passed between systems.
- Facilitate 'plug and play' functionality between systems.

However, Benson (Benson, 1998) has highlighted the fact that standards documents are often so complex and ambiguous that they look expensive to implement. Therefore they don't seem to offer a reduction in interfacing costs. He also indicated that to make these standards workable that they "should stop developing mega-messages that aim to do all things for all men", (Benson, 1998) and rather develop standards that were relevant to a specific context or task.

Frassica (Frassica, 2004) identified other issues pertaining to a core set of evolving standards, namely HL7 v2.x. He outlined how system vendors would build communication engines to a specific version of the standard. Once this initial development was complete, they were slow to subsequently update these interfaces, as newer versions of the same standard(s) were published and implemented by other vendors. Subsequently, as a result of versioning of the

standard, it was often found that different systems that were both compliant with a given standard could have incompatibility/inoperability issues.

It has been mentioned in the previous chapter that in April 1991 the ASTM developed two messaging standards for electronic messaging between AIs and LIS systems, E1381-91 and E1394-91 (Kataoka, 2010). The E1394 standard went on to become (in the authors opinion) one of the most successful health messaging standards ever developed and is still widely in use today. ASTM were also the first to publish a consensus based messaging standard, E1238, that facilitated the transfer of clinical information between independent computers (Huff, 1998).

However, by the late 1990s, there were concerns about the inability of the E1381 and E1394 standards to meet the growing requirements of laboratory automation systems. This ultimately resulted in both the CLSI (Hawker, 2007) and the Japanese Ministry research project (Kimura et al, 1998) developing new standards to supersede them, the AUTO5 and MML/Merit-9 standards, respectively.

Despite the success of ASTM E1394-97, CEN TC251 identified issues pertaining to the high degree of flexibility the standard afforded (Hayes, 2010). The purpose and meaning of a number of data fields were open to interpretation and this could lead to inconsistencies in the application of the standard. Therefore the quality of interfaces and ultimately their operability could be significantly diminished. They proposed the development of the CALM (Clinical Analyser interfaces to Laboratory inforMation systems) standard. This was to be a supplementary modification of the original standard to incorporate profiles. These profiles would outline the fields and their appropriate use for particular tests/purposes. Initially this reached a European pre-standard level, (CEN, 1999). Subsequently in 2003 it was progressed to the European ISO Standard 18812 (EN ISO, 2003).

Recently a high demand for real-time near patient testing has resulted in an increase in the use of POCT (Point Of Care Testing) devices throughout primary

and acute care environments. In the past, many of these standalone devices could not be interfaced with any DMS or LIS. However demands for laboratories to oversee these devices from a quality management perspective, such as for compliance with ISO 2870:2006 (ISO, 2006), has resulted in a need for these devices to be interfaced to a DMS, LIS or both. Again messaging standards such as ISO 11073-90101 (ISO, 2008) have been critical to ensuring this happens in a standardised fashion that ensures quality, reliability and security of all information been passed between the POCT and LIS/DMS.

Finally, Gurguilo commented that "standards are only meaningful if implemented in a consistent and correct way" (Garguilo et al, 2007).

This research hopes to identify the properties of messaging standards that ensure that they are applied consistently and correctly by vendors; to ensure both patient safety and enhance interoperability between systems. In preparation for a detailed description of the results of the investigation in chapter 5, the next chapter will provide an overview of ASTM1394-97 and ISO18812.

2.2 Conclusion

This chapter has:

- Identified the driving forces behind standards.
- Highlighted issues such as complexity and ambiguity.
- Highlighted issues pertaining to versioning of standards.
- Identified the need for standards to change as the messaging needs change.

Chapter 3 provides an overview of both the ASTM 1394-97 and ISO 18812 standards as background and to help our understanding of the findings and analysis that follow in chapter 4.

Chapter 3 ASTM E1394-97 and ISO 18812 Standards

As the ASTM 1394 standard and the ISO profiles in ISO18812 are not likely to be required reading for health informations, it is necessary to provide a background for the work of this project, by describing these two specifications. This chapter will discuss the two standards in order to provide a foundation for the reader. This is to support the findings and analysis that are outlined in chapter 4.

The chapter will begin by discussing the hierarchical message structure of ASTM E1394-97 and the record types that are permitted at each level. Then it will proceed to define the record types and the fields held within them. This is followed in the second half of the chapter by the discussion of the ISO 18812 standard in terms of its message identifiers and profiles, along with attribute optionality and allowed values.

3.1 ASTM E1394-97 Hierarchical Structure

The ASTM E1394-97 standard defines a hierarchical structure within which records of various types are placed. This is the same structure that was employed in an earlier standard by ASTM, namely E1238 (ASTM, 1998a).

It defines a “positional convention”, (ASTM, 1998b), where records positioned higher in the structure relate to all those beneath them. There are five levels associated with this structure, ‘level 0’ to ‘level 4’.

3.1.1 Level 0

Records at 'level 0', the highest level within the structure encapsulate the message, defining the start and finish of each message. Only two records exist at this level:

- *Message Header Record*

  The message header record defines the delimiters to be used throughout the record, the way in which the message is to be processed and information pertaining to both the sender and recipient of the message. The defined fields of the header record are numbered 7.1.1 (Record Type ID) to 7.1.14 (Date and Time of Message) inclusive.

- *Terminator Record*

  All messages must end with a terminator record. Where more than one message is being transmitted, the first message will end with the terminator record and follow immediately with a new header record for the beginning of the second message. The terminator record field has three defined fields that are numbered 13.1.1 (Record Type ID), 13.1.2 (Sequence Number) and 13.1.3 (Termination Code).

3.1.2 Level 1

At the second level of the ASTM E1394-97 there are five record types that may exist:

- *Patient Information Records*

  The patient information records give detailed information about each patient, including demographical, medical and other information that clearly identifies the patient and may impact on the interpretation of any subsequent results. The defined fields within this record are numbered 8.1.1 (Record Type ID) to 8.1.35 (Dosage Category).

- *Request Information Records*

  The request information record, as the name suggests, is used to query either the LIS/DMS or analytical instrument for information pertaining to patient, specimen, test type or other manufacturer specific criteria. Its defined fields are numbered 12.1.1 (Record Type ID) to 12.1.13 (Request Information Status Codes).

- *Scientific Records*

  The scientific record is used for the exchange of test data, such as that used for quality control messages. Its defined fields are numbered 14.1.1 (Record Type ID) to 14.1.21 (Patient Race).

- *Manufacturer Records*

  The manufacturer record allows a manufacturer to specify a custom record type that can be used at any level beneath the message header record. It is only to be used where the manufacturer requirements are not catered for by any of the other record types. Any manufacturer record here will relate to the message header. There are only two record fields defined within the standards, namely 15.1.1 (Record Type ID) and 15.1.2 (Sequence Number).

- *Comment Records*

  Comment records, in the same fashion as manufacturer records, can be placed anywhere within a message. They always relate to the last non-comment record that precedes them, which in this instance will be a comment on the message header; as they cannot follow a message terminator record. There are five fields defined for the comment record that are numbered 11.1.1 (Record Type ID) to 15.1.5 (Comment Type).

3.1.3 Level 2

These are followed, at the third level by three record types which relate to either the preceding patient or request information record:

- *Test Order Record*

  This record contains all the information pertaining to a particular order request from the LIS. It usually relates to a single test on a single specimen. However a single specimen may be subjected to more than one test or a (test) battery. Such a battery will usually involve multiple tests associated with the functionality of a single physiological system, such as a 'Thyroid Function Test' (TFT). In such cases, this may involve more than one test being ordered for a single specimen. Placing multiple test identifiers, separated by a repeat delimiter, in the 'Universal Test ID' field allows for this to be dealt with in a single order record. If a test battery requires multiple specimens, then the standard also accommodates this by allowing multiple specimen identifiers to be placed in the specimen identifier field, again separated by the repeat delimiter. The defined fields for this record type are numbered 9.4.1 (Record Type ID) to 9.4.31 (Specimen Institution).

- *Manufacturer Record*

  Manufacturer defined record, as outlined previously. In this instance it will usually relate to the preceding patient or query information record. As before, there are only two record fields defined within the standards, namely 15.1.1 (Record Type ID) and 15.1.2 (Sequence Number).

- *Comment Record*

  In this instance, the same as the manufacturer record, it will relate to the previous patient or request information record. Again, there are five fields defined for the comment record that are numbered 11.1.1 (Record Type ID) to 15.1.5 (Comment Type).

3.1.4 Level 3

Three record types can exist at the fourth level of the message:

- *Result Record*

  This is the most common fourth level record. It will only follow a preceding third level test order record, to which it relates. As the name indicates, this record contains information pertaining to an individual result. Even if a single test order relates to multiple tests, each of the tests and their result must be reported in individual result records. The defined fields for this record are numbered 10.1.1 (Record Type ID) to 10.1.14 (Instrument Identification)

- *Manufacturer Record*

  Manufacturer defined record, as outlined previously. In this instance it will relate to the preceding test order record. As before, there are only two record fields defined within the standards, namely 15.1.1 (Record Type ID) and 15.1.2 (Sequence Number).

- *Comment Record*

  In this instance, the same as the manufacturer record, it will relate to the previous test order record. Again, there are five fields defined for the comment record that are numbered 11.1.1 (Record Type ID) to 15.1.5 (Comment Type).

3.1.5 Level 4

The final level within the hierarchy is the 'level 4'. Only the comment or manufacturer record types can exist at this level:

- *Manufacturer Record*

  Manufacturer defined record, as outlined previously. In this instance it will relate to the preceding result record. As before, there are only two record fields defined within the standards, namely 15.1.1 (Record Type ID) and 15.1.2 (Sequence Number).

- *Comment Record*

  In this instance, the same as the manufacturer record, it will relate to the previous result record. Again, there are five fields defined for the comment record that are numbered 11.1.1 (Record Type ID) to 15.1.5 (Comment Type).

3.2 ASTM E1394-97 Record Types Defined

3.2.1 Message Header Message

This is the first record of any message and is at the top level of the message hierarchy, as outlined above. All messages must start with this record and eventually terminate using the 'Message Terminator' (discussed later); which is also located at 'level 0'.

The first field of the header, 'Record Type ID' (7.1.1), always contains 'H' as an identifier. This is followed by the 'Delimiter Definition' (7.1.2) that details what delimiters are to be used throughout the message.

A number of fields are associated with the transmission and receipt of the message. Firstly, the 'Message Control ID' field (7.1.3) allows the recording of a unique identifier associated with that individual message transmission. Its purpose was to support other messaging protocols that may utilise such an identifier in order to ensure transmission of the message in a network environment. It should be noted that this standard was developed to operate in a point-to-point communication environment, such as across a serial RS232 interface, which directly connected the analyser with the LIS. It was noted from the research that almost 95% of analysers didn't support the use of this field.

The 'Access Password' field (7.1.4) facilitates the transmission of a pre-agreed password between the AI and LIS. When used, failure to message the correct password would result in the transmission being aborted and the sender being

notified of the security breach. Our research showed limited support for this field, with only over 5% of implementations opting to support it.

The 'Characteristics of Sender' field (7.1.9) may also contain information essential for the successful transmission of the message; such as details of the parity or checksum of the message. The primary function of the 'Receiver ID' field (7.1.10) is to ensure that only the intended recipient has receipt of the message.

There are three fields dealing with identifying the message sender. The 'Sender Name or ID' field (7.1.5) identifies the transmitter of the message. This usually includes such details as the system/instrument name, firmware and/or software version. The location and telephone number of the sender are held in the 'Sender Street Address' (7.1.6) and 'Sender Telephone Number' (7.1.8), respectively.

The Processing ID (7.1.12) field outlines four identifiers that indicate the message type and how it is to be processed; Production (P), Training (T), Debugging (D) and Quality Control (Q). Only the 'Production' type messages are to be processed in the normal manner. The others are to be handled in line with their specific purpose.

The 'Version No' (7.1.13) is to be used to show what version of the ASTM standard was employed in the interface (e.g. ASTM E1394-97).

Finally, the creation date and time of the message is recorded in the 'Date and Time of Message' field (7.1.14). This must conform to either the ANSI X3.30 or ANSI X3.43 standards. Under these standards, all date/times must be recorded as follows:

- ANSI X3.30 – Year, Month, Date – YYYYMMDD
- ANSI X3.43 – Year, Month, Date, Hour, Minute, Second - YYYYMMDDHHMMSS

3.2.2 Patient Information Record

This record commences with the value ‘P’ being placed in the first field of the record, ‘Record Type’ (8.1.1). The second field ‘Sequence Number’ (8.1.2), commencing at ‘1’, contains an incremental number that increases with each instance of a patient information record within the given message.

Next there are three fields that may be used to handle patient identity within this record. The ‘Practice Assigned Patient ID’ (8.1.3) and ‘Laboratory Assigned Patient ID’ (8.1.4) refer to identifiers for the given patient assigned by either the practice or the laboratory, respectively. The ‘Patient ID No. 3’ (8.1.5) is available to place any other unique identifier(s) for the patient, such as a Public Private Social Number (PPSN).

The ‘Patient Name’ (8.1.6) field can be used to record the patient’s name in the format of last name, first name, middle name or initial, suffix and title; divided by a component delimiter. The ‘Mother’s Maiden Name’ (8.1.7), may also be used to help identify the patient; particularly where more than one patient may have the same name and date of birth. If used, this field will only contain a surname.

The patient’s date of birth is recorded in the ‘Birthdate’ field (8.1.8). This must comply with the ANSI X3.30 format (YYYYMMDD), as used with date formatting elsewhere throughout the message. The standard goes on to define three acceptable values for the ‘Patient Sex’ field (8.1.9); namely ‘M’ (Male), ‘F’ (Female) or ‘U’ (Unknown).

The patient’s ethnical origin(s) may be recorded (in the ‘Patient Race – Ethnic Origin’ field (8.1.10)) and more than one origin may be defined. This can take the form of either a code such as ‘W’ or as a full text value such as ‘Native American’. If more than one race is to be recorded, they must be separated by the use of component delimiters.

The ‘Patient Address’ field (8.1.11) comprises of five component fields that each defines a specific element of the address; namely street, city, state/county, zip and country. These elements must be separated by the use of component delimiters and are position dependent. The patient’s phone number and additional supporting information may be recorded in the ‘Patient Telephone Number’ (8.1.13) field; which is a free text field. Multiple numbers can be recorded if required with repeat delimiters separating them.

The ‘Attending Physician ID’ field (8.1.14) is used to identify any attending physician(s) using a code, name or both (which must be separated using component delimiters). Where more than one physician is to be recorded, repeat delimiters must be used to separate their details.

The patient’s height and weight can be recorded in 8.1.17 and 8.1.18, respectively. These are both numeric fields. The default units are centimetres for height and kilograms for weight. If different units are applicable, then an abbreviation for them must be placed in the second component of the respective field. The abbreviation must also conform to the ISO 2955 standard in both cases.

Next a diagnosis may be entered against the patient in 8.1.19 (‘Patient’s Known or Suspected Diagnosis’). This should take the form of an ICD-9 code or a free text value. If there is more than one diagnosis applicable, they should be separated by the use of repeat delimiters.

Details of a patient’s medications or diet, that may influence the interpretation of a result(s) can be recorded in the ‘Patient’s Active Medications’ (8.1.20) and Patient’s Diet (8.1.21) fields, respectively. The dosage group of the patient may also be recorded in the Dosage Category (8.1.35).

Any information that needs to be messaged back in the results, by the practice, can do so by being placed in either 8.1.22 (Practice Field No. 1) or 8.1.23 (Practice Field No. 2).

The admission and discharge dates of the patient may be recorded in 8.1.24. Again these dates must comply with the ANSI X3.30 format (YYYYMMDD) format. If both dates are to be messaged then the admission date is placed in the first component, followed by the discharge dates; separated by component delimiters.

The patient's 'Admission Status' and can also be recorded in 8.1.25 and 8.1.26, respectively. There are five abbreviations listed for 'admission status', which are OP (outpatient), PA (pre-admit), IP (in-patient) and ER (emergency room). Other pre-agreed codes, between the sender and receiver, may also be used. The 'location' (8.1.26) generally refers to the patient's location within the clinic/hospital, such as their ward or bed.

An alternative diagnostic code and classification may be entered in 8.1.28. If used, the class of the code or classifier should be entered in 8.1.27.

The 'Patient Religion' field (8.1.29) supports the messaging of the patient's religion in the format of a code, abbreviation or name as pre-agreed with both parties prior to the message transmission. Their marital status may also be recorded in 8.1.30, but must have a value which is either 'M' (married), 'S' (single), 'D' (divorced), 'W' (widowed) or 'A' (separated).

Any precautions that need to be taken with regards a member of staff or the patient can be listed in 'Isolation Status' (8.1.31); which may be coded or free text value(s).

The patient's language may be recorded in 8.1.32 ('Language'), which may be invaluable when it differs from the principle/spoken language of the location.

The patient's assigned hospital service and institution may be recorded in 8.1.33 and 8.1.34 respectively. These can be a coded and/or full text values. If both are used they must separated using a component delimiter.

3.2.3 Test Order Record

The 'Record Type ID' (9.4.1) will contain 'O', signifying a test order record. This is followed by the 'Sequence Number' field (9.4.2), which will contain a sequential number, commencing at '1'; which will increment for every instance of a test order for the given patient.

The Sequence Number is followed by two fields associated with identifiers for the specimen; 'Specimen ID' (9.4.3) and 'Instrument Specimen ID' (9.4.4). The 'Specimen ID' is the unique sample identifier assigned by the LIS/system which is to be returned by the instrument. Further identifying components, such as the well or cup number, may follow this identifier; separated by component delimiters.

The 'Instrument Specimen ID' is an identifier assigned by the AI, if different from the computer assigned identifier in 9.4.3, which is returned with results. This can be used as a reference to the sample in queries and results.

The 'Universal Test ID' field (9.4.5) is used to define a test or battery that is performed on the given specimen. It comprises of four components that are position dependent:

- *Universal Test ID (9.4.5.1)* – this is reserved for the use of a universal test identifier, which is currently not used.
- *Universal Test ID Name (9.4.5.2)* – This would be the name of the test identified in 9.4.5.1.
- *Universal Test ID Type (9.4.5.3)* – This would identify what coding scheme was used by the first two identifiers (in 9.4.5.1 and 9.4.5.2).
- *Manufacturer or Local Code (9.4.5.4)* – This identifier is coded by the manufacturer. Additional components may be added to further define the elements of the test or specimen location that is being tested.

There are five possible priority status flags which can be used in the 'Priority' field (9.4.6). These are 'S' (stat), 'A' (as soon as possible), 'R' (routine), 'C' (call-back)

and ‘P’ (preoperative). If more than one flag is to be used, then repeat delimiters must be used to separate the flags.

A number of date and time fields exist in the test order record, which are used to track the progress of a specimen from order placement to final result(s) reporting. These commence with the ‘Requested/Ordered Date and Time’ field (9.4.7). It represents the date and time at which the order is considered to be placed and may be at a future point in time to the actual message. All priorities, as set out in 9.4.6, should be considered in terms of this timestamp.

The actual time that the specimen is obtained is placed in 9.4.8 (‘Specimen Collection Date and Time’). In the case of a timed specimen collection, the ‘Collection End Time’ (9.4.9) gives the date and time such a collection would have ceased. The ‘Date/Time Specimen Received’ field (9.4.15) can be used to record the date and time the specimen was logged into the laboratory; this is the time against which laboratory turnaround times may be gauged.

The ‘Date/Time Results Reported or Last Modified’ field (9.4.23), as the name suggests, is the date and time when:

- The initial results are reported
- A modification to the results is reported
- The status of either the report types (in 9.4.26) or status of the result (in 10.1.9) is reported or has changed

All the date and time fields mentioned above must conform to the ANSI X3.43 format (YYYYMMDDHHMMSS).

There are two more fields related to collections. The ‘Collection Volume’ field (9.4.10) records the total volume of specimens associated with a bulk collection. The default for this field is millilitres. If an alternate measurement unit is to be used, an abbreviation of the unit of measurement must be placed in the second

component of this field (9.4.10.2) and it must conform to the ISO 2955 abbreviations for measurement. An identifier for the collector of the specimen(s) can also be recorded in the 'Collector ID' field (9.1.11).

The 'Action Code' field (9.4.12) outlines a course of action with regards the specimens of the current order or those preceding it. The valid values for this field are C, A, N, P, L, X and Q.

Any potential hazards that a specimen may pose can be highlighted in the 'Danger Code' field (9.4.13). This can be the name of a test or a code associated with the danger.

Any clinical information that may have a bearing on the interpretation of the specimen results can be placed in the 'Relevant Clinical Information' field (9.4.14). The type and source of the specimen may also be recorded in the 'Specimen Type' (9.4.16.1) and 'Specimen Source' (9.4.16.2) fields, respectively; these are separated by component delimiters.

The 'Ordering Physician' field (9.4.17) contains details of the physician or healthcare worker who placed the order. This may be in the form of a unique code/identifier or the name of the person concerned. If both a code and name are messaged, then the code is placed in the first component (9.4.17.1) and separated from the name in the preceding components. There is also a specific order to how the name is messages, which is last name, first name, middle name or initial, suffix and title. If a developer wishes to construct a message containing more than one identifier, these identifiers must be separated by repeat delimiters.

A contact telephone number(s) may be placed in the 'Physician's Telephone Number' (9.4.18) field. Specific information pertaining to the phone number or contact details can also be placed in this field. If required, multiple numbers can be recorded in this field, with repeat delimiters separating them.

Fields 9.4.19 and 9.4.20 are user fields that are available for requesters to insert text formatted messages. Subsequently, the sender can forward back the original message with any comments that they want to add.

The two laboratory fields that follow (9.4.21 and 9.4.22) are available to be used for any purpose by the laboratory.

A billing cost associated with the test(s) carried out by the AI can be sent to the LIS in the 'Instrument Charge to Computer System' (9.4.24) field. This can be in the form of either a specific cost or cost code for test(s) associated with the test order.

The 'Instrument Section ID' (9.4.25) can be used to identify what section of what instrument carried out the test; which may be useful for auditing purposes.

There are only seven codes that can be placed in the 'Report Type' field (9.4.26), namely:

- O – indicates that the message is an order for the given tests, being placed by the user
- C – indicates that the message is an update, giving a correction of previously transmitted results
- P – indicates that the results issued are only preliminary
- F – indicates that the results indicated are 'Final'
- X – indicates that the AI cannot perform the order and that the order is therefore cancelled
- I – indicates that the order is in the AI pending completion
- Y – indicates that there is no order on record for this test (in response to query)
- Z – indicates that there is no order for a given patient (in response to query)
- Q – indicates that this message is a response to a request-information query message

If the specimen is collected from a different ward from where the patient resides, then the specimen's location can be recorded in the 'Location or Ward of Specimen Collection' field (9.4.28).

If the service responsible for the specimen collection from the patient differs from the service assigned to the patient (in 8.1.33), then it may be recorded in the 'Specimen Service' field (9.4.30). Also if the specimen was collected in a different hospital to the patient assigned hospital (in 8.1.34), then this can be recorded in the 'Specimen Institution' (9.4.31).

Finally the 'Nosocomial Infection Flag' field (9.4.29) is used to highlight whether an identified organism had originated from a hospital acquired nosocomial infection.

3.2.4 Result Record

The result record commences with 'R' being placed in the first field (Record Type ID, 10.1.1). This is followed by the 'Sequence Number' field (10.1.2), which will contain a sequential number, commencing at '1'. This will increment for every instance of a result record for a given test order. Once a record of at a higher level occurs, in this instance a new test order, the number will be reset to '1'.

The third field of the result record is the 'Universal Test ID' (10.1.3). This is the same type of identifier as used in the test order record (see 9.4.5) to identify the test associated with the sample. In this instance it associates the particular test with the result that follows it. As previously outlined, it consists of four components which are position dependent:

- *Universal Test ID (10.1.3.1)* – this is reserved for the use of a universal test identifier, which is currently not used.
- *Universal Test ID Name (10.1.3.2)* – This would be the name of the test identified in *10.1.3.1*.
- *Universal Test ID Type (10.1.3.3)* – This would identify what coding scheme was used by the first two identifiers (in *10.1.3.*1 and *10.1.3.*2).

- *Manufacturer or Local Code (10.1.3.4)* - This identifier is coded by the manufacturer. Additional components may be added to further define the elements of the test or specimen location that is being tested.

The 'Data or Measurement Value' field (10.1.4) records the actual test result. This can be in a numeric, coded or text format, but must be recorded in ASCII text notation. The standard states that in cases where the result contains "qualifying elements of equal stature", (ASTM, 1998b), then component delimiters must be used to separate them. This is an example of an ambiguous statement that we will discuss further in section 4.6. Where multiple values or results are to be reported against a single test order, they must be reported individually in separate result records. Therefore the test identifier (10.1.3) must be detailed enough to ensure that each result can be clearly identified and associated with its corresponding test.
The units associated with any numeric results (10.1.4) are reported in the 'Units' field (10.1.5). They must be in an abbreviated format that is compliant with ISO 2955. Any reference ranges associated with the results can be reported in the 'Reference Ranges' field (10.1.6), which will usually take the form of "lower limit to upper limit". Any text descriptions are separated from them using a component delimiter. Where more than one reference range is being reported upon, they must be separated by repeat delimiters.

The level of abnormality pertaining to the result may also be set using one of the seven flags associated with the 'Result Abnormal Flag' field (10.1.7). The 'Nature of Abnormality Testing' field (10.1.8) will denote, where used, the type of normal testing undertaken. There are three values allowed:

- 'A' – Age based population
- 'S' – Sex based population
- 'R' – Race based population

More than one value may be recorded, but they must be separated using repeat delimiters.

The ‘Result Status’ field (10.1.9) has 12 allowable codes associated with it, which are as follows:

P – Preliminary Results
S – Partial Results
F – Final Results
I – In instrument, results pending
M – This result is a MIC level
R – This result was previously transmitted
C – Correction of previously transmitted results
N – This result record contains necessary information to run a new order
Q – This result is a response to an outstanding query
X – Order cannot be done
V – Operator verified/approved result
W – Warning: Validity is questionable

The ‘Date of Change in Instrument Normative Values or Units’ field (10.1.10) will contain no entry unless there has been a change in normals or units. If so, this date must comply with the ANSI X3.30 or ANSI X3.43 standards.

An identifier associated with the person performing the test is recorded in the first component of 10.1.11 (‘Operator Identification). If used, the second component identifies the person who verified the test.

The commencement and completion times associated with results reporting are placed in the ‘Date/Time Test Started’ (10.1.12) and ‘Date/Time Test Completed’ (10.1.13) fields, respectively. The ‘Instrument identification’ field (10.1.14) indicates what instrument or section of instrument performed the relevant test.

3.2.5 Comment Record

The comment record is denoted by 'C' being placed in the 'Record Type ID' field (11.1.1). As with previous sequence number fields, the 'Sequence number' field (11.1.2) contains a sequential number than increments by one for each comment record. Once a record of at a higher level occurs or another comment record that is placed at a higher level is encountered, then this number will be reset to '1'.

Three values ('P' - practice, 'L' – computer system and 'I' – clinical system instrument) can be used in the 'Comment Source' (11.1.3) field. The 'Comment Text' (11.1.4) field will usually contain text comments associated with the previous higher level record. However, where codes or mnemonics are recorded, they must precede the text and be separated from it using a component delimiter.

The 'Comment Type' (11.1.5) field can use one of the five types (G, T, P, N or I) outlined in the standard or the vendor may choose to use a comment type of their own that's representative of the comment message type.

3.2.6 Request Information Record

The letter 'Q' is placed in the 'Record Type ID' field (12.1.1) to denote a request information record. This is followed by the 'Sequence Number' field (12.1.2), which is used to distinguish between the different requests in a given message.

Next is the 'Starting Range ID Number' (12.1.3) which has one or more identifiers pertaining to the patient, specimen or test for which information is being sought. It consists of three or more components where the first three components are positional dependent. Queries are based on one or more of these components. The first two components hold the system patient and LIS/system specimen identifiers, respectively. The third and subsequent components are manufacturer defined.

The value 'ALL' can be placed in the first component of this field. In this instance it will be viewed depending on whether the LIS or the AI is sending the request. A

LIS/system request will be interpreted as a request from the AI for all results ordered by the system. A request by the instrument (AI) will be interpreted as all demographical information and tests being ordered should now be transmitted down to the AI.

Whether identifiers are used or the word 'ALL', as outlined above, this information is combined with the dates in 12.1.7 and 12.1.8 and the test(s) in 12.1.5 to create the subset of patients/specimens/tests to which the query pertains. The standard doesn't define the data retention period required by any AI nor does it stipulate that any analyser must be capable of supporting all the search functionality that this field supports. It is only expected that a subset of the data in storage by either the LIS or AI, as defined by the query request, will be returned to the requesting party.

The 'Ending Range ID Number' (12.1.4) is defined in the standard as similar to 12.1.3. However it doesn't define in any detail its purpose or usage.

The 'Universal Test ID' (12.1.5) is defined as having three different formats. The first is the same as used elsewhere in the message. This takes the form of four position dependent components, with the first three relating to a universal identifier and the fourth (and any subsequent) component(s) being manufacturer defined.

The second format for this field is the placing of placing of multiple codes, separated by repeat delimiters, within this field. Finally the value "ALL" can be used. This will be interpreted as a request for all results for all the tests as pertaining to the identifiers specified in the starting and ending range fields and between the specified dates (as defined by 12.1.7 and 12.1.8).

The 'Nature of Request Time Limits' field (12.1.8) specifies what the date and times in 12.1.7 and 12.1.8 refers to: 'S' will refer to the specimen collection time and date that was recorded in 9.4.8. 'R' will be the result test date, as recorded in 9.4.23. If nothing is entered in this field, it will assume it to be the latter.

The ‘Beginning Request Results Date and Time’ field (12.1.7) is used to represent either:

- A single date and time
- Individual dates and times
- Date/Time at the beginning of a requested range

If no value is placed in this field, then it’s assumed that all information, as defined by the other criteria, is to be requested. All dates and times must conform to the ANSI X3.43 standard format (YYMMDDHHMMSS).

The ‘Ending Request Results Date and Time’ field (12.1.8) is used to define the most recent date and time, if used in conjunction with 12.1.7 to define a date/time search range. Again this date/time must conform to the ANSI X3.43 format.

The identity of the physician requesting the results is placed in 12.1.9. This must take the format of last name, first name, middle initial or name, suffix and title; separated by component delimiters. If an identity code for the physician is messaged, it must precede the name in the first component of the field and separated by a component delimiter.

The ‘Requesting Physician Telephone Number’ (12.1.10), as with other phone numbers recorded in the message is a free text field where contact number and any specific information pertaining to it are recorded. If required, multiple numbers can be recorded with the use of repeat delimiters to separate them.

12.1.11 and 12.1.12 are user-defined fields that are not defined in the standard.

The ‘Request Information Status Codes’ field (12.1.13) must use one of the twelve codes defined in the standard. A number of them (C, P, F, X, I, S, M, R and N)

have the same meaning as defined in the 'Result Status' field (10.1.9) previously. There are three previously undefined that may be used:

- 'A' – Abort/cancel last request criteria (allows a new request to follow)
- 'O' – Requesting test orders and demographics only (no results)
- 'D' – Requesting demographics only (e.g. patient record)

3.2.7 Message Terminator Record

The letter 'L' is placed in the 'Record Type ID' field (13.1.1) to denote a message terminator record. The 'Sequence Number' field (13.1.2) always has the value '1' placed in it. Finally the 'Termination Code' field (13.1.3) contains one of seven possible codes:

- Nil, N – Normal Termination
- T – Sender aborted
- R – Receiver aborted
- E – Unknown system error
- Q – Error in last request for information
- I – No information available from last query
- F – Last request for information processed

3.2.8 Scientific Record

The purpose of the scientific record differs from the all previous records. It is intended to be used to exchange information around AI performance, method development and quality assurance.

The 'Record Type ID' (14.1.1) contains 'S', which denotes the record. The incremental 'Sequence Number' field (14.1.2) commences with a value of '1' and continues to increment till a record type of a higher level is encountered.

The ‘Analytical Method’ (14.1.3) and ‘Instrumentation’ (14.1.4) are both defined text fields that must conform to Appendix 1 of Elevitch and Boroviczeny (Elevitch and Boroviczeny, 1985). The later must be an identifier that is a combination of the instrument and manufacturer codes combined by a dash.

The ‘Reagents’ field (14.1.5) should include a listing of constituent reagent codes, that conforms to the scheme of the American Chemical Society. These agents must be separated by a subfield ID. The units of measure associated with this record are specified in 14.1.6 (‘Units of Measure’) and should conform to ISO 2955.

There are a number of fields that are defined in the scientific record, but for which a specification is to be developed:

- Quality Control (14.1.7)
- Container (14.1.10)
- Analyte (14.1.12)

There are a number of fields that should be represented in the same manner as other fields within the standard:

- ‘Specimen Descriptor’ field, 14.1.8 and 9.4.16
- ‘Result Units’, 14.1.14 and 10.1.5
- ‘Collection Date and Time’, 14.1.15 and 6.6.2
- ‘Result Date and Time’, 14.1.6 and 6.6.2
- ‘Patient Birthdate’, 14.1.19 and 8.1.8
- ‘Patient Sex’, 14.1.20 and 8.1.9
- ‘Patient Race’, 14.1.21 and 8.1.10

The ‘Specimen ID’ field (14.1.11) will contain a unique specimen identifier that is assigned by the system and returned by the AI. The ‘Result’ field (14.1.13) should contain a numeric value which is the ascertained value of the analyte.

Any pre-processing steps that have been undertaken are recorded in the 'Analytical Preprocessing Steps' field (14.1.17). The 'Patient Diagnosis' field (14.1.18) should only have an ICD-9 code that is representative of their diagnosis placed in it. There is also one reserved field (14.1.9) that has been left in the scientific record for any future development.

3.2.9 Manufacturer Record

This is the final record type under the ASTM standard. Its intended purpose is to be only used by vendors when a required functionality is not accommodated elsewhere within the standard. There are only two defined fields for this record. These are the 'Record Type ID' (15.1.1) which contains the letter 'M' to denote manufacturer record and the 'Sequence Number' field (15.1.2). As with other sequence number fields, previously discussed, it increments (from '1') with each occurrence of a manufacturer record. When a record of a higher level is encountered the value is reset to one.

3.3 The ISO 18812 Standard

3.3.1 Background

It has been mentioned in section 2.1 that by the late 1990s, CEN TC 251 had acknowledged that there were issues around the implementation of ASTM E1394-97. It was felt that there were three main contributing factors:

- The extensive range of data items made it possible for the same information to be messaged in numerous ways.
- Lack of clear implementation guidelines meant that clauses in the standard could be interpreted by vendors in many different ways.
- As the standard was developed primarily for the United States, it didn't cover European requirements.

So by 1999 an initial draft of ISO 18812 was prepared by CEN/TC 251, (CEN, 1999), with a final draft being published by them in 2001, (CEN, 2001). That same year it also became the ISO 18812 standard, (EN ISO, 2003).

ISO 18812 attempts to overcome the problems identified above through the use of message profiles. These profiles are intended to simplify the development of interfaces based on ASTM E1394-97 standard. They enable a standardised approach to be taken by all vendors so that all information pertaining to a particular scenario is messaged the same way.

As each profile has a different level of complexity associated with it, implementers can choose a profile that best matches their needs. This makes it possible for simple instruments to be interfaced using simple and easy to follow messages.

The standard also offers guidance on how particular fields and functions outlined in ASTM E1394-97 should be implemented. It adapts the ASTM E1394-97 standard to encompass European requirements, which it did not take into consideration.

3.3.2 Message Descriptions

The ISO 18812 standard, (EN ISO, 2003), defines six message identifiers. These are used to define the message types within the message profiles in the following section. They are defined as:

- *M1 (Result)* – for sending results from AI to LIS
- *M2 (Results by Query)* – for sending results from AI to LIS in response to a Query for Results message (M6) sent from LIS to AI
- *M3 (Results by Query)* – for sending results from LIS to AI in response to a Query for Results message (M6) sent from AI to LIS
- *M4 (Order)* – for sending orders from LIS to AI, either unsolicited or in response to a Query for Order Message (M5)
- *M5 (Query for Order)* – for sending a query for an order from AI to LIS
- *M6 (Query for Results)* – for sending a query for results from LIS to AI, or AI to LIS

It is noted that while M2 and M3 are both queries for results, the ASTM E1394-97 standard requires that different fields are required for these different queries.

The record fields associated with each message type and the direction of the message flow are detailed below in table 1:

Message	**Direction**	**Records**
M1: Result	AI → LIS	H, P, O, R, C, L
M2: Results by Query	AI → LIS	H, P, O, R, C, L
M3: Results by Query	LIS → AI	H, P, O, R, C, L
M4: Order	LIS → AI	H, P, O, C, L
M5: Query for Order	AI → LIS	H, Q, L
M6: Query for Results	AI ←→ LIS	H, Q, L
H - Header Record; P – Patient Information Record; O – Test Order Record; R – Result Record; C - Comment Record; Q – Request Information Record; L - Terminator Record		

Table 1 - ISO 18812 Message Profiles

3.3.3 Message Profiles

The profiles are defined P1 to P5 inclusive. The standard defines both the aforementioned message descriptors (M1 to M6) and the ASTM E1394-97 record types that are to be used for each profile. The record types are abbreviated as follows:

- H - Header Record
- P – Patient Information Record
- O – Test Order Record
- R – Result Record
- C - Comment Record
- Q – Request Information Record
- L - Terminator Record

No scientific or manufacturer records are employed in the profiles.

Profile 1 (P1)

This is the simplest profile that is used to transfer results from an instrument (AI) to the LIS. Only a result (M1) is messaged to the LIS.

Profile 2 (P2)

This is also a simple profile that supports the transfer of orders from the LIS to the AI and subsequently the messaging of results back to the LIS. The initial order is a M4 message and the subsequent result is M1.

Profile 3 (P3)

This is an extension of P2, where the process begins with an initial request query (M5) by the analyser to the LIS for order. The same sequence as P2 then ensues with the transfer of order to the AI (M4) and the subsequent messaging of results to the LIS (M1).

Profile 4 (P4)
The fourth profile supports three scenarios. The first is the same as outlined above for P3. The second scenario is a query for results (M6) by the LIS to the AI, followed by the AI sending the results to the LIS (M2). With the third scenario being a query for results (M6) by the AI to the LIS and the subsequent reply (M3).

Profile 5 (P5)
The final profile is any other way of messaging that is compliant with the ASTM E1394-97 standard. The message can flow between the AI and LIS in any direction or both. There are no restrictions in terms of what message types (M1 - M6) or what record types are to be used within the messages.

Section 6.4 of the standard defines the “attribute optionality and allowed values” associated each message identifier, (EN ISO, 2003). These are broken down by record type and record field. The implementation guidelines, commencing on page 31 of the standard, also defines each record field in terms of attribute optionality and the permitted values for each field.

However it was found during this study, that there were discrepancies between section 6.4 and the implementation guidelines regarding the attribute optionality of four of the aforementioned fields; namely 9.4.3, 9.4.4, 12.1.3 and 12.1.13. This will be discussed further in section 4.8.

It was also noted by TC 215, within the standard, that most European laboratories tended to be certified under some accredited quality management scheme and this is very much the case today. However as ASTM E1394-97 doesn’t explicitly handle data associated with quality management, it can only be messaged through the use of manufacturer defined fields.

3.4 Conclusion

In this chapter we have:

- Identified the ASTM hierarchical message structure and the levels at which each record type can be used.
- Defined each clause for each record type, detailing allowed values where applicable.
- Detailed the ISO 18812 message descriptors and profiles, optionality and allowed values.

The next chapter provides an initial outline of the research methodology employed in the study. This is followed by a discussion of the findings in terms of compliance of the implementations with ASTM E1394-97 and ISO 18812. We then conclude each section with an analysis of the findings.

Chapter 4 A Study of 30 ASTM Implementations

In the last chapter we discussed the ASTM 1394-97 and ISO 18812 message standards. This chapter now describes the main research activity of this work, which focused on thirty ASTM 1394-97 implementations.

- Firstly we will describe the methodology used in analysing these implementations; with respect to both ASTM E1394 and ISO 18812 standards.
- We then examine their compliance, or lack thereof, with the different parts of the ASTM E1394 standard. This is followed by an analysis of these findings and what can be learnt from them.
- We then proceed to examine the compliance of these implementations with ISO 18812. Again this is followed by a further analysis of these implementations to determine what can be learned from their compliance or non compliance with regards the ISO 18812 standard.
- We will also discuss how ASTM differs from most other standards in terms of adoption, using what the author refers to as “the pyramid of adoption”.

4.1 Ethics Approval

Before commencing this study, the proposed research had to be reviewed in terms of ethical approval. It was determined that no approval was necessary in terms of the aspect of the research pertaining to a review and analysis of the ASTM implementations. However ethical approval was required with regards interviews that were held with:

- A key member of the CEN group that drafted the CALM (Clinical Analyser interfaces to Laboratory inforMation systems) standard in 2003.
- One of Ireland’s leading ASTM implementation experts

- A leading interface expert from one of the world's main analytical instrument manufacturers.

4.1.1 Ethical Approval Requirement

Since 2009 all Trinity College Dublin (TCD) studies involving human subjects must get prior ethical approval before commencement (School of Computer Science and Statistics, 2010). A review of the proposed research was therefore undertaken to assess:

- What aspects of the proposed research required ethical approval?
- Whether the proposed research would also require approval from the Health Service Executive's Research Ethics Committee?

It was determined that the main study being undertaken would not involve any human subjects. However the proposed semi-structured interviews with the Laboratory System developers/implementers would require ethical approval. As these subjects were not Health Service Executive (HSE) employees, no ethical approval would be required on behalf of the HSE. However, approval would need to be sough from the School of Computer Science and Statistics (SCSS) ethics committee.

4.1.2 Ethical Approval Process

A completed ethics proposal (see Appendix E-2), a completed ethics protocol form (see Appendix E-3) and proposed draft documentation were forwarded to the SCSS ethics committee. A series of correspondence (see Appendix E-1) between the author and this committee commenced whereby the following documentation went through a number of iterations:

- Cover letter outlining study to A/Director of Information Systems, HSE North Eastern Area (see Appendix E-4).

- Letter of Consent for A/Director of Information Systems, HSE North Eastern Area (see Appendix E-5).
- Cover letter for implementers/developers (see Appendix E-6).
- Consent letter for implementers/developers (see Appendix E-7).

Once the above letters were approved and a signed copy of consent from the A/Director of Information Systems (HSE North Eastern Area) was forwarded to the SCSS committee, ethical approval for the study was given.

4.2 Primary Research Methodology Employed

The primary research was conducted around a total of 30 ASTM interface specifications for centralised and non-centralised clinical analysers, 27 AIs and 3 Data Management Systems. These were evaluated in relation to both the ASTM E1394 specification (ASTM, 1998b) and the ISO 18812 standard, (EN ISO, 2003).

Initially it was felt that a review of all the ASTM interfaces being employed in laboratories throughout the HSE North Eastern Area would be large enough to suffice.

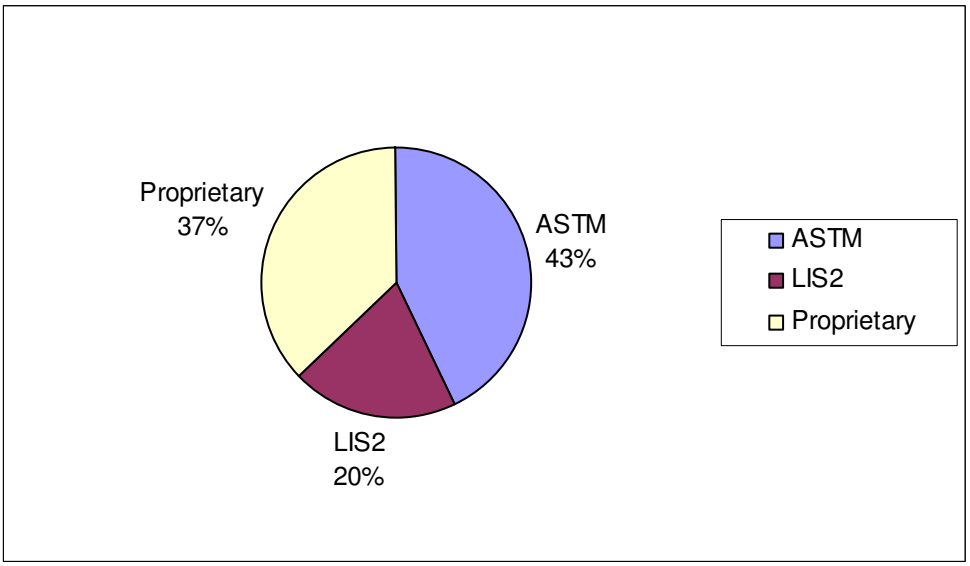

Figure 2 - HSE NE Area - Analysers by Messaging Protocol Employed

A survey was undertaken to determine the manufacturer, model, quantity and messaging protocol being used by analysers located throughout the five hospitals in the region. A review of the findings found that there were 35 analysers in use in hospitals throughout the HSE North Eastern Area. It was found that of the analysers encountered by the author in this study, almost 50% of the 35 analysers were interfaced using the ASTM E1394-97 standard; see figure 2 above. An additional 20% of analysers were found to be using the LIS2 standard.

At this point an additional study was conducted to see what differences, if any, existed between the ASTM E1394-97 and LIS2-A2 standards; see Appendix B. It was found that only 2 fields differed slightly in name. On examination of the relevant clauses it was found that there was no change in usage for the given fields. In the first instance the wording of the field title had changed from "computer systems" in 9.4.24 (ASTM E1394-97) to "information system" in 8.4.24 (LIS2-A2). In the second instance the word "ward" had been removed from the title of 9.4.28 (ASTM E1394-97), so that it referred to location only. This was reflected also in the explanation of the 8.4.28 (LIS2-A2). So LIS2-A2 is effectively the same document as ASTM1394-97. Clearly this amounts to only cosmetic differences between the two specifications.

Based on these findings, almost two-thirds of the centralised clinical analysers surveyed comply with some form of the ASTM E1394 standard, with the remaining third using their own proprietary protocol. Although this is still a rather small sample and is limited to a single geographical region, it should be noted that this is a significant finding.

Therefore on average 2 out of 3 analysers use the ASTM standard. To give a sense of the value of this market worldwide, the value of the closely related global IVD market grew from $19 billion in 1988 (CEN TC 140, 2010) to $32.2 billion in 2005 and was expected to reach $45.6 billion in 2010 (Burnell, 2008). That would signify a potential market of $30 billion annually for analysers operating in a similar realm to the one governed by ASTM E1394.

Returning to our study, it was found that while 43% of the analysers were using ASTM E1394, this amounted to only nine different ASTM E1394-97 interface implementations/manuals; one manual could not be obtained, further limiting the study to only eight manuals. It was therefore decided to expand the scope of the study to include an additional twenty two implementation manuals; thus bringing the total number of implementations up to thirty.

The study was undertaken by first detailing the AI implementations in individual worksheets. This was followed by entering worksheets pertaining to each ASTM record type. Within these worksheets the ASTM field descriptors were entered within the first six columns of each worksheet; see sample below in figure 3.

Chapter				Attribute	ISO 18812 Use Type	Analyser XXXX				
					Use Type (Message Descriptions)	Values	Use	Compatibility with ISO 18812 Messages Descriptions		Compatibility with ISO 18812 Profiles
O	9	4	1	Record Type ID	M (M1, M2, M3, M4)	=O	M	All Profiles	M1,M2,M3,M4	P1, P2, P3, P4
O	9	4	2	Sequence No.	M (M1, M2, M3, M4)	>0, <65536	M	All Profiles	M1,M2,M3,M4	P1, P2, P3, P4

Figure 3 - Sample 'Record Type' Worksheet – Analyser Entry

The next two columns pertained to the ISO 18812 standard. The first, 'Use Type' refers to whether the field in question is mandatory (M), prohibited/do not use (D) or optional (O) with regards compliance with ISO 18812. The second indicates what ISO 18812 message descriptions apply to the field in question.

These were followed by five columns in each instance pertaining to each analyser. The first 'Values' indicated what value(s) were used in the field under investigation. This was followed by the 'Use' field for the analyser, which indicated whether the field was mandatory (M), prohibited/do not use (D) or optional (O) with regards to each vendor's implementation manual.

Chapter				Attribute	ISO 18812 Use Type	Analyser XXXX			
					Use Type (Message Descriptions)	Values	Use	Compatibility with ISO 18812 Messages Descriptions	Compatibility with ISO 18812 Profiles
Q	12	1	5	Universal Test ID	O (M5, M6)	^^^ALL	D	All Profiles M5, M6	All Profiles
Q	12	1	6	Nature of Request Time Limits	D	R or S	M	NOT Compatible with M5 or M6	Not Compatible with any Profiles

Figure 4 - Sample 'Record Type' Worksheet – Non Compliance Example

Standard's Use	Vendor's Use	Compliance with ISO 18812
Mandatory (M)	Mandatory (M)	Compliant
Mandatory (M)	Optional (O)	Compliant
Mandatory (M)	Do Not Use (D)	Non Compliant
Optional (O)	Mandatory (M)	Compliant
Optional (O)	Optional (O)	Compliant
Optional (O)	Do Not Use (D)	Compliant
Do Not Use (D)	Mandatory (M)	Non Compliant
Do Not Use (D)	Optional (O)	Compliant
Do Not Use (D)	Do Not Use (D)	Compliant

Figure 5 - ISO 18812 Optionality Compliance Chart

Any non-compliance with ASTM E1394-97 was highlighted by changing the background colour of the relevant cells to yellow; such as shown above in figure 4. The next two columns indicated whether the implementation was compatible with the ISO 18812 standard in terms of optionality, allowed values and ISO 18812 message profiles.

For example, if the vendor's manual indicated that a field was mandatory, yet the standard indicated that it was prohibited, this was viewed as a simple case of non-compliance. If however the vendor's manual indicated that the field was optional, then it was assumed that the implementer was free to follow the standard and prohibit the use of the field within the implementation in order to comply with the

standard. The chart above, figure 5, shows all possible combinations and inferred compliance for each scenario.

Chapter				Attribute	ISO 18812 Use Type	Analyser A	Analyser B	Analyser C
					Use Type (Message Descriptions)	Values	Values	Values
O	9	4	1	Record Type ID	M (M1, M2, M3,M4)	=O	=O	=O
O	9	4	2	Sequence No.	M (M1, M2, M3,M4)	>0, <65536	>0	>0

Figure 6 - Sample of 'Values Only' Spreadsheet Entries

Number Using Field	Compliance With ASTM	% ASTM Compliance	Compliance with ISO 18812 Profiles	% ISO 18812 Profiles Compliant
30	30	100%	30	100%
30	29	97%	29	97%

Figure 7 - Recording of ASTM and ISO 18812 Profiles Compliance

A simplified version of this master spreadsheet was also created to ease analysis (as per figure 6 above); where only the value field for each analyser was recorded. This made it easier to identify issues pertaining to ASTM E1394-97 compliance. An additional five columns were added to the right hand side of each record type sheet to record overall compliance, by field, in terms of ASTM E1394-97 and ISO 18812 profiles (as per figure 7). It was found that on average there was 94% compliance with the ASTM E1394-97 standard and 89% compliance with the ISO 18812 profiles; see figure 8 below for graphical representation of compliances across all record types. To further aid analysis, all the instances of non-compliance for both ASTM E1394-97 and ISO 18812 were recorded in mind maps; please see Appendix D.

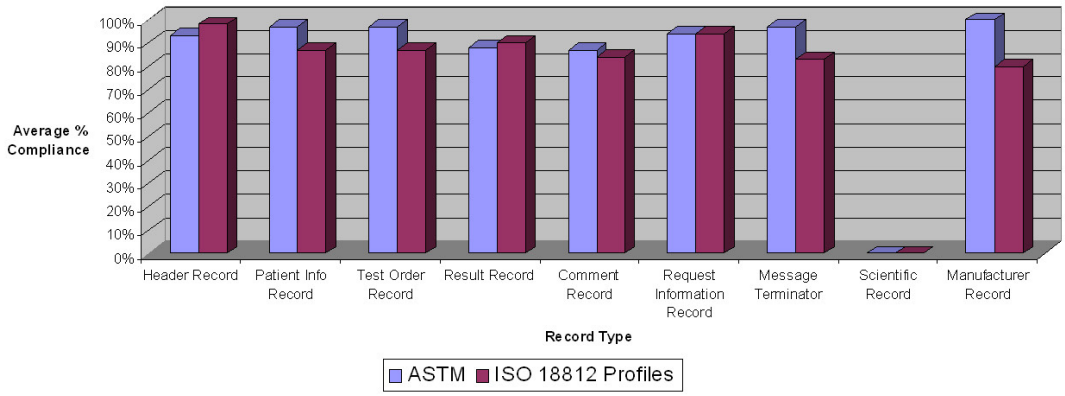

Figure 8 - ASTM E1394-97 and ISO 18812 Profiles Compliance per Record Type

A further study was undertaken with respect to the seven fields that have "allowed values" under the ISO 18812 standard, (EN ISO, 2003). The following assumptions were made when assessing compliance with respect to these fields:

- If the vendor supported values/flags in a given field that were not specified as 'allowed' in the ISO 18812 standard, then the instance was deemed to be non-compliant.
- If the meaning/representation of the flag/value in question differed between that of the vendor and the ASTM 1394-97 standard, then it was deemed that this instance was non-compliant.
- With three of the fields, namely 9.4.12, 10.1.9 and 12.1.13, the 'allowed values' differed depending on what message type was being used. In these instances compliance was assessed separately for each message type.

It was found that on average there was a 34% compliance with the use of allowed values for the given fields; see figure 9 below to see average compliance with ISO 'Allowed Values' in comparison to ASTM E1394-97 standard with respect to the given fields.

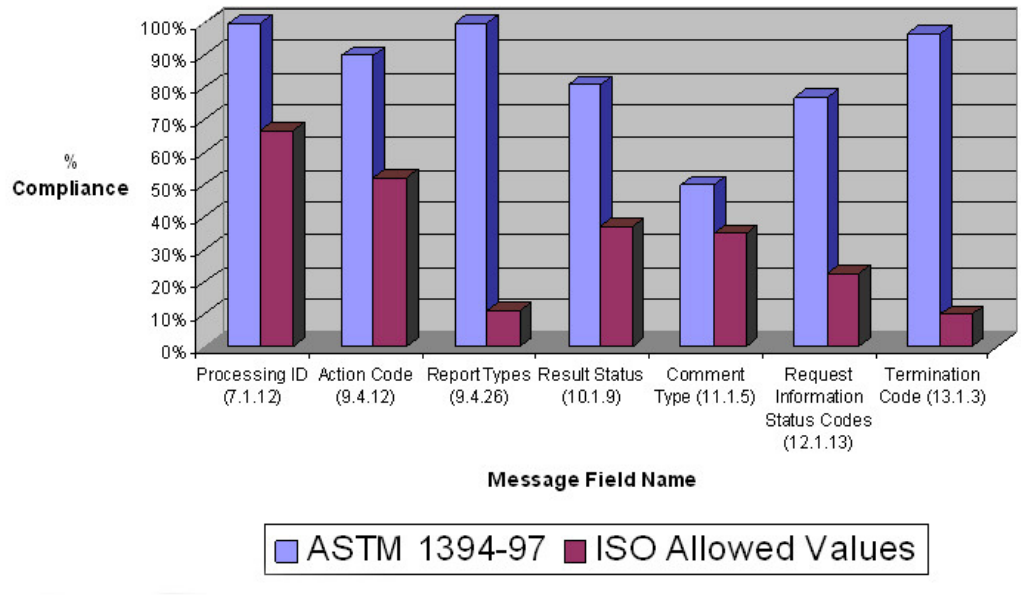

Figure 9 - Compliance with ASTM and ISO 18812 Allowed Values

Mind maps were then generated for each record type defining both ASTM 1394-97 and ISO 18812 non-compliance instances to aid analysis, see appendix E – Mind Maps. A higher-level analysis of these findings was then conducted in terms of how this reflects on the overall standard.

4.3 ASTM Compliance

4.3.1 Header Message

A majority of the interfaces/vendors fully supported the 'Header Message' specification. Just a few inconsistencies were found.

There was only one system that did not support the 'Escape Delimiter' (7.1.2). All vendors supported the proper use of delimiters within the header message and its usage throughout the other components of the message.

One of the more recent specifications supports the recording of IP addresses of both the AI (7.1.5) and host (7.1.10) as part of their identifiers. Two earlier

specifications had also supported the recording of the receiver's IP addresses as part of the receiver id (7.1.10). However it should be noted that the E1394-97 standard was developed for point-to-point connections (e.g. RS232). None of the supporting e31 standards supported messaging over any form of network.

Almost two-thirds of the interfaces had the software revision field (7.1.13) set to '1'. This should have indicated which version of the standard was being used (i.e. E1394-91, E1394-97, LIS2-A or LIS02-A2). Only one vendor had placed the version of the software interface in this field.

There was only one AI interface that didn't comply with the proper date and time formatting within the header message in field 7.1.14.

4.3.2 Patient Information Record

Once again only a small number of interfaces were non-compliant with the 1394 standard, within this component.

A single implementation forced all elements of the patient's name, excluding the initial surname, to be concatenated into a single value that was placed in the second component of the 'Patient Name' field (8.1.6); referred to as 'Rest of Name'. A couple of interfaces, notably by the same vendor, added an extra component for 'Age' and 'Age Unit' to the 'Birthdate' field (8.1.8). This seemed to be an attempt to facilitate the recording of the age of infants, whose age couldn't be recorded using units of years; a missing requirement of the standard.

Almost all the vendors who used the 8.1.10 field followed the examples set out in the standard's documentation with the exception that some used 'N' instead of 'NA' for 'Native American'. It was still compliant but showed that most vendors preferred to use a single value for this field.

There were 2 deviations from the standard with regards the 'Patient Address' (8.1.11). In one instance the components of the address were correctly messaged

to the Data Management System (DMS). However when the DMS stored this address, it first concatenated it and proceeded to store it as a single record within its database. Subsequently, when it was required to upload the address, it placed the complete address in the first component of this field (i.e. 8.1.11.1), therefore resulting in non-compliance with the standard.

The second implementation took the approach of storing the full address in the first field (8.1.11.1) and using commas to delimit the components, again resulting in non-compliance with the standard.

4.3.3 Test Order Record

The greatest deviation by AI manufacturers from the ASTM standard occurred in this segment of the messaging standard.

Almost 50% of the interfaces placed additional information along with the specimen identifier in the 'Specimen ID' (9.4.3) field. The majority of this non-compliance pertained to information relating to the location and position of the specimen within the analyser. Another pair of interfaces included details pertaining to the isolate and organism associated with the corresponding specimen. However, while the standard didn't further define the additional components, it did however indicate that components of this nature were congruous, as it stated that they "may contain the specimen number followed by the isolate number, well or cup number", (ASTM, 1998b). Two implementations also stored barcodes pertaining to the specimen in this field.

In the case of the 'Instrument Specimen ID' (9.4.4), as with the previous field 9.4.3, many interfaces included details pertaining to location and position of the specimen within the analytical instrument. It is questionable whether this is appropriate, as the standard doesn't make reference to any additional components or their possible usage.

Three implementations had completely omitted an identifier, only placing the location/positioning information in this field. Another interface used this field to store the barcode identifier of the specimen. A further implementation stored identifiers for more than one specimen in 9.4.4.

All vendors, who used the Test Order Record, complied fully with the standard's usage of the 'Universal Test ID' field (9.4.5). They refrained from populating any of the first three components of this field. They only placed their own test identifiers and additional information in the preceding components. There was only one instance where a vendor placed his own test identifier in the first component of this field.
One vendor had added their own test code 'N' (for 'Normal') to two AI interfaces that was not supported by the standard. Also another vendor supported a proprietary code 'ADD_QUALITY' for the Action Code field (9.4.12). In support of this Quality Control functionality the same implementation supported a number of non-compliant values (HPC, MPC, LPC and NC) in the Specimen Source field (9.4.16).

4.3.4 Result Record

The Universal Test ID field (10.1.3) was used in the same manner as its equivalent sister field in the Test Order Record (9.4.5). There was however one exception where an AI interface supported the use of error codes in this field, in addition to the manufacturer's code(s) in the fourth component, onwards.

Two implementations were found to be non-compliant with the standard in the 'Data or Measurement Value field' (10.1.4). In both instances they used a dot to delimit the components of the measurement ('Hours.Tenths'). They should have used the component delimiter to separate these components, in order to comply with the standard.

There were a number of issues pertaining to the population of the 'Data or Measurement Value' field (10.1.4). Firstly, in two instances the values were

accompanied by an additional 'flags' component. A number of different manufacturers allowed the recording of multiple values/results within this field, in complete contradiction to the stated usage in the standard document. There was also variance in the manner in which the additional values were recorded, with four interfaces opting to treat them as components and place a component delimiter between them. In one other instance the vendor choose to separate the values using the repeat delimiter.

Half of the interfaces that supported this field, incorrectly placed the lower limit in the first component of the field with the upper limit in the second component (10.1.6.2) separated by a component delimiter. Whereas the standard had indicated that both components (the single reference range) should be placed in the first component (10.1.6.1) only.

The 'Abnormal Result Flag' field had a significant number of unsupported values/flags associated with it by a number of vendors. These included flags to highlight the result as a quality control result, to indicate an alarm code and to indicate manual entry of a result(s) by the operator. One implementation supported the use of additional 2 components.

The 'Result Status' field (10.1.9) is to be occupied by one of the outlined 12 result codes. There was again non-compliance in the population of this mandatory field as follows:

- In two instances, a Null Value was used in this field.
- Two implementations by the same vendor saw the additional recording of 'Test Status' and 'Error Code' in the 2nd and 3rd components of this field, respectively.
- Almost 50% of all implementations supported the use of their own non-standard values in this field.

There was a single deviation from the standard in the Date/Time Test Completed field (10.1.13), with the value being stored in the second component (10.1.13.2) of the field while a 'Result/Status Date/Time' was recorded in the first component (10.1.13.1). This same implementation also added an unsupported additional field (10.1.15) to the Result Record in order to facilitate the recording of multiple results. In one implementation additional information pertaining to the test result was recorded in the second and subsequent components of the 'Instrument ID' field (10.1.14).

4.3.5 Comment Record

Only three of the twenty-two analysers supporting this record used un-supported values for the 'Comment Source' (11.1.3). One analyser used a completely different set of values for the 'Comment Type' (11.1.5), while another used an additional three unsupported values.

4.3.6 Request Information Record

There were only 2 deviations from the standard with regards the 'Starting Range ID' (12.1.3):

- One analyser used the first two components of the field to indicate the rack number and tube position of the sample, as opposed to patient ID and specimen ID, respectively. Then it recorded the sample ID and sample number attribute in the third and fourth components, respectively.
- Three other analysers, all by the same manufacturer choose to record specimen location information in the third and subsequent components along with the relevant patient and specimen IDs.

Once again there are issues around the population of the 'Universal Test ID' field (12.1.5). One implementation places a 'Test ID' and 'Test Status' in the first two components of this field. Another implementation places more than one manufacturer test code in this field, contravening the standard.

Instead of placing a status in the 'Nature of Request Time Limits' (12.1.6) field, a date and time value were placed in the field, in one implementation.

Two un-supported flags, 'X' and 'A' were used in the 'Request Info Status Codes' (12.1.13) field by a number of implementations.

4.3.7 Message Terminator Record

There was no deviation by any implementation from the defined values for any fields in this record. However 5 analysers didn't define a terminator record and 2 gave the option not to use one. All ASTM messages must contain a header and terminator record. Therefore non-use is a categorical non-compliance with the standard. It was also noted that one implementation choose to use the 'F' (last request for information processed) termination code flag in 13.1.3, rather than the 'N' (normal termination) flag.

4.3.8 Scientific Record

Significantly, none of the 40 implementations used a scientific record within their message(s).

4.3.9 Manufacturer Record

Two implementations defined their own specific manufacturer record format. One was primarily used to facilitate the messaging of result errors and alarm codes to the LIS.

4.4 Analysis of ASTM Findings

Overall compliance with the ASTM E1394-97 standard was high across all record types; averaging 94%. The majority of non-compliance issues centred on the need for the missing functionality as outlined in section 4.4.11 below.

4.4.1 Delimiters

Virtually all interfaces complied with the proper usage of the delimiters and chose to use the delimiters as laid out in the standard's documentation. There was only one implementation that didn't support an 'escape delimiter' in the header of the message.

Two implementations chose to use commas as delimiters in the 'Patient Address field (8.1.11), which was a clear case of inappropriate usage and non-compliance. The non conforming vendors should have used the component delimiter in the same manner as they delimited other components throughout their implementation. In another instance, a period/full-stop was used to separate components within the 'Data or Measurement Value' field (10.1.4). Once again the vendor should have used the component delimiter as used elsewhere in their implementations. There were also six instances of the inappropriate use of a delimiter within a field. The vendors had placed the component delimiter in the middle of the two range values within the 'Reference Ranges' field (10.1.6); which was both inappropriate and non-compliant with the standard.

4.4.2 Multiple Values

There were instances where vendors inappropriately placed multiple values in fields that supported only the recording of a single entity.

In two implementations, multiple sample identifiers were placed in the 'Instrument Specimen ID' field (9.4.4) of the test order record. This resulted in one of these implementations reporting multiple results in the 'Data or Measurement Value' field (10.1.4); also contravening the standard. This is a contradiction in the sense that

each order can only relate to a single sample and that each result must be reported individually within its own result message.

4.4.3 Unsupported Values

Ten fields were affected by the use of unsupported values. The 'Priority' field (9.4.6) saw the use of 'N' (Normal) instead of the standard's 'R' for "Routine". There was no obvious reason why the vendor chose to use this replacement value in their implementation, as they had used the 'R' value in all of their other interfaces.

The 'Result Abnormal Flag' (10.1.7), saw five implementations using this field to flag expired reagents, quality control errors and result entry types. There was the addition of the 'D' for Data Management System to the range of values for the 'Comment Source' field (11.1.4). This could be viewed as a necessary revision to support the recording of Data Management Systems as another messaging source.

Only two implementations chose to use their own comment types in 11.1.5 ('Comment Type' field). In one case, two of the values which corresponded to those supported, namely 'P' and 'I', had a completely different meaning from that specified in the standard and didn't relate in any way to the intended purpose of this field.

There were also a number of fields throughout the test order, result and comment records where vendors had placed unsupported values in order to support the messaging of quality control, calibration, error and alarm messages. This seemed to indicate a shortfall of the standard in not having a clear method for supporting such message types. One implementation had created a manufacturer record to support error and alarm code messaging, in an attempt to avoid this problem.

4.4.4 Misinterpretation of Fields

There seemed to be some confusion around the use of the 'Software Revision' field (7.1.13), as most simply placed the numeric '1' in it. This was non compliant as it required the version level of the standard (e.g. E1394-97) to be placed here.

There was virtually complete adherence to the time/date formatting, as interfaces complied with either the ANSI X3.30 or ANSI X3.43 standards.

4.4.5 Concatenation of Multiple Components

One interface concatenated the patient's complete address into a single entry that was recorded within a single field within the DMS. Consequently the DMS placed the complete patient address in the first component of the address field (8.1.11.1). Once information from multiple fields is concatenated, it is impossible to extract it into its original format. Therefore all concatenation of information should always be avoided.

4.4.6 Different Flags

As previously described, two implementations chose to use 'N' (normal) rather than 'R' (routine) flag in the priority field (9.4.6), as defined by the standard. As both flags have the same meaning, this was an unnecessary deviation from the standard on the part of the vendor.

In the second instance, the vendor chose to use a number of flags, already defined in the standard, to represent other comment types (in 11.1.5). This again was unnecessary, as alternative values not defined in the standard could have been used to signify the new comment types.

4.4.7 Additional Components

In two instances there were additional components added to the field that were not specified or outlined in the standard; the 'Instrument ID' field (10.1.14) and 'Nature of Time Request Limits' field (12.1.6). In both instances these added further

information to support the value in the first field. However, these were the only times that any implementation recorded such detail. Therefore this would indicate this was to meet a specific vendor requirement.

4.4.8 Use of Test Identifiers

The standard allows the creation of local laboratory test codes through use of the third and subsequent components of the 'universal test identifier' fields throughout the message. This enables the vendors to permit laboratories to devise their own laboratory test codes, which in turn leads to ambiguity when laboratory results are being sent between organisations.

The LOINC lab coding system has now reached maturity. The later revisions of the standard should have stipulated that, where possible, coding systems such as LOINC (Logical Observation Identifiers Names and Codes) or SNOMED-CT (Systematized Nomenclature of Medicine -- Clinical Terms) were used to identify laboratory tests, so as to aid interoperability among systems and organisations. This would have furthermore aided the ability to correlate information pertaining to given tests from any number of laboratories or organisations.

4.4.9 Data Types

HL7 Seq	HL7 Element Name	Max Len	HL7 Data Type	Opt	Repeat	Table	Item #	Description
1	NTE.1 - Set ID - NTE	4	SI	O			00096	This field may be used where multiple NTE segments are included in a message. Their numbering must be described in the application message definition.
2	NTE.2 - Source of Comment	8	ID	O		0105	00097	This field is used when source of comment must be identified.
3	NTE.3 - Comment	65536	FT	O	Y		00098	This field contains the comment contained in the segment.
4	NTE.4 - Comment Type	250	CE	X		0364	01318	Not Currently Used.

Figure 10 – National GP Messaging Standard – NTE Segment

A lack of strong data typing was also identified as a shortcoming of the ASTM standard. All fields should have had a specified data type associated with them; in the same manner as the 'GP Messaging Standard' (Health Information and Quality

Authority, 2010a); as shown in figure 10 below. In addition, the data types specified should be in compliance with a standardised set, such as the proposed ISO/DIS 21090 standard, (ISO, 2010b).

In the case of the ' Data or Measurement Value' field (10.1.4), where there may be more than one data type, reporting of different data types should have been confined to specific components of the field. In this way, a system could easily determine how to process/analyse a particular result, dependent on its given position within the field.

4.4.10 The use of Standards within Standards

There are two instances of mandated compliance to formatting standards within the ASTM E1394-97 standard. The first mandates that all messaged dates and times comply with the ANSI X3.30 or ANSI X3.43 standards. This seemed to be a move towards a standardised format for dates and times, as the ASTM E1238 standard upon which it was based used a "ddmmyyhhmm" format, (NCCLS, 2004). Also virtually all the implementations complied with the ANSI standards. The single non-compliance related to a single field within an implementation where all other recording of dates and times did comply with either the ANSI x3.30 or X3.43 standards.

The second instance, with reference to the usage of the 'Units' field (10.1.5), requires the abbreviation for units to comply with the ISO 2955 (ISO, 1983) standard. The only other reference to a standardised format or coding system occurred in the 'Patient's Known or Suspected Diagnosis' field (8.1.19), which mentioned usage of the ICD-9 coding system.

However there were a number of instances where other coding systems or standards could have been enforced to improve the quality of the messages. The standard could have been updated to support the Unified Code for Units of Measure (UCUM) code sets, (Schadow et al, 1999), as units of measurement.

The street addresses defined by the 'Sender Street Address' field (7.1.5) and the 'Patient Address' (8.1.11) should have required conformance with the ISO 3166 standard (ISO, 2010a). As previously mentioned in section 4.4.8, coding systems such as SNOMED-CT or LOINC should have been used to improve the quality of the test identifiers.

4.11 Missing Functionality as Suggested by Implementations

A number of implementation features were either encountered repeatedly in different implementations or were otherwise considered to be noteworthy and candidates for inclusion in a future standard. These features are described below.

Age for Infants

As stated earlier, the addition of age related components within the 'Birthdate' field (8.1.8), in one implementation, indicated the possible need for a method of recording the age and age units (days, weeks, months) of infants; which the standard failed to address. This could be viewed as a requirement for any future revision of the standard.

Specimen Location/Position

There was a very clear need for a field to support information pertaining to the specimen location/position within the analyser. This can clearly be seen from the large number of implementations that placed such information in one or more of the Specimen ID (9.4.3), Instrument Specimen ID (9.4.4), Universal Test ID (9.4.5) or Starting Range ID (12.1.3) fields.

Network Address of Sender and Receiver

The recording of sender and receiver IP addresses was also highlighted in a few instances where this information was placed in the Sender or Receiver ID field(s). Considering that most analysers are now networked, it would good sense to have a dedicated field to support the recording of such details for both the sending and receiving systems.

Barcodes for Specimens

The recording of barcodes was also highlighted by a few implementations that placed them in the Specimen ID (9.4.3) or Instrument Specimen ID (9.4.4) field. Plebani has stated that "the accuracy of patient identification is the first and most important goal in improving patient safety" and that it "should be improved by the extensive use of bar-code technology", (Plebani, 2009). With this in mind, it is essential that a dedicated field should be introduced to support the recording of specimen barcodes. In addition it should be stipulated that use of this field must comply with the CLSI LIS-7A standard; "Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory" (CLSI, 2010b), (AACC, 2010).

Support for Calibration/Error/QC and Training Messages

There was a clear lack of proper support, within the standard, for the messaging of calibration, error, QC or training messages between the LIS and AI. Those implementations that attempted to get around this used fields within the test order record and/or the result record. Only a few implementations used manufacturer records for this purpose. The standard had great shortcomings in relation to this functionality. There were no guidelines or examples within the standard that outlined how to structure such messages. One of the following approaches should have been taken to avoid forcing vendors to create their own approach to this, namely:

- The standard should have outlined a clear and concise set of guidelines and specified flags for message composition, for each message type, using the existing record types within the standard.

Or

- The standard should have had one or more additional dedicated record types specifically addressed this type of messaging. It should also have clearly outlining the usage of both these record types and any values/flags associated with them.

The use of the ‘M’ flag to represent manual result entry by an operator in the ‘Result Abnormal’ field (10.1.7) may be viewed as a required flag that was omitted from the standard originally. However the use of ‘D’ in the ‘Comment Source’ (11.1.3) to represent a Data Management System (DMS) may be viewed as an required update to the standard; as it would have predated the use of data management systems in laboratories; considering it was written almost 20 years ago.

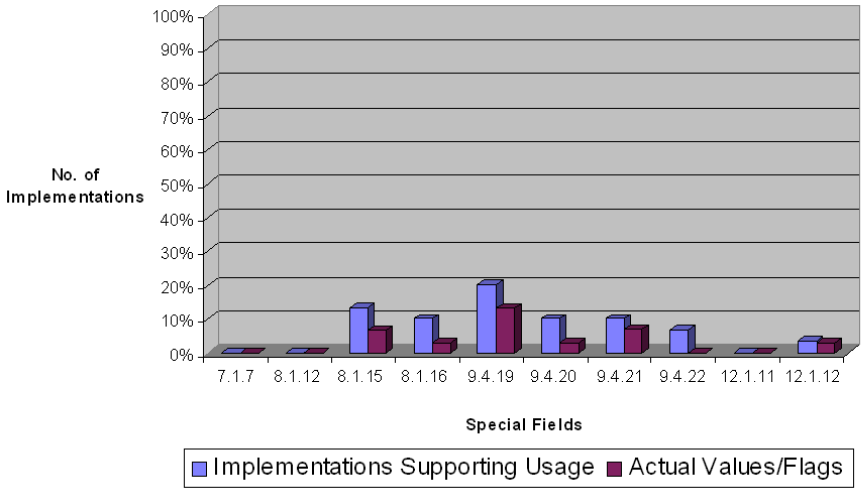

Figure 11 - Usage of 'Special' or 'Reserved' fields by vendors

4.5 Reserved or Special Use Fields

A number of fields within the ASTM E1394-97 standard are designated for optional usage by vendors or are reserved for future use. The expectation might be that vendors would have used these fields to support new functionality or other proprietary requirements that could be deemed as non-compliant with the standard. However it was found that usage of these fields, by vendors, was extremely low; as shown in figure 11 above. It was also noted that on average only 3% of implementations actually detailed the usage of these fields, in terms of flags/values, when compared to 7% of implementations supporting their usage.

4.6 Language Usage within the ASTM 1394-97 Standard

It has been found that "the 500 most used words in English have on average 23 meanings" and that "phrases and whole sentences can be interpreted in more than one way", (Kamsties, Berry and Paech, 2001). Natural language is fraught with differences in meaning and the writing of any specifications, requirements or standards have to contend with this. It is therefore imperative that when using natural language to define a specification or standard that every precaution possible is taken to avoid ambiguity.

A requirement or clause within a standard is defined as ambiguous if "it has multiple interpretations despite the reader's knowledge" of the given area/context, (Kamsties, Berry and Paech, 2001). Therefore we must "use a restricted natural language which is inherently unambiguous and more precise", (Berry and Kamsties, 2001), to help avoid this.

4.6.1 Non-Compliance with ASTM 1394-97 and Language Usage

To determine whether language usage within the standard had contributed to the instances of non-compliance with the ASTM E1394-97 standard, a further study was undertaken.

Initially all the non-compliant ASTM instances were placed in a mind map (see figure 28 – 'Overall Language Usage and ASTM E1394-97') with each instance of ASTM non-compliance being categorised according to the language usage within the given clause. The backgrounds were colour coded as follows:

- Red – Imperative
- Green – Optionality
- Yellow – Indicative/Other

This was further refined into three mind maps; namely usage of “shall”, other imperatives and non-imperatives (see figures 29, 30 and 31 in Appendix F). From these the following is ascertained:

- The ‘Reference Ranges’ field (10.1.6) was the only one clause that caused confusion and ultimately one instance of non-compliance. It states that the value placed in it “shall be reported in the following sample format: (lower limit to upper limit; example: 3.5 to 4.5)”, (ASTM, 1998b). There are two issues with this clause. Firstly, there is the ambiguity brought about by the use of the imperative “shall” followed by the wording “sample format”, indicating some form of optionality. Secondly, there is the requirement to separate the ranges by the use of the wording “to” rather than by some form of delimiter. This failure is compounded by the fact that 9 out of the 16 implementations choose to separate these ranges using a component delimiter, with a further instance choosing to use a dash (-). This meant that only 6 implementations or 38% complied with the standard; this was the message field with the lowest level of compliance within the ASTM 1394-97 standard.
- The majority of non-compliance was found to relate to attempts by vendors to implement functionality that is missing from the standard and as such did not relate to the language usage within the given clause(s).
- In all other instances, it was clear that the vendor had chosen to ignore the standard and had decided to either alter the usage of the field or use alternative values, flags or delimiters; again not related to language usage.

4.6.2 Language Usage and Ambiguity within the Documentation

A further review of the standard was undertaken in an attempt to identify any further issues pertaining to language usage and cases of ambiguity within the standard.

In addition to the issue with regards the 'Reference Ranges' field (10.1.6) discussed above in section 4.6.1, it was found that there is a lack of guidelines for usage of the following fields:

- *'Patient Active Medications' (8.1.20)* – There are no guidelines on how to record more than one medication or any other information pertaining to the medication(s), such as strength of medication or how often they are taken.
- *'Dosage Category' (8.1.25)* – There are no clearly defined categories or coding for these within the standard; but rather examples of some.
- *'Operator Identification' (10.1.11)* – Lack of clarity on how to record multiple operators.

There is also the issue pertaining to recording of race or ethnic origin in the 'Patient Race-Ethnic Origin' field (8.1.10). In some instances this information can play a major role in the interpretation of results; such as the link between sickle cell anaemia and those of African descent (Ashley-Koch, Yang and Olney, 2000). Only 17% (5 implementations) used this field. Notwithstanding this, the standard should have clearly defined a number of the most prominent ethnic groups in terms of both codes and descriptions.

The 'Result Abnormal Flags' field (10.1.7) specifies a number of flags that have no logical meaning; such as "LL – below panic normal". As stipulated by the ISO 18812 standard, in its guidelines for usage (EN ISO, 2003) , only the "<" and ">" flags should be used in this instance in order to eliminate the ambiguity surrounding the use of these flags. It should therefore be noted that all qualifying elements within a message need to be clearly defined and to be logically understood.

4.7 The 'Pyramid of Adoption'

The ASTM E1394-97 standard is only used to message information between a central laboratory analyser and a LIS. It was developed by the E31 committee and subsequently has been implemented by a relatively small number of vendors; with possibly less than 200 different devices/implementations. Since no further modification/localisation of the ASTM E1394-97 message (analyser output) is possible, control over the standard and implementation of same has been confined to this relatively small group, see figure 12, below. Also localisation of the messaging standard is also impossible. Therefore the original ASTM E1394-97, with slight variances from AI vendors, impacts directly on all patient blood results that are messaged using this standard.

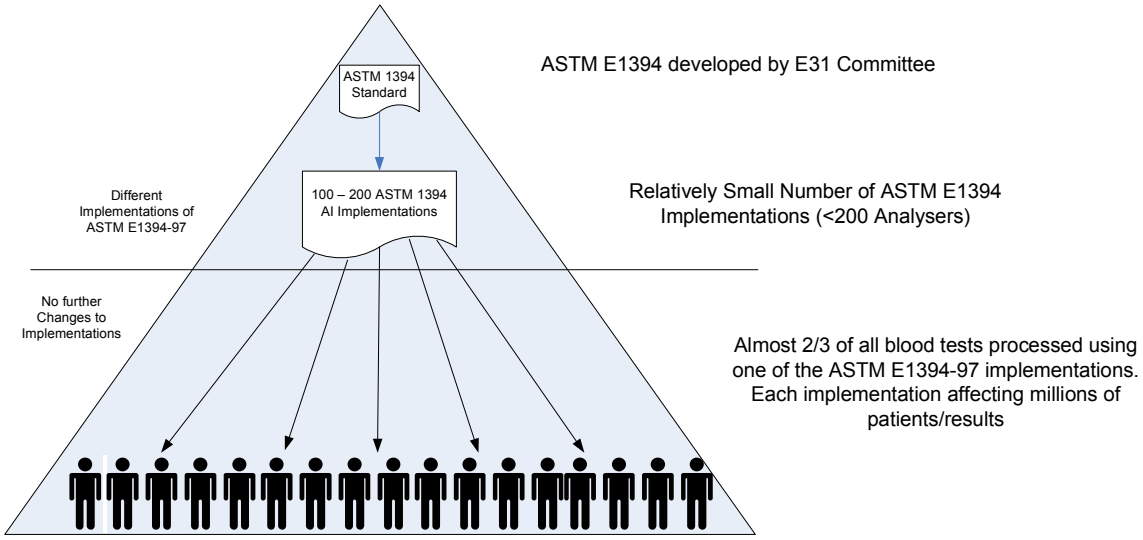

Figure 12 - ASTM Pyramid of Adoption

In comparison, the HL7 v2.4 standard is one of the most widely used standards for messaging throughout healthcare. There are a number of HL7 workgroups involved in the development of the standard and changes to the standard requires broad consensus across these groups. Furthermore there are numerous national localisations of the standard, such as the national 'GP Messaging Standard' (Health Information and Quality Authority, 2010a). But control often extends

beyond this to the local implementation; e.g. how each field is populated can vary among individual implementations, see figure 9 below.

Therefore the ASTM E1394-97 standard has a smaller control group and the standard is not localised to the specific laboratory environment.

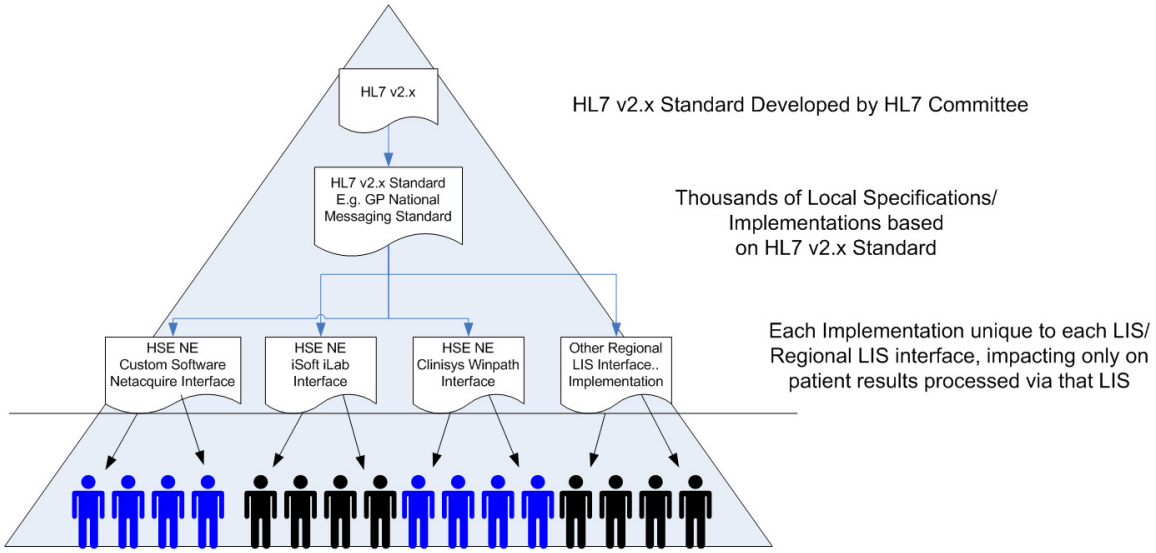

Figure 13 - HL7 Pyramid of Adoption

4.8 ISO 18812 Profiles and Optionality Compliance

This section details the issues of non-compliance with the ISO 18812 profiles and optionality by record type. On reviewing the ISO 18812 documentation it was found that there were a number of inconsistencies within it. These are discussed in sections 4.8.3 (Test Order Record) and 4.8.6 (Request Information Record) below.

4.8.1 Header Record

There were only 2 non-compliance issues pertaining to the header message. Two implementations choose to make the use of an 'Access Password' (7.1.4) compulsory, where the standard indicated that this field was not to be used. One

implementation made the use of the 'Sender Street Name' (7.1.6) compulsory, also contravening the standard.

4.8.2 Patient Information Record

Four implementations enforced the use of a laboratory assigned identifier in 8.1.4, with three implementations also making it mandatory to use a practice assigned ID (8.1.3). Another implementation made the use of 8.1.6 (Patient Name) and 8.1.8 (Birthdate) also compulsory, thereby breaching the standard.

4.8.3 Test Order Record

There was some initial confusion around the proper interpretation of the following Test Order Record fields, due to inconsistencies within the ISO 18812 documentation, (EN ISO, 2003):

- 9.4.3 - Specimen ID (M1, M2) – Page 8 (D), Page 40 (O)
- 9.4.4 – Instrument Specimen ID (M3, M4) – Page 8 (D), Page 40 (O)

The use of a Specimen ID in message types M1 and M2 is stated as 'Do Not Use (D)'. However on page 40, Table C.4, it indicates that this field is 'Optional (O)'. This caused some confusion in terms of the most logical interpretation we must adhere to.

A review of the scenarios laid out in the ISO 18812 documentation (EN ISO, 2003) was therefore carried out. They seem to suggest that the original sample identifier that is assigned by the LIS should be placed in 9.4.3 (system specimen ID); which complies with the ASTM E1394-97 standard (ASTM, 1998b). However when the result for the sample is messaged back to the LIS, according to the ISO 18812 scenarios, this identifier now moves from the 'System ID' field (9.4.3) to the 'Analytical Instrument's ID' field (9.4.4). The only logical reasoning for this would be to indicate that the specimen identifier is being acknowledged and as such is moved from one field to the other.

The non-use of the Specimen ID (9.4.4) in message types M3 and M4 could be seen to support this argument, as these are only used to hold the sample identifier in result type messages (M1 and M2).

The reverse could also be viewed as being true. Under the ISO 18812 standard, 9.4.3 (System Specimen ID) is a 'Mandatory' field for message types M3 and M4, while 9.4.4 (Instrument Specimen ID) is a 'Mandatory' field for message types M1 and M2. Therefore vendors would have no choice but to move the identifier between 9.4.3 and 9.4.4, depending on the message type.

However, following much consideration, the author believes that this interpretation contradicts the ASTM E1394-97 standard, (ASTM, 1998b). The standard clearly outlines that "this text field shall represent a unique identifier for the specimen assigned by the computer system and returned by the instrument", (ASTM, 1998b). Therefore the 'Specimen ID' in 9.4.3 should be messaged at all times in this field.

Also the standard clearly states that 9.4.4 "shall represent a unique identifier assigned by the instrument, if different from the computer system identifier, and returned with results for use in referring to any results", (ASTM, 1998b). Again in contradiction to the ISO 18812 this clearly indicates that it should only have an identifier that's different from the computer system identifier (already present in 9.4.3).

Subsequently as a result of the above, while assessing the compliance of all implementations to the ISO 18812 standard, (EN ISO, 2003), it was felt that the most logical interpretation was that 9.4.3 should be 'Optional' for messages types M1 and M2, while 9.4.4 should be 'Optional' for message types M3 and M4. All mandatory conditions should remain as is.

Just over one third of the implementations had 9.4.4 set as 'Do Not Use'. As such these implementations would be incapable of messaging results under the ISO

18812 standard, as the passing of the sample id to the LIS in 9.4.4 would be prohibited.

According to the ISO 18812 standard, 9.4.5 (Universal Test ID) field should be only mandatory for M4 (Order) type messages. It should not be used (D) for any result type messages (M1, M2 or M3 type messages). However two-thirds of the implementations had 9.4.5 (Universal Test ID) set as a mandatory field for all messages and therefore were contravening the standard. An additional four implementations had this set as 'Do Not Use'. They would be compliant in terms of messaging results, but non-compliant in terms of messaging orders due to prohibited use of a universal test identifier in order messages. All the other implementations had this set as an 'Optional' and were therefore compliant with whatever requirements the standard placed upon them.

There were four other fields within the message that were prohibited under the ISO 18812 standard. The prohibited 'Requested/Ordered Date and Time' (9.4.7) and 'User Field 1' (9.4.19) are prohibited by the standard. However one implementation has made 9.4.7 a mandatory field and an additional eight implementations have made 9.4.19 compulsory. The 'Sample Descriptor' (9.4.16) and 'Report Types' (9.4.26) fields are only to be used in order messages. However in one implementation 9.1.16 was set as mandatory, as was 9.4.26 in six others.

4.8.4 Result Record

Only one implementation didn't support the use of the 'Universal Test ID' field (10.1.3) in the result record. Another implementation made it mandatory to use the 'Reference Ranges' field (10.1.6), while four implementations made it mandatory to use the 'Date/Time Test Started' field (10.1.12), which is prohibited under ISO 18812.

4.8.5 Comment Record

One third of all implementations made it mandatory to use the 'Comment Source' field (11.1.3). Over one third of implementations also failed to comply by not supporting the use of the 'Comment Type' (11.1.5) field.

4.8.6 Request Information Record

This was the second record in which there were discrepancies between different sections of the standard's documentation. The 'Starting Range ID Number' (12.1.3) field was 'Mandatory' on page 9 of the documentation (for query messages, type M5 and M6), while being 'Optional' in Table C.7 on page 40. On review of all 30 implementations it was found that all analysers utilising this record type would not be impacted in terms of compliance, as they all supported the use of 12.1.3.

There was also confusion around the 'Request Information Status Codes' (12.1.13) field. It had been defined on page 9 as 'Optional' for 'Query for Order' (M5) messages, while being defined as 'Mandatory' in Table C.7 on page 40.

On review, it was found that six implementations would be impacted in terms of compliance with request information records. If viewed as 'Optional', they would be compliant with only the 'Query for Order' (M5) type messages. If viewed as being 'Mandatory', then none of the six implementations were compliant with the standard.

There was also some non-compliance with 12.1.6, 12.1.7 and 12.1.8, where some implementations enforced their use, while the standard prohibited it.

4.8.7 Message Terminator Record

There were only four implementations (13%) that didn't support the usage of the 'Termination Code' (13.1.3) field, which was mandatory under ISO 18812. Also one analyser supported the non-compliant use of the 'T' flag in 13.1.3.

4.8.8 Scientific Record

As stated previously, none of the 40 implementations supported the use of a scientific record.

4.8.9 Manufacturer Record

There were six implementations (20%) that were non-compliant as they supported the use of manufacturer records.

4.9 Analysis of ISO 18812 Findings

Overall compliance with the ISO 18812 profiles and optionality was high across all record types, as shown in figure 8 above. In three of the record types it had a higher compliance level than ASTM E1394-97, but was slightly lower over all with an average message compliance level of 89% to ASTM's 93%. The analysis of the findings in section 4.6 is now discussed in more detail.

4.9.1 Unnecessary Messaging

Almost 50% of the non-compliance instances with ISO 18812 related to fields that were deemed under the standard not to be required and therefore prohibited. Only the prohibiting of the use of the 'Access Pwd' field (7.1.4) seemed unusual. The most logical reason for prohibiting its use would be that the ASTM E1394-97 standard was originally intended to be only used in point to point networks. Nevertheless considering that many ASTM interfaces now run over a network, maybe the ISO 18812 should now deem this as an acceptable usage. Otherwise these non compliances could be deemed to be purely the needless messaging of redundant information.

4.9.2 Orders Only Fields

An additional 30% of non-compliance issues pertained to those fields that should only be used when messaging orders. Again in almost all instances the non-compliances would seem to be the messaging of additional superfluous information, when used in result messages.

The limiting of the usage of the 'Report Types' field (9.4.26) in order messages would be an endorsement of the additional restrictions placed upon the field in terms of "allowed values", by the standard. By placing this restriction, the additional values that relate to messaging of results are henceforth redundant.

4.9.3 Mandatory Fields

The 'Comment Type' field (11.1.5) was not used by over one third of implementations. On further review of the 'Comment Text' field (11.1.4) in each of these instances, it was found that the comments specified were always of the same type; namely generic/free text. This would help explain the omission of a comment type in 11.1.5.

It was also noted that over one third of implementations used the 'Comment Source' field (11.1.3), which was prohibited by ISO 18812. The opposite could almost be true here, where the standard has deemed the field unnecessary as all comments should be only related to results; namely those being sent to the LIS by the AI as additional information pertaining to results.

The only other non-compliance with an ISO 18812 mandatory field related to the usage of the 'Termination Code' field (13.1.3). The only conclusion for lack of usage was possibly that in all instances the record would always terminate normally. It was also noted that these implementations predated the ISO 18812 standard.

4.10 ISO 18812 Allowed Values Compliance

The ISO 18812 deemed it necessary to restrict the usage of seven fields within the ASTM E1394-97 message. This was accomplished by allowing only certain values/flags to be used, which was also further restricted by message type in three of the instances.

A review was carried out with regards compliance with these values. Due to the fact that ISO deemed it necessary to restrict the usage of these fields in this manner, it was determined that any implementation supporting any non compliant values would be viewed as non-compliant. As can be seen above in figure 9, the level of compliance with the ISO 18812 allowed values was extremely lower than the overall compliance with regards the field usage and optionality as specified by the ISO 18812 profiles.

It was found that a majority of the non-compliances related to the support of values that were valid under ASTM E1394-97 standard, but prohibited under the ISO 18812 standard. This could primarily be due to the fact that most of the implementations predated the ISO 18812 standard. Most other non compliances related to the use of proprietary values by vendors or non support of mandatory fields.

4.11 Conclusion

This chapter detailed the findings with respect to the 30 implementations that were assessed for compliance with both the ASTM E1394-97 and ISO 18812. It was noted that overall compliance with both the ASTM E1394-97 standard and ISO 18812 profiles and optionality was high; see figure 8.

The analysis in section 4.3, of the ASTM E1394-97 non-compliance issues detailed in section 4.2, highlighted a number of issues that could be viewed as being specific to ASTM, but also relevant to other messaging standards. This was

followed by a discussion around language usage and its impact on compliance in section 4.4. The 'Pyramid of Adoption' model gave a comparison on how ASTM differed from other standards in terms of:

- *Control* – Only a relatively small number of people control the standard; ASTM development group and the vendors that implement it.
- *Localisation* – No localisation takes place as the message cannot be modified from that specified by the vendor.

This was followed by an analysis of the ISO 18812 non-compliance issues. In terms of the profiles and optionality, it was found that in most instances these would only relate to surplus information being messaged and would have no impact on the actual quality of the messages. In the case of mandatory fields it was found that the analysers in question would have interpreted the use of that particular record type as normal and therefore not required the usage of these fields; that might signify otherwise.

The analysis of the "allowed values" under ISO 18812 found that compliance was extremely low across all specified fields. However this was probably due to the fact that the non-compliant implementations predated the ISO 18812 standard. Chapter 5 is going to look at these findings in terms of what constitutes good health messages.

Chapter 5 What constitutes good health messages

5.1 Good Health Messages

The ASTM E1394-97 standard has been one of the most successful messaging standards worldwide. It is a powerful standard, as previously stated. Indeed if you extend the one of the findings of this work to other countries it may well be responsible for the first messaging journey of two thirds of all centrally analysed lab results in the developed world, whether they relate to blood, urine, faecal, tissue or other sample types.

It is acknowledged that the ASTM E1394-97 has a very definitive application, to enable messaging between a laboratory information system and an analytical device, when compared with other standards such as HL7 that enable messaging between many different systems throughout healthcare. However it is the author's opinion that many of the successful traits that have been identified from the study and analysis outlined in chapters 3 and 4, are preeminent in other successful messaging standards. So let's discuss the traits discovered from the study of this messaging standard that will generally apply to others.

Simplicity is the first key element of a successful messaging standard. The simplicity of a standard makes it usable. The ASTM E1394-97 standard is simple by virtue of its simple message format (by use of delimiters) and hierarchical message structure. It should also be noted that it's not a large complex cumbersome document for vendors to wade through, physically consisting of a 15 page document, including an appendix.

The localisation of HL7, in cases such as the GP Messaging standard, can also be viewed as attempts to simplify the standard by profiling or limiting the fields and even attribute/values to be used in a specific messaging context. The ISO 18812 profiles even further simplified the ASTM E1394-97 message in this manner also.

One of the major objectives of health messaging in 1991, when the ASTM E1394-97 standard was first published, would have been to achieve syntactic interoperability. The simplicity of the ASTM standard enabled vendors to achieve this. It is important to remember that semantic interoperability in messaging, a modern goal for health messaging, cannot be achieved without first achieving syntactic interoperability.

The key to ensuring compliance with a given messaging standard is the use of language within it. In order for it to be properly implemented, it must be clear and unambiguous. Clarity can be achieved through the use of prescriptive clauses, such as in ASTM E1394-97, whereby the standard clearly defines all the usage of all aspects of the message from structure and format through to where and when particular values/flags are to be used. Where optionality presents itself within a clause, the standard should attempt to clearly define the different instances of usage of the given field and the allowable values within these instances; an example of this would be the “allowed values” defined within the ISO 18812 standard.

It is essential that any supporting information be present within the standard itself. Omissions of this nature can make it more difficult for vendors to implement the standard in question. The recently published GP messaging standard (Health Information and Quality Authority, 2010a) represents such an instance. It defined an abbreviated data type for each field of the message, while referencing these back to the original HL7 documentation. However a copy of the HL7 data types table within the standard itself would have been more helpful. Where possible reference tables (as used in HL7) should be included and used in documentation to help ensure consistency in the most commonly used values for a given field(s).

There is the question around optionality associated with field usage, such as addressed by the ISO 18812 profiles. Some may take the view that optionality can lead to ambiguity and therefore should be limited. However it is evident that optionality is key to enabling both usability and applicability of a standard.

Instances where a field is either mandatory or prohibited may result in some vendors being unable to use the standard. Optionality is the best alternative, where if required for a particular application the vendor has the choice of using this field. It should be noted that while the field is optional, its usage should be clearly prescribed; such as the 'allowed values' in ISO 18812. The 'Veteran's Military Status' field (PID.27) in the GP messaging standard, (Health Information and Quality Authority, 2010a), is a clear case of ensuring the applicability of the HL7 to a specific usage.

Optionality is essential to ensuring that all pertinent information is messaged. There are fields that may be seldom used, but nonetheless essential. The 'Patient Death – Date & Time' field (PID.29) within the GP messaging standard (Health Information and Quality Authority, 2010a) is a prime example of this. It will possibly be messaged only once, but the standard needs to accommodate it.

It should be noted that while optionality enables usability, it may be at the expense of the quality of the messages. The 'universal test id' field within the ASTM E1394-97 standard was flexible enough to allow the usage of local/manufacturer codes as test identifiers. However, if there had been a serious attempt to enforce usage of a standardised code set such as LOINC or SNOMED-CT (where possible), then the quality of the messages would have being significantly improved. This clearly means that by improving the quality of the information at the source (in this study information being captured from the AI), all systems that subsequently utilise this information will therefore have better quality information.

We can therefore summarise the usage of 'optionality' within health messaging as:

- Optionality is necessary in order to allow for fields within the message that have occasional or once-off usage, but nonetheless are an essential part of the electronic health record (e.g. 'Date of Death' field, as outlined above).
- Optionality is useful in ensuring that when looking for consensus among standard developers that compromise can be reached through the use of

optional field(s), even if they serve only one vendor or purpose (e.g. 'Veteran's Military Status', as outlined above).

- Optionality should be avoided where it may impact on the quality of the message, such as in the case of message identifiers (e.g. patient identifier or test identifiers)
- But it must always be used in a responsible manner so as to not jeopardise the patient's safety (such as the ISO 18812 'allowed values').

This leads to the use of standards within health messages. Firstly, the use of standardised coding such as LOINC, SNOMED-CT or ICD-10 is essential to enhancing message quality. This also helps bring about semantic interoperability. If all the systems are using the same coding sets and codes within these sets then a particular diagnosis or test is understood.

But we must be aware that many of these code sets (such as LOINC) comprise of thousands of codes, with often more than one code relating to a specific test/observation. In the case of LOINC this can be resolved locally by mapping all the local test codes to a set of specific LOINC codes; one LOINC code for each test.

However, this only resolves the local issue. If information from multiple LOINC sources (i.e. laboratory systems) needs to be correlated, then this ambiguity once more becomes an issue. In one study it was found that "75% of failures to match the same tests between different institutions using LOINC codes were due to differences in local coding choices", (Baorto et al, 1998). It is therefore essential that a national or European profile is created that matches each laboratory test to a specific LOINC code.

In terms of such profiles, there are two ways of developing them. The first approach would the establishment of a working group either at a national or European level (for example through CEN, as in the case of ISO 18812). This

would need to comprise of experts in both the laboratory medicine and health informatics domains who would define the LOINC profile.

The alternative would be to have the LOINC profile defined/driven by the analytical instrument vendors. This would seem to be a more effective approach as:

- The manufacturer of the analytical device should be best placed in identifying the most appropriate LOINC code(s) that corresponds with the test(s) that the instrument performs.
- The code set should be smaller as only those tests/codes employed are defined in the profile.

Either way, this profile would also need to be published as a standard; in the same manner as the ISO 18812 standard. The benefit of this would be that vendors could indicate that their instruments comply with such a LOINC profile. This in turn would raise awareness of the profile, which could result in the usage of LOINC codes for test identifiers in all analytical instruments. Furthermore use of the specified profile would enhance the quality of the information.

But standardisation is not limited to code sets. Further standardisation in terms of data typing, such as conformance with the draft ISO/FDIS 21090 standard, ensures that the type of data being messaged is understood and may therefore be computable. Add to this the use of standards such as the ISO 2955 (ISO, 1983) or UCUM (Schadow et al, 1999) standards for abbreviation of units and health messaging is moving more and more towards semantic interoperability between systems.

There is also the need for a unique patient identifier. This may take the form of a patient's PPSN or the proposed national Unique Patient Identifier (UID), (Health Information and Quality Authority, 2009). It may also be a regional or local identifier such as the patient's Medical Record Number (MRN). Whatever identifier is chosen, it must be clearly identified within the message.

An interesting factor noted during the research was the impact of data quality measures, such as enforcing the use of LOINC coding for laboratory tests. When introduced at the data source, i.e. the analytical device in this instance, then all systems that subsequently utilise this information will also adhere to this standard and as such employ a higher quality of information. Expanding on this same point, it can be deduced that only the messaging standard at the information source (such as the ASTM e1394-97 standard in the capture of information from the AI) needs to enforce the data quality measure, once all subsequent standards support the messaging of the information in question (e.g. the LOINC code).

To look at a possible real world scenario, in an Irish context, if the following held true:

- There is a European LOINC profile.
- AI instrument supports messaging of LOINC identifiers.
- ASTM E1394-97 enforces use of LOINC and is used to message the result.
- HL7 supports messaging of LOINC codes.
- The GP messaging portal (e.g. Healthlink in Ireland) supports the messaging of LOINC codes.
- The GP practice management system supports LOINC codes for test identifiers.

Then regardless of the location of either the analyser/laboratory or GP in Europe, the GP will know with certainty the test undertaken on the given sample; one significant step closer to semantic interoperability.

Versioning of code sets or standards is also an issue, which must be recognised. In the first instance it relates to difference between major versions of standards or coding such as ICD-9 and ICD-10 (Schulz et al, 1998). Or those associated with minor versions, such as between different versions of HL7 v2x (Frassica, 2004). Where possible every effort should be made to ensure backward compatibility or

some form of defined mapping. It may also be possible to confine the usage to a specific standard and code set within a given health domain. The GP messaging standard utilises HL7 v2.4 and if it also used a specific LOINC profile or specified that ICD-10 was to be used, it would avoid such issues.

The second issue pertains to local or regional code sets. There can be disparity between say a European LOINC profile and an American one. Because of this it is important that any profiles are agreed at the highest level possible. This will also ensure semantic interoperability for the given profile across a much larger area.

Based on the ASTM E1394-97 study and our discussion till now, as outlined previously, it is estimated that there are less than 200 different models of analysers used worldwide. If a majority of these supported the use of LOINC codes, then a comprehensive listing of these codes could be amalgamated into an international LOINC profile quite easily. If in turn ASTM E1394-97 or LIS02 were to enforce the usage of LOINC codes (where possible) then a significant proportion of blood tests worldwide could be clearly identified; which from this study indicates could be up to 66% of all blood tests.

Another important feature/requirement for any messaging standard is that it meets all of the required functionality demanded by the given device/system. In the case of the study of ASTM E1394-97, it was found that the majority of non-compliance related to missing functionality. This is essential in ensuring that the standard is both usable and applicable. This may require annual or bi-annual review of the standard and possible revisions to same to ensure this.

Another interesting finding in the ASTM E1394-97 study was that the vendors using the ASTM E1394-97 standard acted responsibly in their approach to resolving issues around missing functionality. In the case of the ‘universal test id’ and details pertaining to the location of the specimen within the device, they placed this information in the fourth and subsequent components of the test

identifier's field. In this way they clearly linked the test to the specimen while also attempting to comply with the standard by placing this information in the local codes section of the field. It was found that most vendors tended to follow this approach therefore resulting in a de- facto implementation/approach across vendors. In such instances the relevant standards body should revise the standard accordingly to support this responsible approach and therefore support the new functionality.

A standard must also address all messaging requirements in a given domain. In the case of the ASTM E1394-97 and the laboratory domain, the attempted messaging of QC, calibration, errors or alarm codes information resulted in a significant level of non-compliance in the ASTM E1394-97 study. There had been no real attempt or guidelines given in the ASTM standard to detail how to support this type of messaging.

It should be noted that the ASTM E1394-97 was written almost 20 years ago and is still successful today; a remarkable achievement. It predates many of the features that make good health messages today; such as the use of LOINC or SNOMED-CT coding, which have only become widely used in the past decade. As a standard developed in 1991, it was remarkably simple, clear in definition and met all the functionality required of it at the time. Unfortunately, one of the biggest downfalls of the standard was the lack of revision to it to meet the changing laboratory instrument requirements.

Finally, the specification of 'special use' or 'reserved fields' within messaging standards should be kept to a minimum. These fields tend to lend themselves to non compliant usage by vendors and may therefore inhibit interoperability.

5.2 Summary of Findings

In essence there are a number of properties that make a messaging standard successful. These relate to both the applicability of the standard to a given domain and the usability of the standard from a user's perspective.

In summary these features are:

- *Simplicity* – A simple standard lends itself to being usable, while also applicable to a particular application. It also supports syntactic interoperability, laying the foundation for semantic interoperability
- *Use of Language* – A standard that clearly prescribes usage will be easier to use and apply to any given task, as it's clearly defined and understood.
- *Optionality* – makes the standard more flexible. It firstly aids consensus among developers of the standard. It also makes it possible for a standard to allow for the messaging of essential information that may only be messaged occasionally or in one instance. However where optionality applies to flags/values within a field caution must be used to ensure patient safety.
- *Standardised Codes* – are essential to enabling better quality messaging. The only difficulty that may arise is with the complexity of some of these code sets. Ideally a national/international profile, for a given code set, should be defined for a specific domain, as this would aid the usability of same. It should also be possible to update this set as the need arises.
- *Data Standards* – are essential to good standards. They ensure clear understanding of the information in question and therefore support semantic interoperability between systems.
- *Data Typing* – A defined data type for a given field or piece of information enabling semantic interoperability between systems.
- *Required Functionality* – All system/device requirements need to be understood at the development stage of a standard. There needs to be a process in place to ensure that messaging standards are continuously reviewed within a reasonable time period. This is essential so as to ensure

that they meet the every changing demands of the environment in which they reside. In this way it helps maintain interoperability among systems.

5.3 Other Findings

During the course of this research there were a number of other topics, while not directly related to the research question, were deemed to be sufficiently important that they deserve mentioning.

5.3.1 Consistency between Standards

There seems to be a consistency between successful messaging standards. It is this consistency that helps enable interoperability and ensures that they are usable when messaging between heterogeneous systems.

ASTM Record Type						HL7 v2.4
Result Record						OBX segment (observation result)
R	10	1	1		Record Type ID	Element Name
R	10	1	2		Sequence No.	OBX.1 - Set ID
R	10	1	3		Universal Test ID	OBX.3 - Observation Identifier
R	10	1	4		Date or Measurement Value	OBX.5 - Observation Value
R	10	1	5		Units	OBX.6 - Units
R	10	1	6		Reference Ranges	OBX.7 - References Range
R	10	1	7		Result Abnormal Flags	OBX.8 - Abnormal Flags
R	10	1	8		Nature of Abnormality Testing	OBX.10 - Nature of Abnormal Test
R	10	1	9		Result Status	OBX.11 - Observation Result Status
R	10	1	10		Date of Change in Instrument Normative Values or Units	OBX.12 - Date Last Observation Normal Value
R	10	1	11		Operator Identification	OBX.16 - Responsible Observer
R	10	1	12		Date/Time Test Started	OBX.14 - Date/Time of the Observation
R	10	1	13		Date/Time Test Completed	
R	10	1	14		Instrument ID	OBX.18 - Equipment Instance Identifier

Table 2 - Comparison between ASTM Result Record and HL7 OBX Segment

A quick comparison between the fields in the ASTM E1394-97 Result Record and HL7 v2.4 OBX segment demonstrate this consistency; see Table 2 above. The majority of fields both follow a similar sequence and relate to messaging of the same information. Furthermore it was noted that in the case of the 'OBX.5' (value) field that the data type in HL7 was not specifically defined, possibly so to ensure it could deal with any value in the same manner as ASTM's 10.1.4. The only fields

that seemed not to map were the date and time fields (10.1.12 and 10.1.13) pertaining to the specimen in the ASTM E1394-97 standard and the date and time of observation (OBX.14) in the HL7 message. But this is due to the specific application of the ASTM standard in a laboratory environment, where information is specimen/sample centric. ASTM is patient centric and as such is more concerned about the time the observation or sample is taken from the patient.

5.3.2 Errors in Documentation

A couple of errors were identified in the documentation of the ASTM E1394-97 and the ISO 18812 standards, during the course of this research The most prominent issue pertains to the ISO 18812 standard and usage of fields within the 'Test Order' and 'Request Information' records; as previously discussed in section 4.7 of this study.

Within the ASTM E1394-97 standard there is incorrect referencing to dates in the 'Universal Test ID' field (12.1.5). It specifies that the query relates to dates specified in 12.1.6 and 12.1.7. However it should be the 'Beginning Request Results Date and Time' (12.1.7) and the 'Ending Request Results Date and Time' (12.1.8).

5.3.3 Nosocomial Infections

Since ASTM was written in 1991, the incidence of hospital acquired infections has risen significantly. In 1995, it was estimated that "nosocomial infections cost $4.5 billion and contributed to more than 88,000 deaths—one death every 6 minutes" in the United States (Weinstein, 1998).

The 'Nosocomial Infection Flag' (9.4.29) in the 'Test Order Record' attempts to address the flagging of such infections. However the documentation is very vague in terms of usage of the field. It is recommended that the standard be revised so that specimens originating from patients that have been identified as having a nosocomial infection are flagged, by means of a clearly defined flag in the test

order record; which may only require a clarification of the existing 9.4.29 field in terms of usage. In addition, any results testing positive for a nosocomial infection need to be flagged in the result record. This would potentially require a new flag being added to the 'Result Abnormal' field (10.1.7) or a new dedicated field being added to the results record.

5.4 Future Work

This study acknowledges that the ASTM E1394-97 standard is a very effective and successful standard. However it has also identified issues specifically around missing functionality and also the need to address how ASTM E1394-97 can be used to facilitate the messaging of QC, error, alarm or calibration messages. It is therefore imperative that its successor, the LIS02-A2 standard be reviewed in an attempt to resolve these issues.

It is important that some, if not all, of the quality measures outlined are considered and implemented where possible within the ASTM E1394-97 and/or CLSI LIS02-A2 standard(s). This will help achieve semantic interoperability.

It must be noted that ASTM E1394-97 or the CLSI LIS02-A2 standard is probably in the best position of any laboratory messaging standard in achieving semantic interoperability as:

- It involves the communications of laboratory test information between analytical devices and laboratory systems.
- This information has little or no free text; by the nature of result messages.
- It has the ability to control the quality of the information source by use of quality measures, as outlined previously, which can enhance and make this information more intelligible/computable.

The proposed review of the ASTM E1394-97 (or its successor the LIS02-A2 standard) and the ISO 18812 standard should be conducted in the ISO arena. The LIS02-A2 could be brought in via the TC212 committee, which CLSI use to bring in many of their process and performance standards. The ISO 18812 could be reviewed by the TC251 committee.

From a research standpoint, there are a few areas of research that may follow from this study:

- Research into the ways in which consistency between standards impacts on their success.
- Research into other messaging standards, such as HL7, in relation to use of quality measures to improve data quality and ultimately semantic interoperability
- Research into how auxiliary messaging, such as QC, calibration, alarm or error codes should be addressed in a consistent manner across major messaging standards.
- Something that may encapsulate all of the above would be a revision of the ASTM E1394-97 standard in a minimalistic way.

5.5 The ISO 18812 Standard and this Research

A number of inconsistencies were identified in the ISO 18812 documentation, as outlined in section 5.3.2. In an attempt to get clarification on what interpretation to take with regards optionality of fields, correspondence was entered into with members of the TC251 group. This took the format of an email outlining the initial findings in terms of widespread use of the ASTM E1394-97 standard, along with details pertaining to the discrepancies in the ISO 18812 documentation.

Unbeknownst to the author was the fact that the TC251 committee were in the process of a review of the ISO 18812 standard. TC251 had received no feedback

regarding the status of the standard and had therefore determined that it was no longer in use and had been superseded by HL7. They had therefore scheduled the deletion of the ISO18812 standard for a meeting in December 2009. However due to the workload on the day, it was rescheduled for the next meeting on the 16th June 2010.

Just as the meeting was about to commence on June 16th, the email arrived and the standard was reprieved based on the findings of this study. So this research into ISO 18812 assisted in saving the ISO 18812 standard from deletion.

Chapter 6 Conclusion

In conclusion, this study endeavoured to identify those properties of a messaging standard that makes it successful in terms of its usability and applicability (specifically that it's implementable by anyone who wishes to use it for the purpose for which it was intended).

The research question was answered through the review and analysis of the 30 ASTM E1394-97 implementations in terms of compliance with the ASTM and ISO 18812 standards. From this analysis it was determined that features like simplicity, optionality and use of language enabled messaging standards to be both usable and applicable. It was also recognised that the use of standardised code sets, data standards and data typing enhance the quality messaging and lead to semantic interoperability.

Finally SDOs must endeavour, through the use of regular reviews, to ensure that the changing requirements of systems/devices are met by messaging standards in order to prevent against unnecessary non-compliance by vendors.

Appendices

Appendix A – Laboratory Standards Timeline

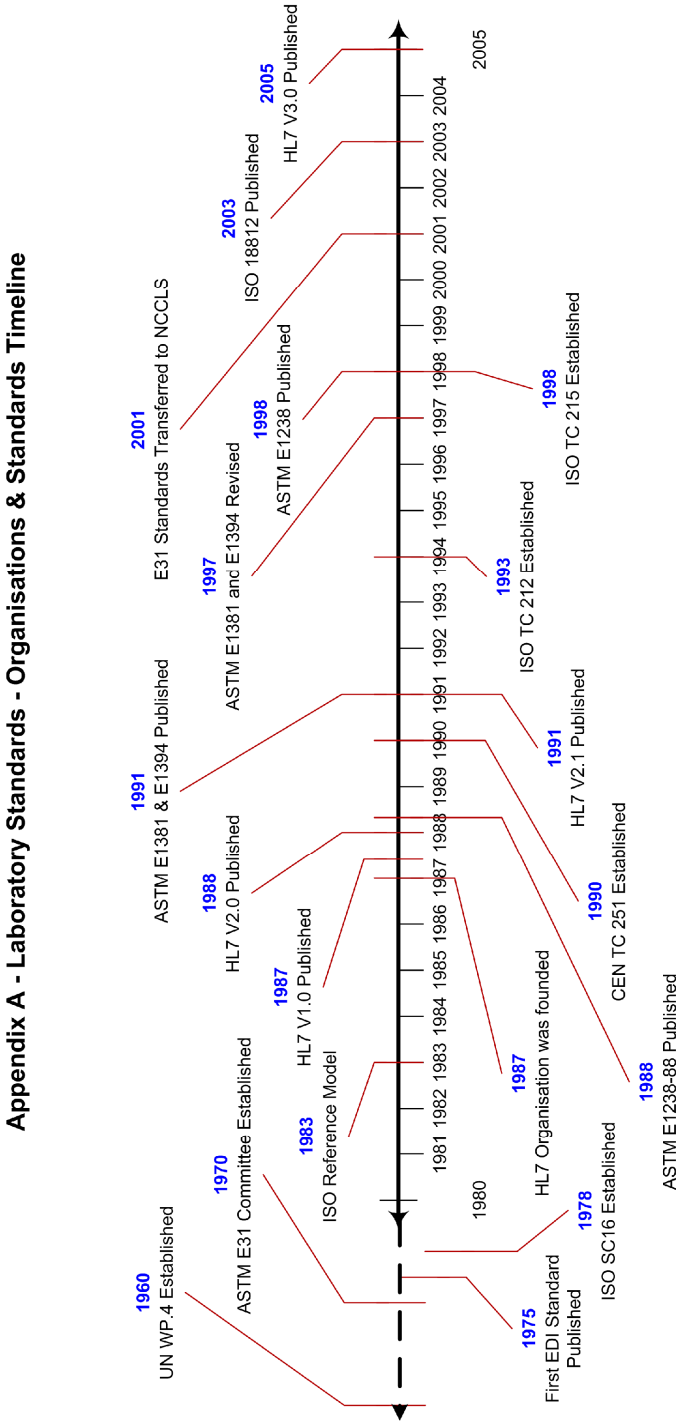

Figure 14 - Laboratory Standard Organisations and Standards Timeline

Appendix B – ASTM E1394-97 to LIS2-A2 Comparison

Table 3 - ASTM E1394-97 to LIS2-A2 Comparison

ASTM Record Type						LIS2-A2					
Chapter					Attribute	Chapter					Attribute
Message Header Record											
H	7	1	1		Record Type ID	H	6	1			Record Type ID
H	7	1	2		Delimiter definition	H	6	2			Delimiter definition
H	7	1	3		Message Control ID	H	6	3			Message Control ID
H	7	1	4		Access Password	H	6	4			Access Password
H	7	1	5		Sender Name or ID	H	6	5			Sender Name or ID
H	7	1	6		Sender Street Address	H	6	6			Sender Street Address
H	7	1	7		Reserved Field	H	6	7			Reserved Field
H	7	1	8		Sender Telephone No.	H	6	8			Sender Telephone No.
H	7	1	9		Characteristics of Sender	H	6	9			Characteristics of Sender
H	7	1	10		Receiver ID	H	6	10			Receiver ID
H	7	1	11		Comment or special instructions	H	6	11			Comment or special instructions
H	7	1	12		Processing ID	H	6	12			Processing ID
H	7	1	13		Version No.	H	6	13			Version No.
H	7	1	14		Date and Time of Message	H	6	14			Date and Time of Message

Patient Information Record											
P	**8**	**1**	**1**		**Record Type ID**	**P**	**7**	**1**			**Record Type**
P	8	1	2		Sequence No.	P	7	2			Sequence No.
P	8	1	3		Practice Assigned Patient ID	P	7	3			Practice Assigned Patient ID
P	8	1	4		Laboratory Assigned ID	P	7	4			Laboratory Assigned ID
P	8	1	5		Patient ID No. 3	P	7	5			Patient ID No. 3
P	8	1	6		Patient Name	P	7	6			Patient Name
P	8	1	7		Mother's Maiden Name	P	7	7			Mother's Maiden Name
P	8	1	8		Birthdate	P	7	8			Birthdate
P	8	1	9		Patient Sex	P	7	9			Patient Sex
P	8	1	10		Patient Race-Ethnic Origin	P	7	10			Patient Race-Ethnic Origin
P	8	1	11		Patient Address	P	7	11			Patient Address
P	8	1	12		Reserved Field	P	7	12			Reserved Field
P	8	1	13		Patient Telephone No.	P	7	13			Patient Telephone No.
P	8	1	14		Attending Physician ID	P	7	14			Attending Physician ID
P	8	1	15		Special Field No. 1	P	7	15			Special Field No. 1
P	8	1	16		Special Field No. 2	P	7	16			Special Field No. 2
P	8	1	17		Patient Height	P	7	17			Patient Height
P	8	1	18		Patient Weight	P	7	18			Patient Weight
P	8	1	19		Patient's Known or Suspected Diagnosis	P	7	19			Patient's Known or Suspected Diagnosis
P	8	1	20		Patient's Active Medications	P	7	20			Patient's Active Medications
P	8	1	21		Patient's Diet	P	7	21			Patient's Diet
P	8	1	22		Practice Field No. 1	P	7	22			Practice Field No. 1
P	8	1	23		Practice Field No. 2	P	7	23			Practice Field No. 2
P	8	1	24		Admission and Discharge Dates	P	7	24			Admission and Discharge Dates

P	8	1	25		Admission Status	P	7	25			Admission Status
P	8	1	26		Location	P	7	26			Location
P	8	1	27		Nature of Diagnostic Code and Classification	P	7	27			Nature of Diagnostic Code and Classification
P	8	1	28		Alternative Diagnostic Code and Classification	P	7	28			Alternative Diagnostic Code and Classification
P	8	1	29		Patient Religion	P	7	29			Patient Religion
P	8	1	30		Marital Status	P	7	30			Marital Status
P	8	1	31		Isolation Status	P	7	31			Isolation Status
P	8	1	32		Language	P	7	32			Language
P	8	1	33		Hospital Service	P	7	33			Hospital Service
P	8	1	34		Hospital Institution	P	7	34			Hospital Institution
P	8	1	35		Dosage Catagory	P	7	35			Dosage Catagory

Test Order Record											
O	**9**	**4**	**1**		**Record Type ID**	**O**	**8**	**4**	**1**		**Record Type ID**
O	9	4	2		Sequence No.	O	8	4	2		Sequence No.
O	9	4	3		Specimen ID	O	8	4	3		Specimen ID
O	9	4	4		Instrument Specimen ID	O	8	4	4		Instrument Specimen ID
O	9	4	5		Universal Test ID	O	8	4	5		Universal Test ID
O	9	4	6		Priority	O	8	4	6		Priority
O	9	4	7		Requested/Ordered Date and Time	O	8	4	7		Requested/Ordered Date and Time
O	9	4	8		Specimen Collection Date and Time	O	8	4	8		Specimen Collection Date and Time
O	9	4	9		Collection End Time	O	8	4	9		Collection End Time
O	9	4	10		Collection Volume	O	8	4	10		Collection Volume
O	9	4	11		Collector ID	O	8	4	11		Collector ID
O	9	4	12		Action Code	O	8	4	12		Action Code
O	9	4	13		Danger Code	O	8	4	13		Danger Code
O	9	4	14		Relevant Clinical Information	O	8	4	14		Relevant Clinical Information
O	9	4	15		Date/Time Specimen Received	O	8	4	15		Date/Time Specimen Received
O	9	4	16		Specimen Descriptor	O	8	4	16		Specimen Descriptor
O	9	4	16	1	Specimen Type	O	8	4	16	1	Specimen Type
O	9	4	16	2	Specimen Source	O	8	4	16	2	Specimen Source
O	9	4	17		Ordering Physician	O	8	4	17		Ordering Physician
O	9	4	18		Physician Telephone No.	O	8	4	18		Physician Telephone No.
O	9	4	19		Users Field No. 1	O	8	4	19		Users Field No. 1
O	9	4	20		Users Field No. 2	O	8	4	20		Users Field No. 2
O	9	4	21		Laboratory Field No. 1	O	8	4	21		Laboratory Field No. 1

O	9	4	22		Laboratory Field No. 2	O	8	4	22		Laboratory Field No. 2
O	9	4	23		Date/Time Results Reported or Last Modified	O	8	4	23		Date/Time Results Reported or Last Modified
O	9	4	24		Instrument Charge to Computer System	O	8	4	24		Instrument Charge to **Information System**
O	9	4	25		Instrument Section ID	O	8	4	25		Instrument Section ID
O	9	4	26		Report Types	O	8	4	26		Report Types
O	9	4	27		Reserved Field	O	8	4	27		Reserved Field
O	9	4	28		Location or Ward of Specimen Collection	O	8	4	28		Location of **Specimen Collection**
O	9	4	29		Nosocomial Injection Flag	O	8	4	29		Nosocomial Injection Flag
O	9	4	30		Specimen Service	O	8	4	30		Specimen Service
O	9	4	31		Specimen Institution	O	8	4	31		Specimen Institution

Result Record											
R	**10**	**1**	**1**		**Record Type ID**	**R**	**9**	**1**			**Record Type ID**
R	10	1	2		Sequence No.	R	9	2			Sequence No.
R	10	1	3		Universal Test ID	R	9	3			Universal Test ID
R	10	1	4		Date or Measurement Value	R	9	4			Date or Measurement Value
R	10	1	5		Units	R	9	5			Units
R	10	1	6		Reference Ranges	R	9	6			Reference Ranges
R	10	1	7		Result Abnormal Flags	R	9	7			Result Abnormal Flags
R	10	1	8		Nature of Abnormality Testing	R	9	8			Nature of Abnormality Testing
R	10	1	9		Result Status	R	9	9			Result Status
R	10	1	10		Date of Change in Instrument Normative Values or Units	R	9	10			Date of Change in Instrument Normative Values or Units
R	10	1	11		Operator Identification	R	9	11			Operator Identification
R	10	1	12		Date/Time Test Started	R	9	12			Date/Time Test Started
R	10	1	13		Date/Time Test Completed	R	9	13			Date/Time Test Completed
R	10	1	14		Instrument ID	R	9	14			Instrument ID

Comment Record											
C	**11**	**1**	**1**		**Record Type ID**	**C**	**10**	**1**			**Record Type ID**
C	11	1	2		Sequence No.	C	10	2			Sequence No.
C	11	1	3		Comment Source	C	10	3			Comment Source
C	11	1	4		Comment Text	C	10	4			Comment Text
C	11	1	5		Comment Type	C	10	5			Comment Type

Request Information Record										
Q	**12**	**1**	**1**		**Record Type ID**	**Q**	**11**	**1**		**Record Type ID**
Q	12	1	2		Sequence No.	Q	11	2		Sequence No.
Q	12	1	3		Starting Range ID No.	Q	11	3		Starting Range ID No.
Q	12	1	4		Ending Range ID No.	Q	11	4		Ending Range ID No.
Q	12	1	5		Universal Test ID	Q	11	5		Universal Test ID
Q	12	1	6		Nature of Request Time Limits	Q	11	6		Nature of Request Time Limits
Q	12	1	7		Beginning Request Results Date and Time	Q	11	7		Beginning Request Results Date and Time
Q	12	1	8		Ending Request Results Date and Time	Q	11	8		Ending Request Results Date and Time
Q	12	1	9		Requesting Physician Name	Q	11	9		Requesting Physician Name
Q	12	1	10		Requesting Physician Telephone No.	Q	11	10		Requesting Physician Telephone No.
Q	12	1	11		User Field No. 1	Q	11	11		User Field No. 1
Q	12	1	12		User Field No. 2	Q	11	12		User Field No. 2
Q	12	1	13		Request Information Status Codes	Q	11	13		Request Information Status Codes

Message Terminator Record										
L	**13**	**1**	**1**		**Record Type ID**	**L**	**12**	**1**		**Record Type ID**
L	13	1	2		Sequence	L	12	2		Sequence
L	13	1	3		Termination Code	L	12	3		Termination Code

Scientific Record										
S	**14**	**1**	**1**		**Record Type ID**	**S**	**13**	**1**		**Record Type ID**
S	14	1	2		Sequence No.	S	13	2		Sequence No.
S	14	1	3		Analytic Method	S	13	3		Analytic Method
S	14	1	4		Instrumentation	S	13	4		Instrumentation
S	14	1	5		Reagents	S	13	5		Reagents
S	14	1	6		Units of Measure	S	13	6		Units of Measure
S	14	1	7		Quality Control	S	13	7		Quality Control
S	14	1	8		Specimen Descriptor	S	13	8		Specimen Descriptor
S	14	1	9		Reserved Field	S	13	9		Reserved Field
S	14	1	10		Container	S	13	10		Container
S	14	1	11		Specimen ID	S	13	11		Specimen ID
S	14	1	12		Analyte	S	13	12		Analyte
S	14	1	13		Result	S	13	13		Result
S	14	1	14		Result Units	S	13	14		Result Units
S	14	1	15		Collection Date and Time	S	13	15		Collection Date and Time
S	14	1	16		Result Date and Time	S	13	16		Result Date and Time
S	14	1	17		Analytical Preprocessing Steps	S	13	17		Analytical Preprocessing Steps
S	14	1	18		Patient Diagnosis	S	13	18		Patient Diagnosis
S	14	1	19		Patient Birthdate	S	13	19		Patient Birthdate
S	14	1	20		Patient Sex	S	13	20		Patient Sex
S	14	1	21		Patient Race	S	13	21		Patient Race

Manufacturer Record										
	15	**1**	**1**		**Record Type ID**	**M**	**14**	**1**		**Record Type ID**
	15	1	2		Sequence No.	M	14	2		Sequence No.

Appendix C –Non Compliance with ASTM 1394-97 and ISO 18812

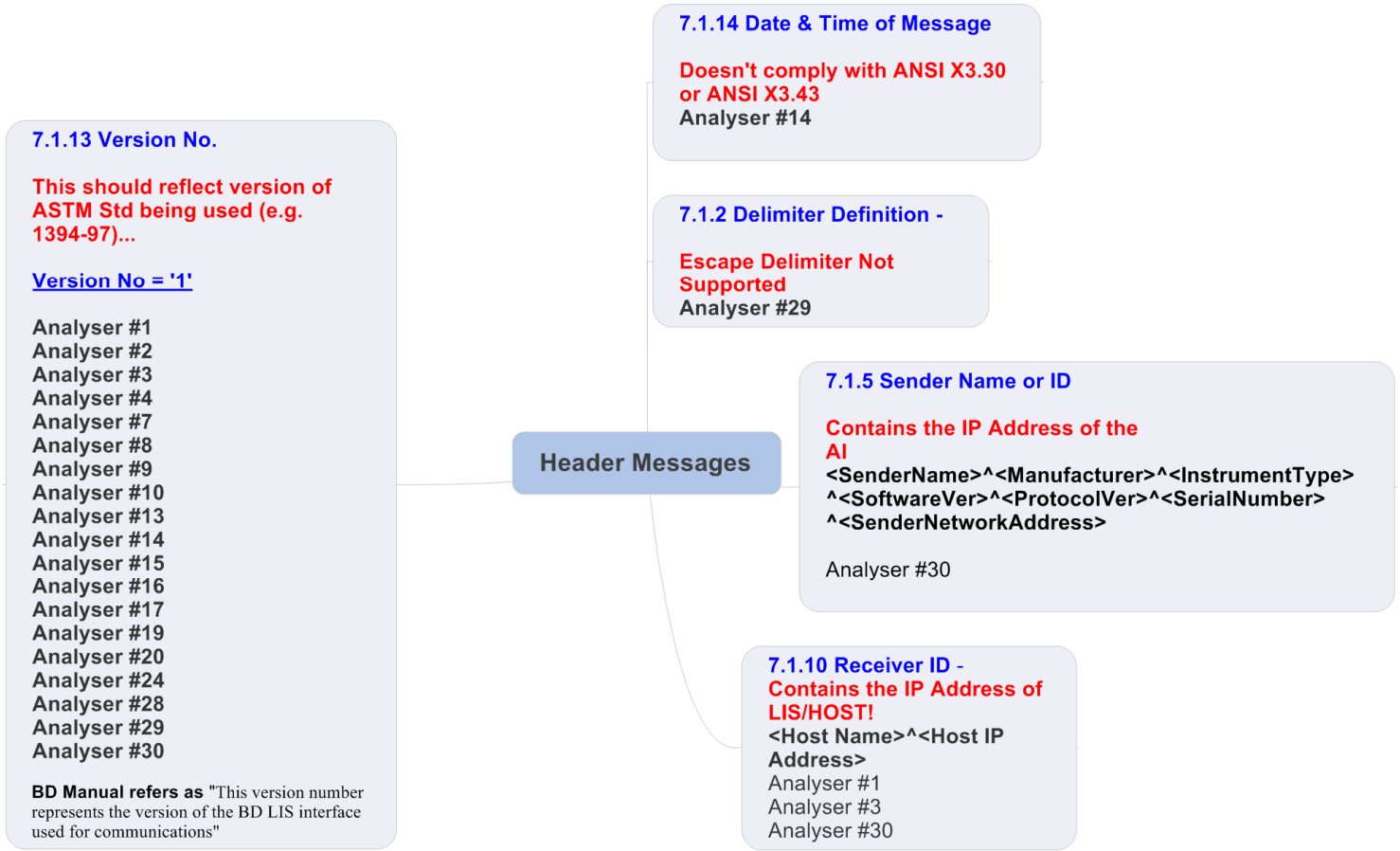

Figure 15 - Mind map of Header Record - Non-Compliances with ASTM E1394-97

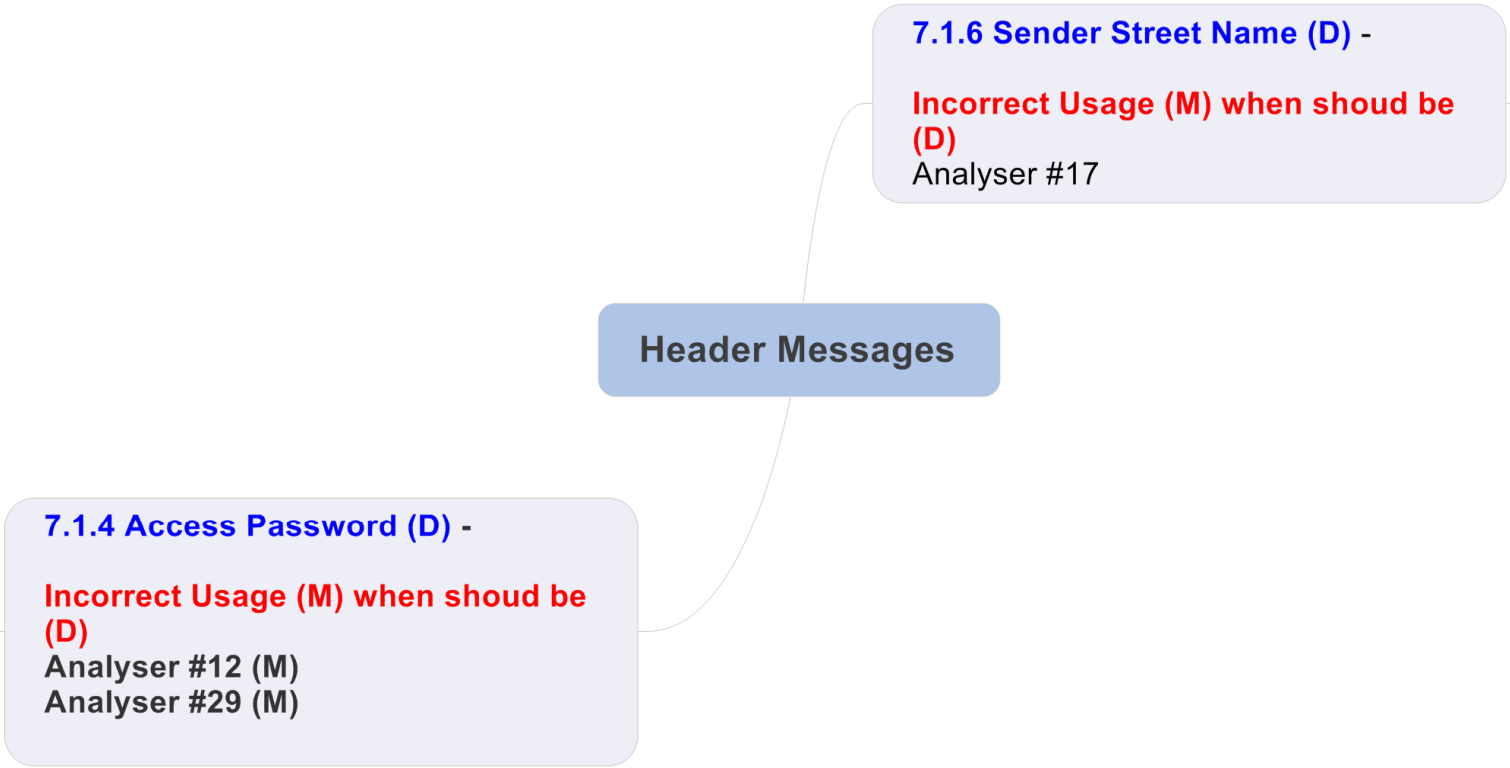

Figure 16 - Mind map of Header Record - Non-Compliances with ISO 18812

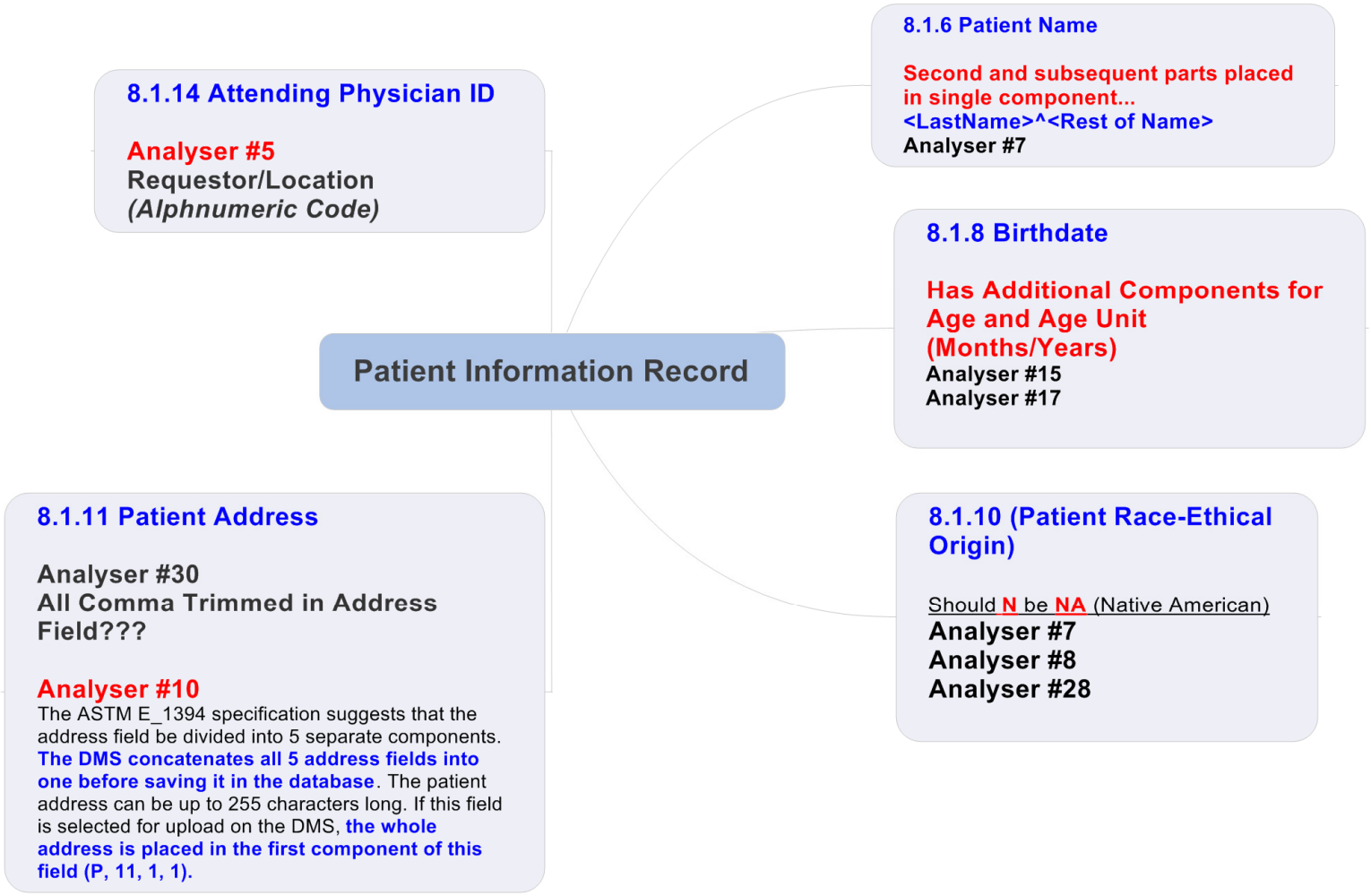

Figure 17 - Mind map of Patient Information Record - Non-Compliances with ASTM E1394-97

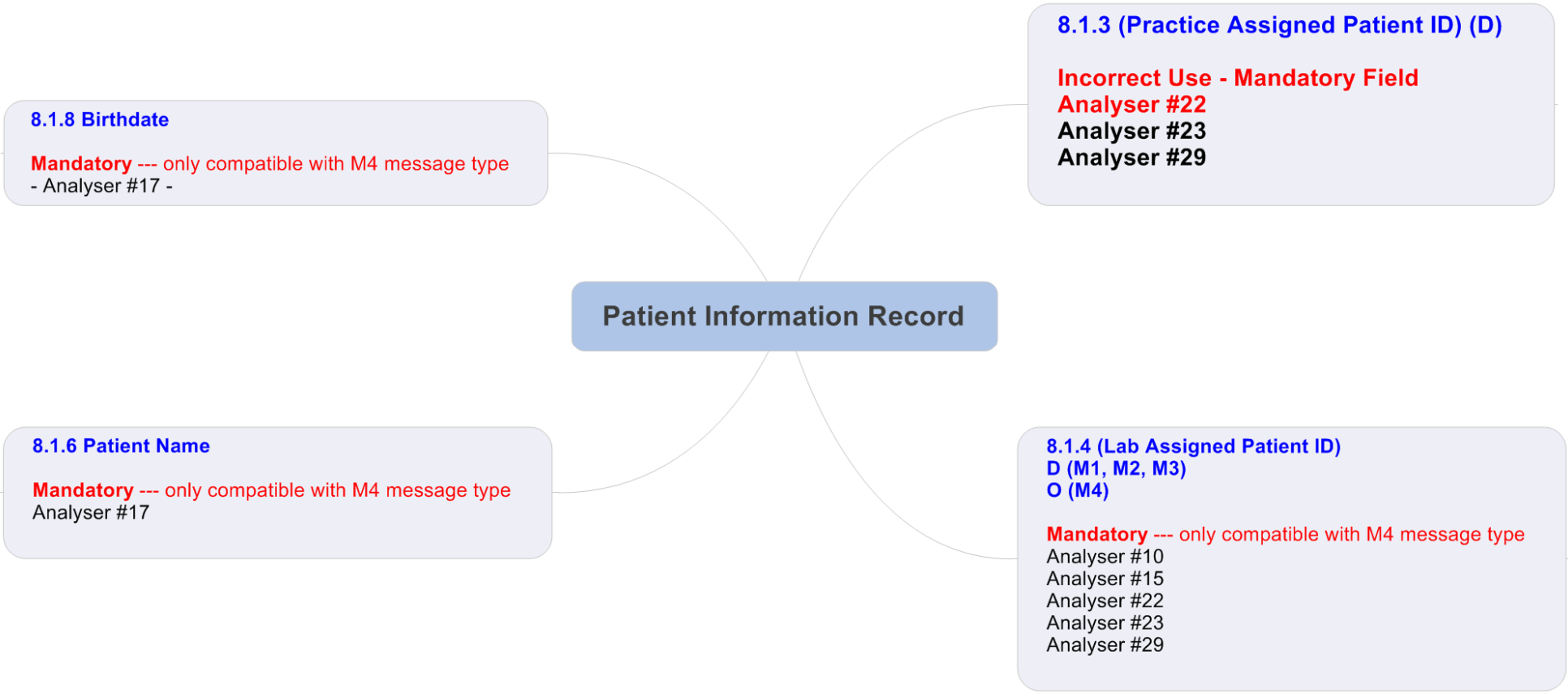

Figure 18 - Mind map of Patient Information Record - Non-Compliances with ISO 18812

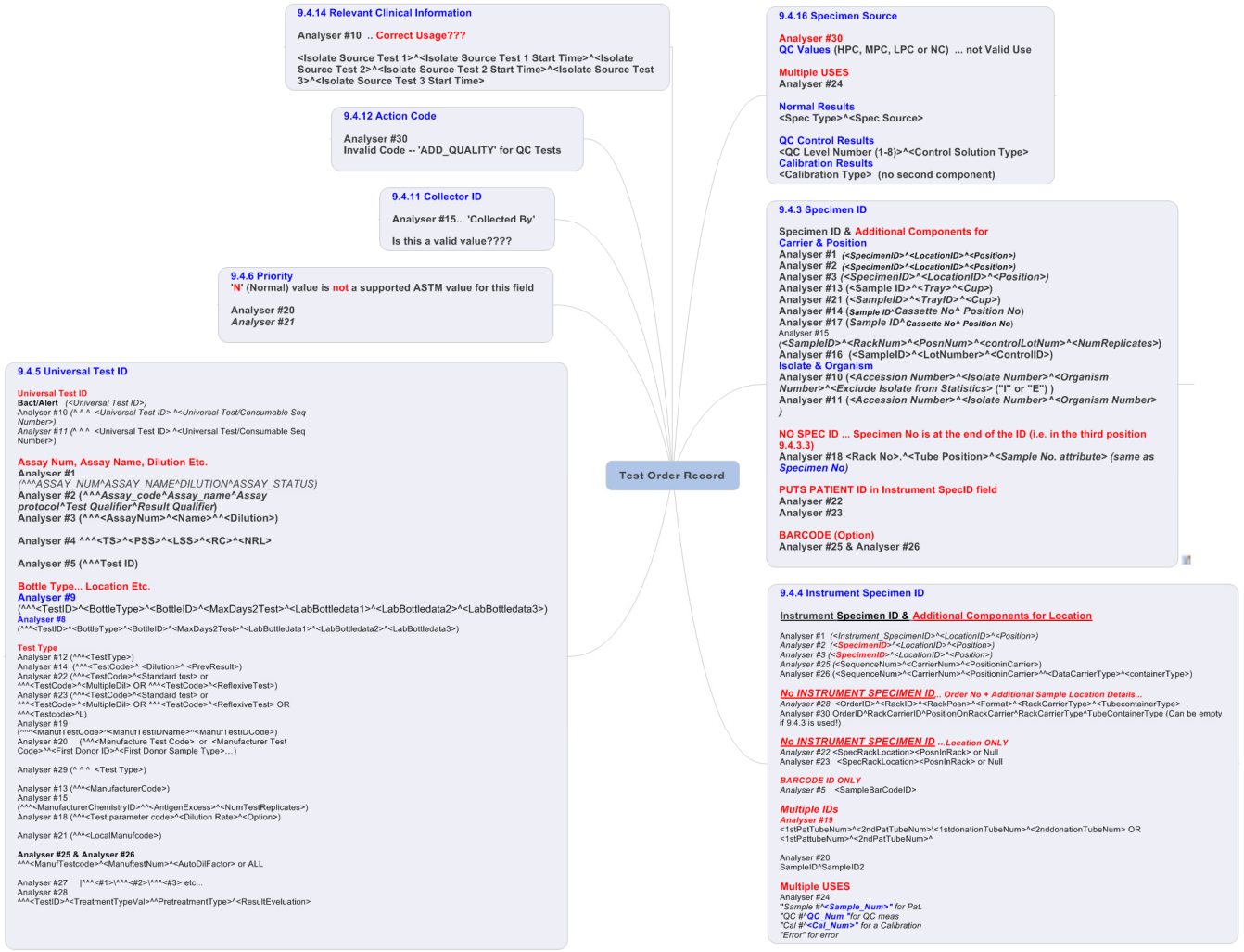

Figure 19 - Mind map of Test Order Record - Non-Compliances with ASTM E1394-97

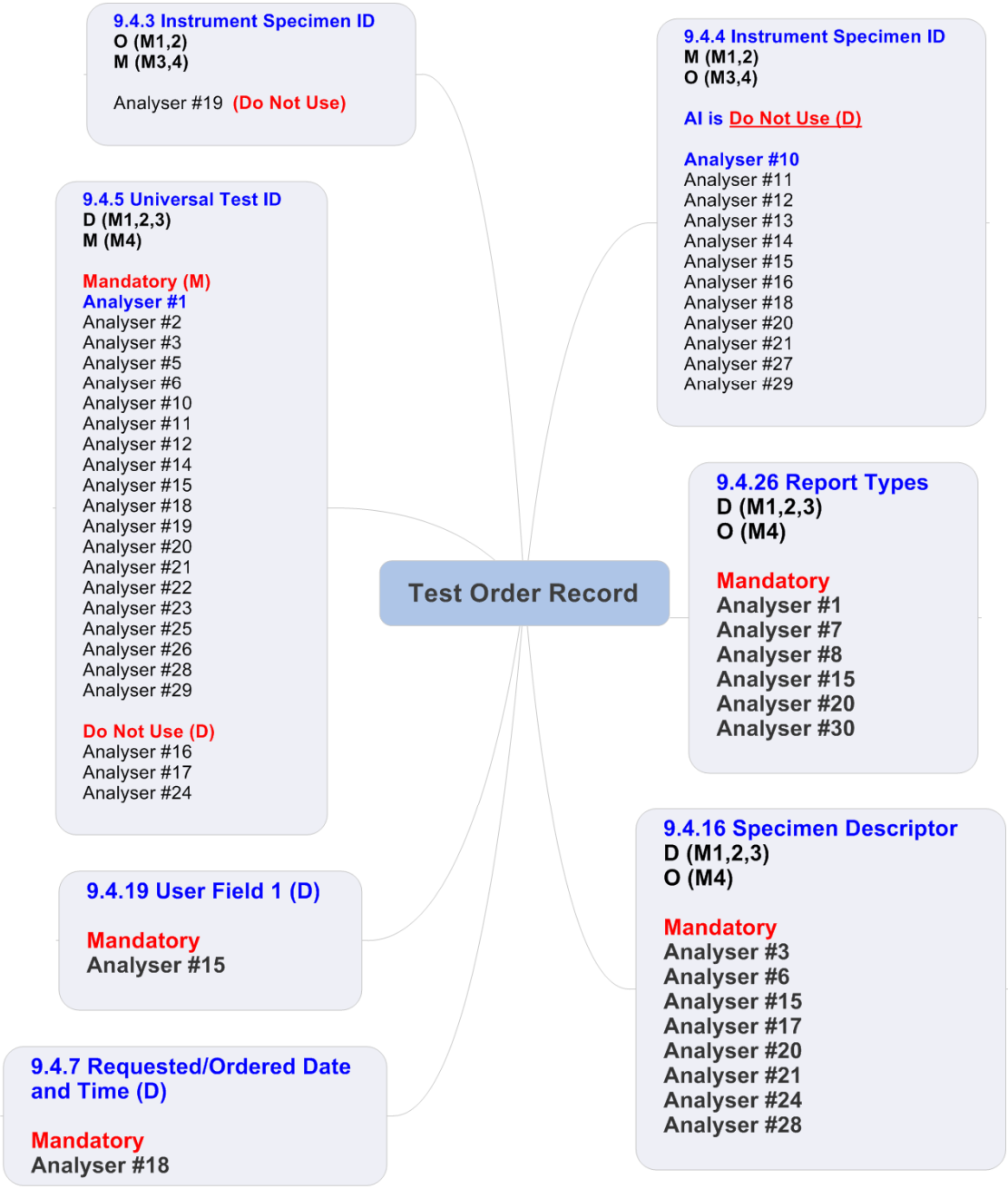

Figure 20 - Mind map of Test Order Record - Non-Compliances with ISO 18812

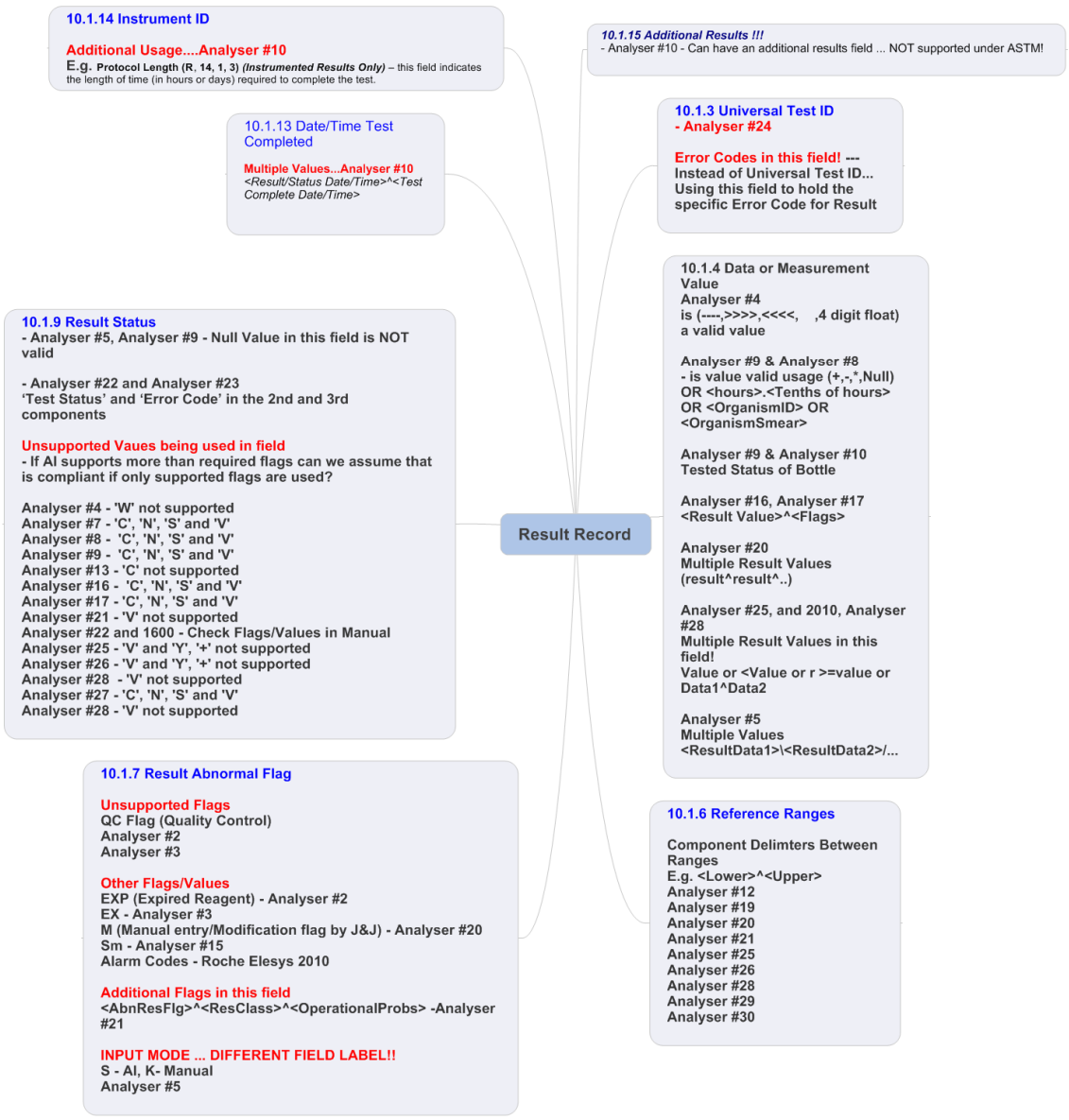

Figure 21 - Mind map of Result Record - Non-Compliances with ASTM E1394-97

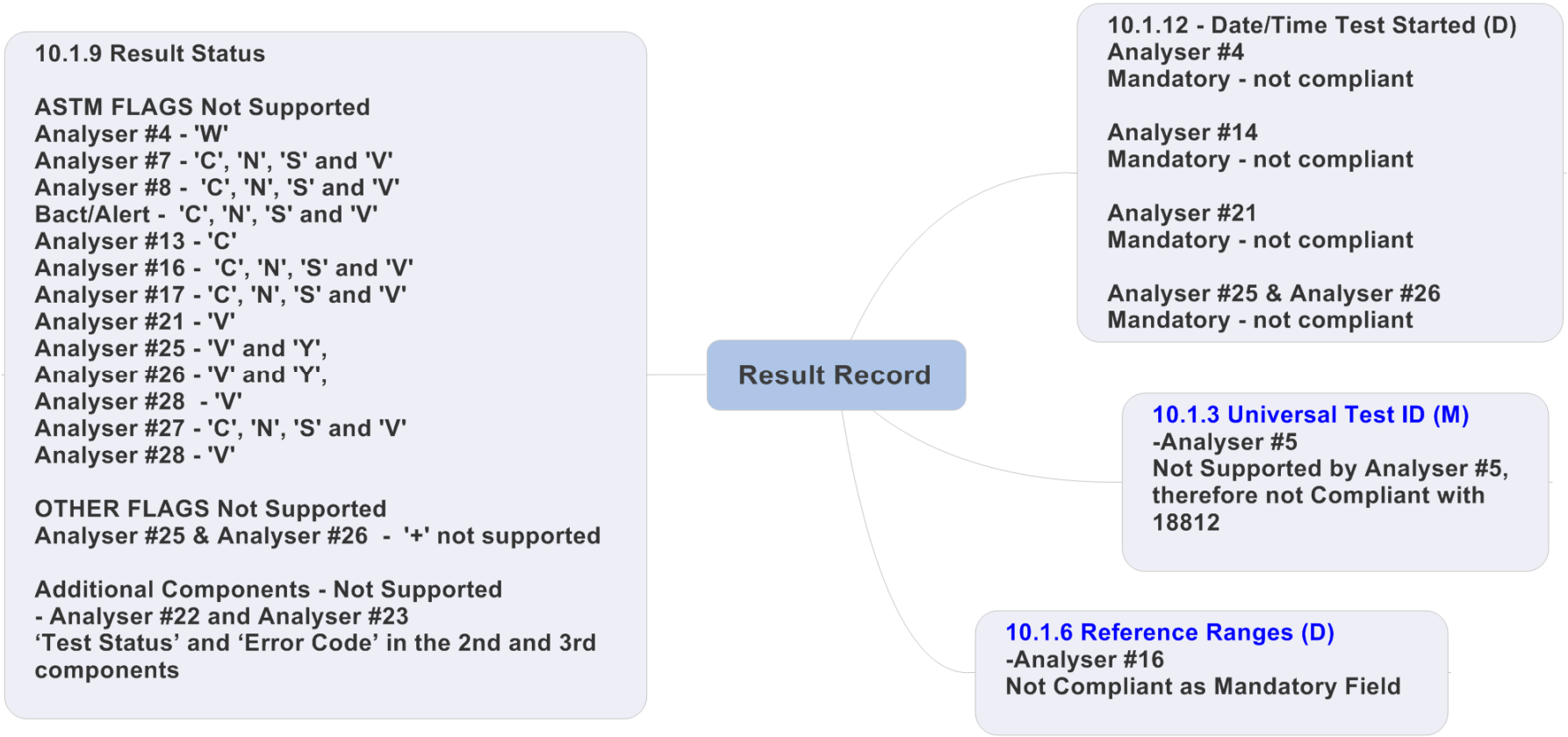

Figure 22 - Mind map of Result Record - Non-Compliances with ISO 18812

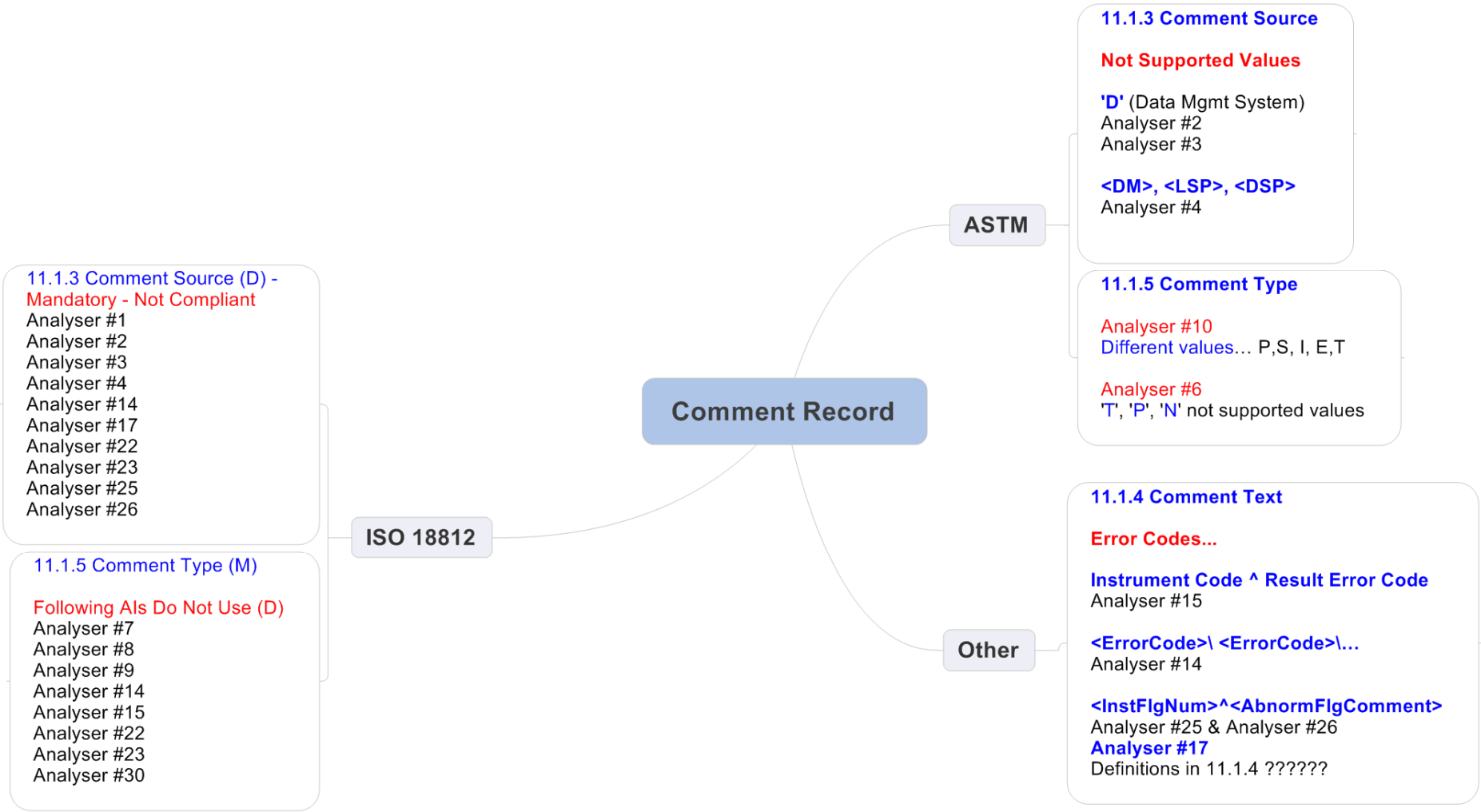

Figure 23 - Mind map of Comment Record - Non-Compliances with ASTM E1394-97 and ISO 18812

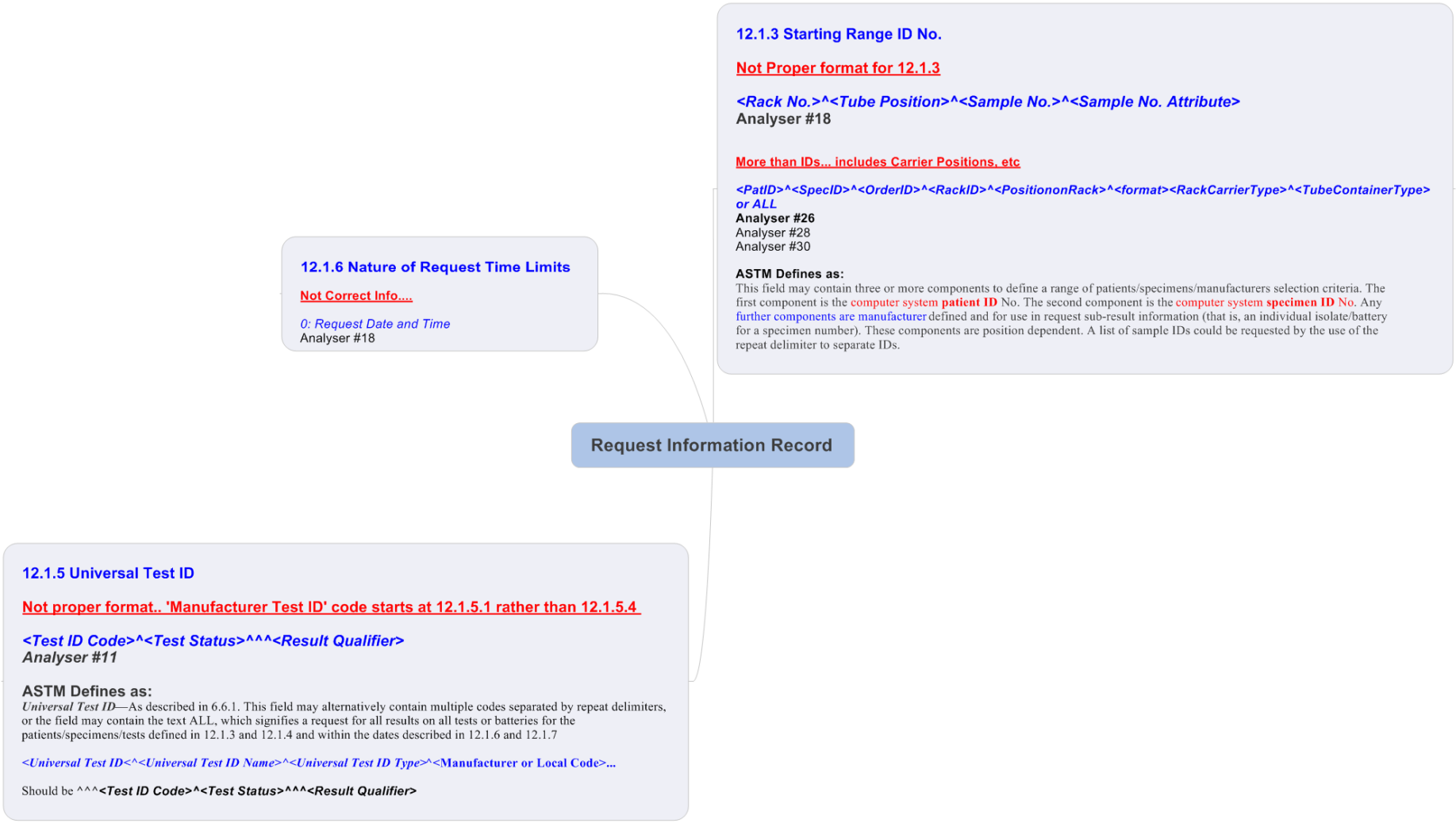

Figure 24 - Mind map of Request Information Record - Non-Compliances with ASTM E1394-97

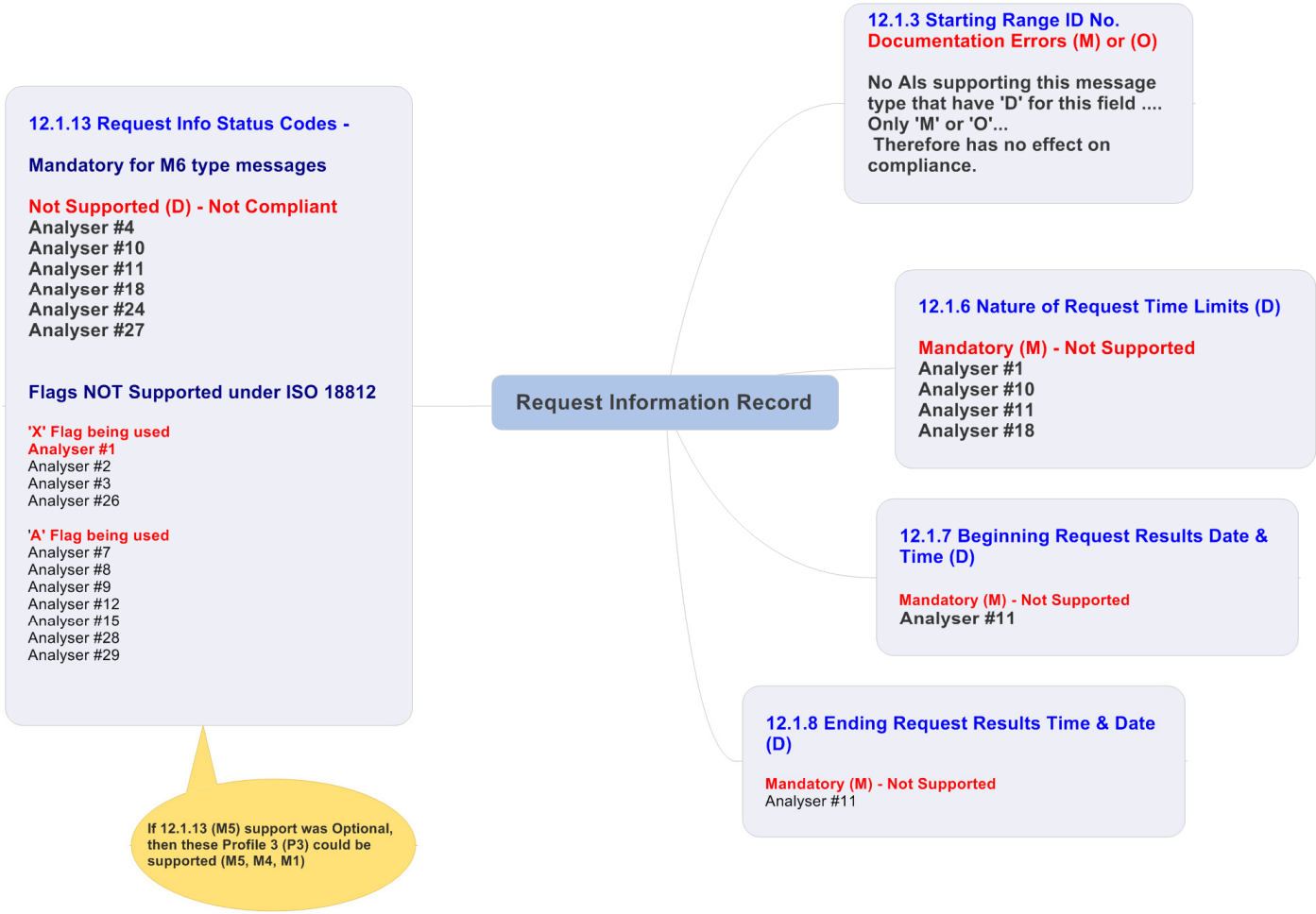

Figure 25 - Mind map of Request Information Record - Non-Compliances with ISO 18812

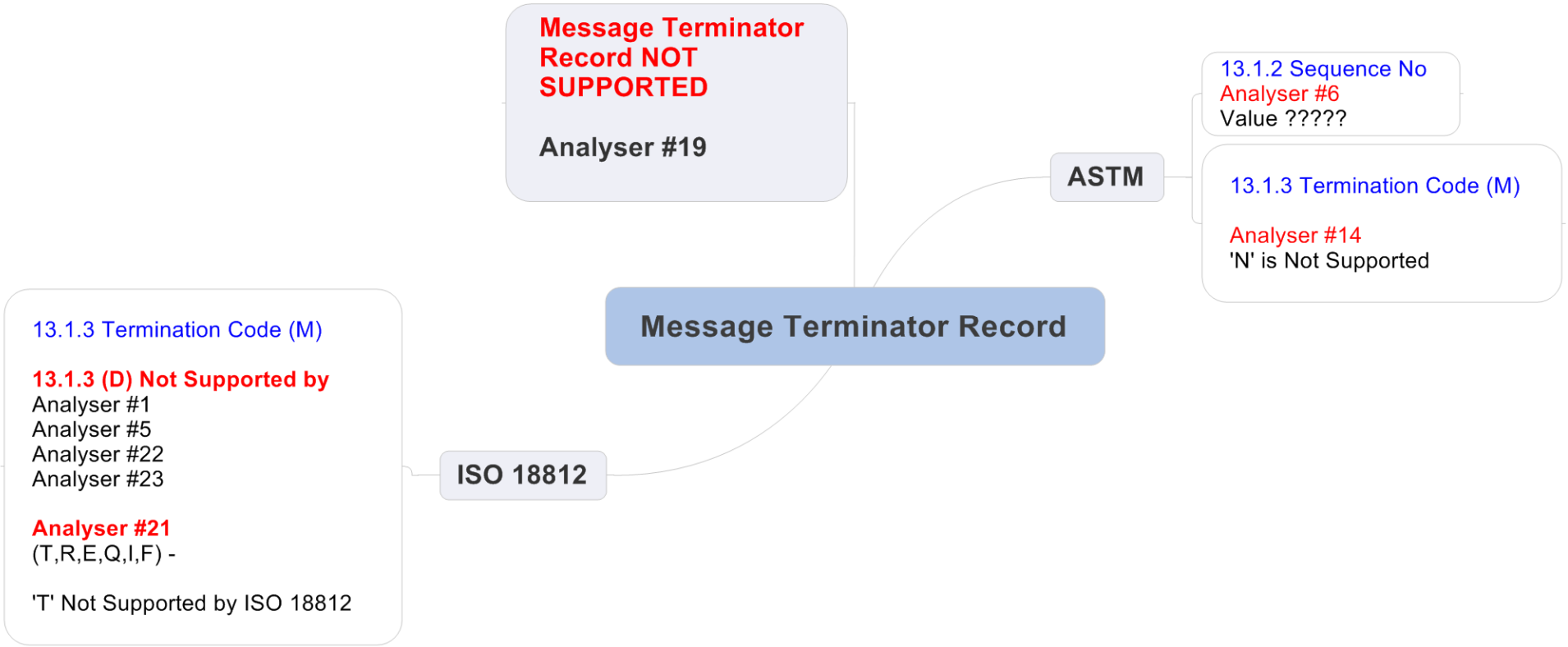

Figure 26 - Mind map of Message Terminator Record - Non-Compliances with ASTM E1394-97 and ISO 18812

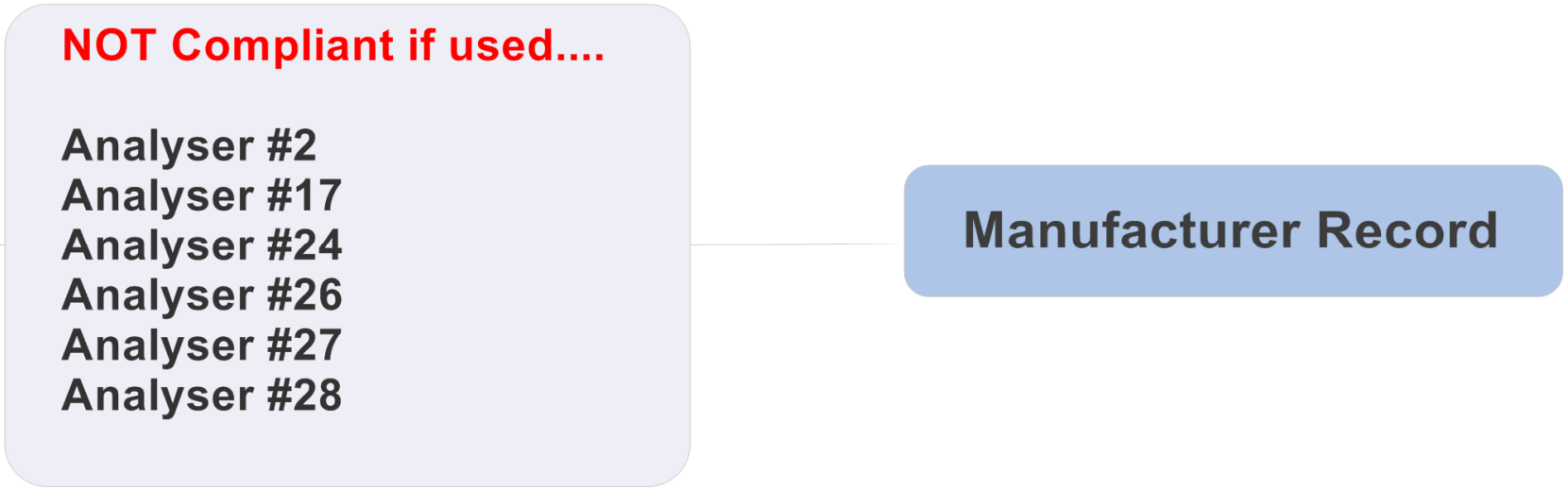

Figure 27 - Mind map of Manufacturer Record - Non-Compliances with ASTM E1394-97 and ISO 18812

Appendix D – Language Usage and Non Compliance with ASTM 1394-97

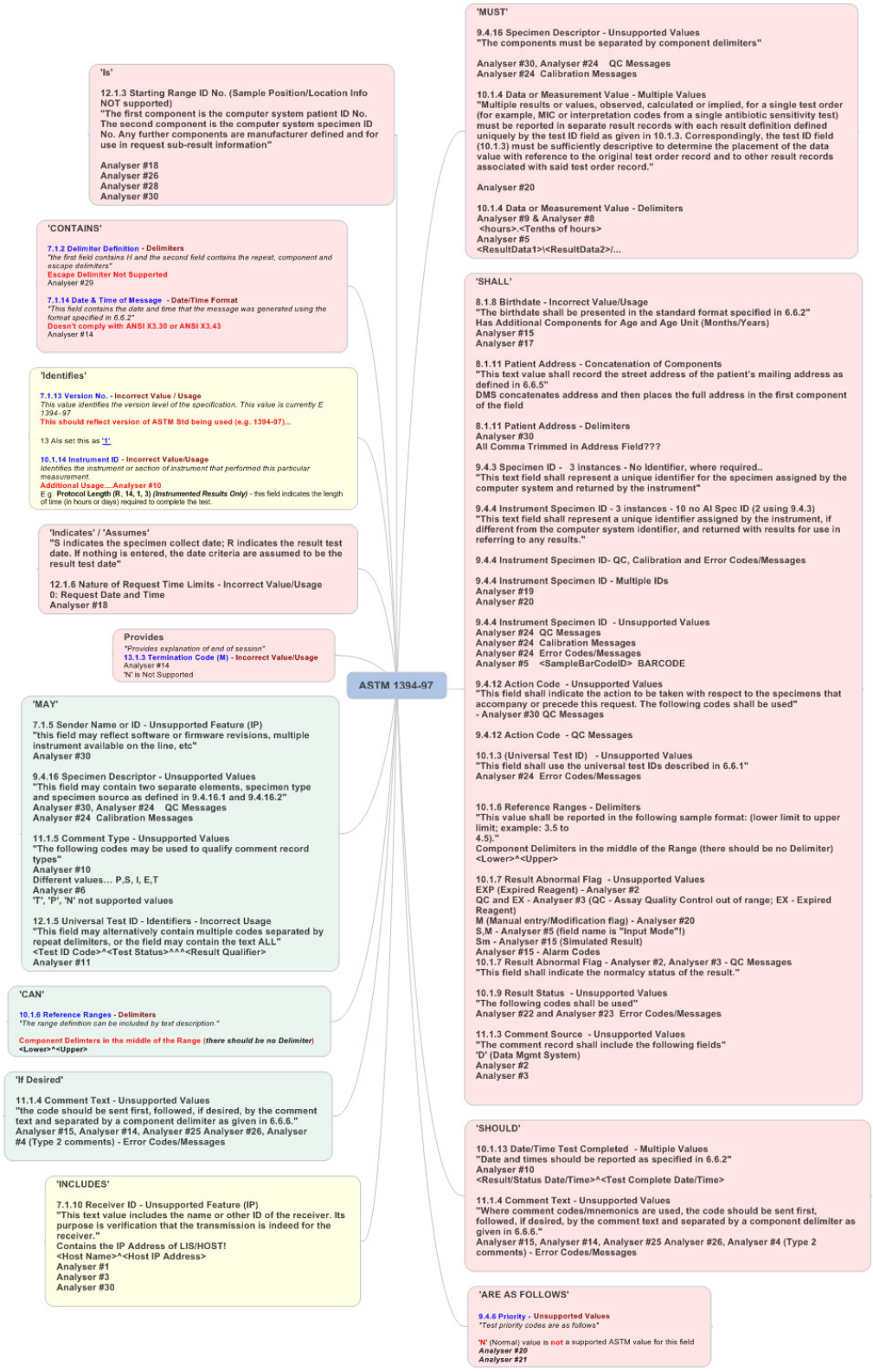

Figure 28 - Overall Language Usage and ASTM E1394-97

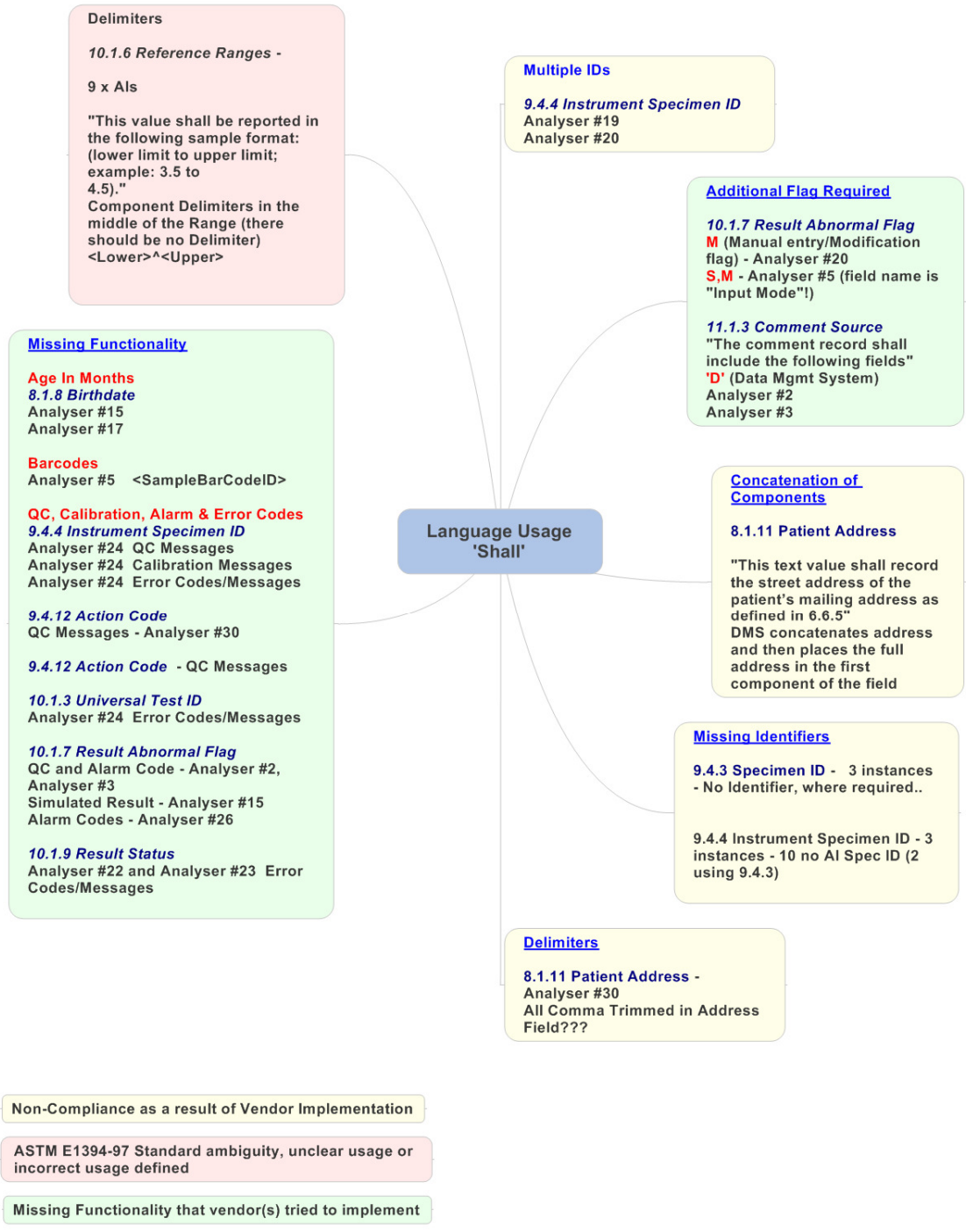

Figure 29 - The use of "shall" and non-compliance with ASTM E1394-97

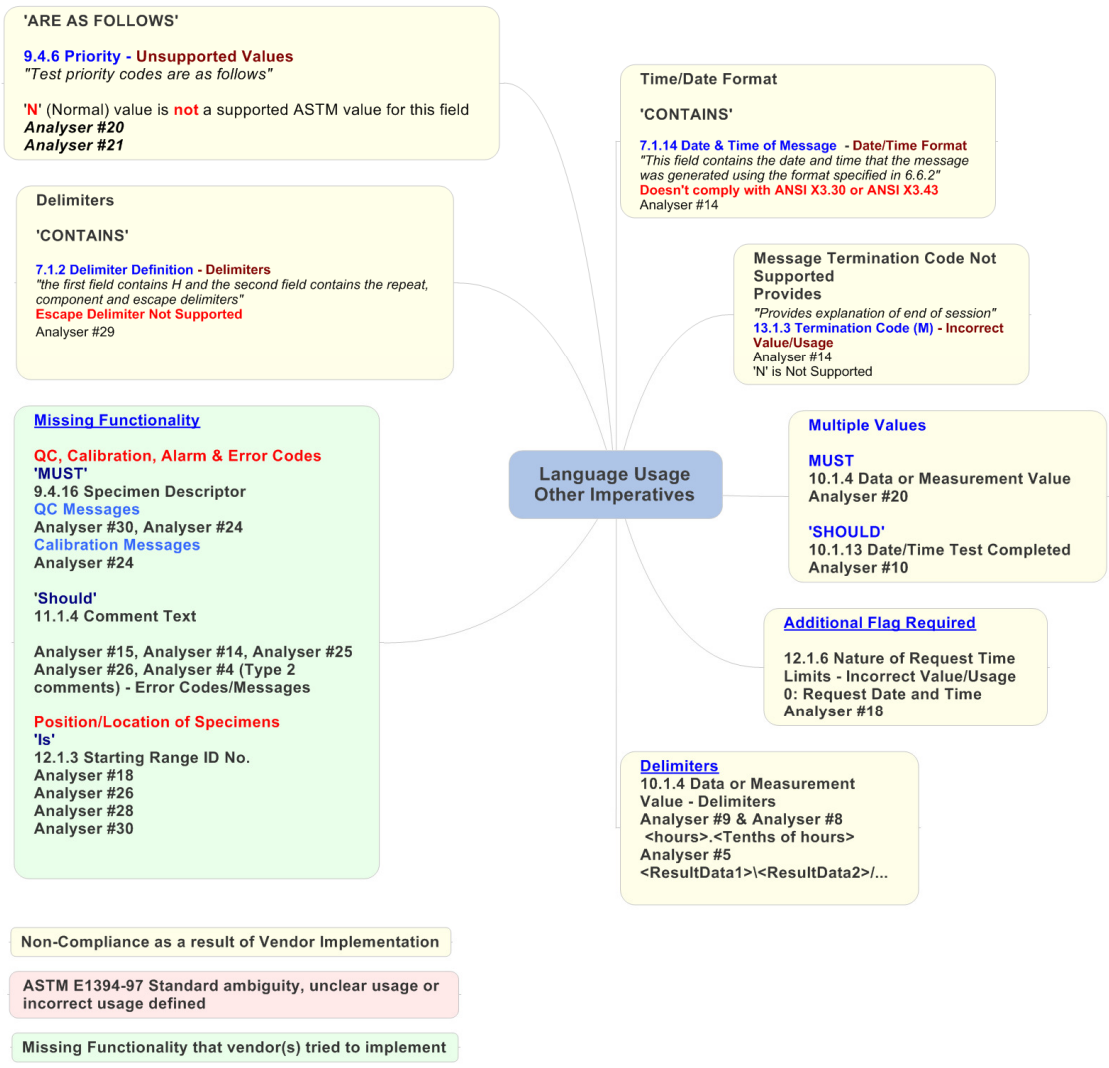

Figure 30 - The use of other imperatives and non-compliance with ASTM E1394-97

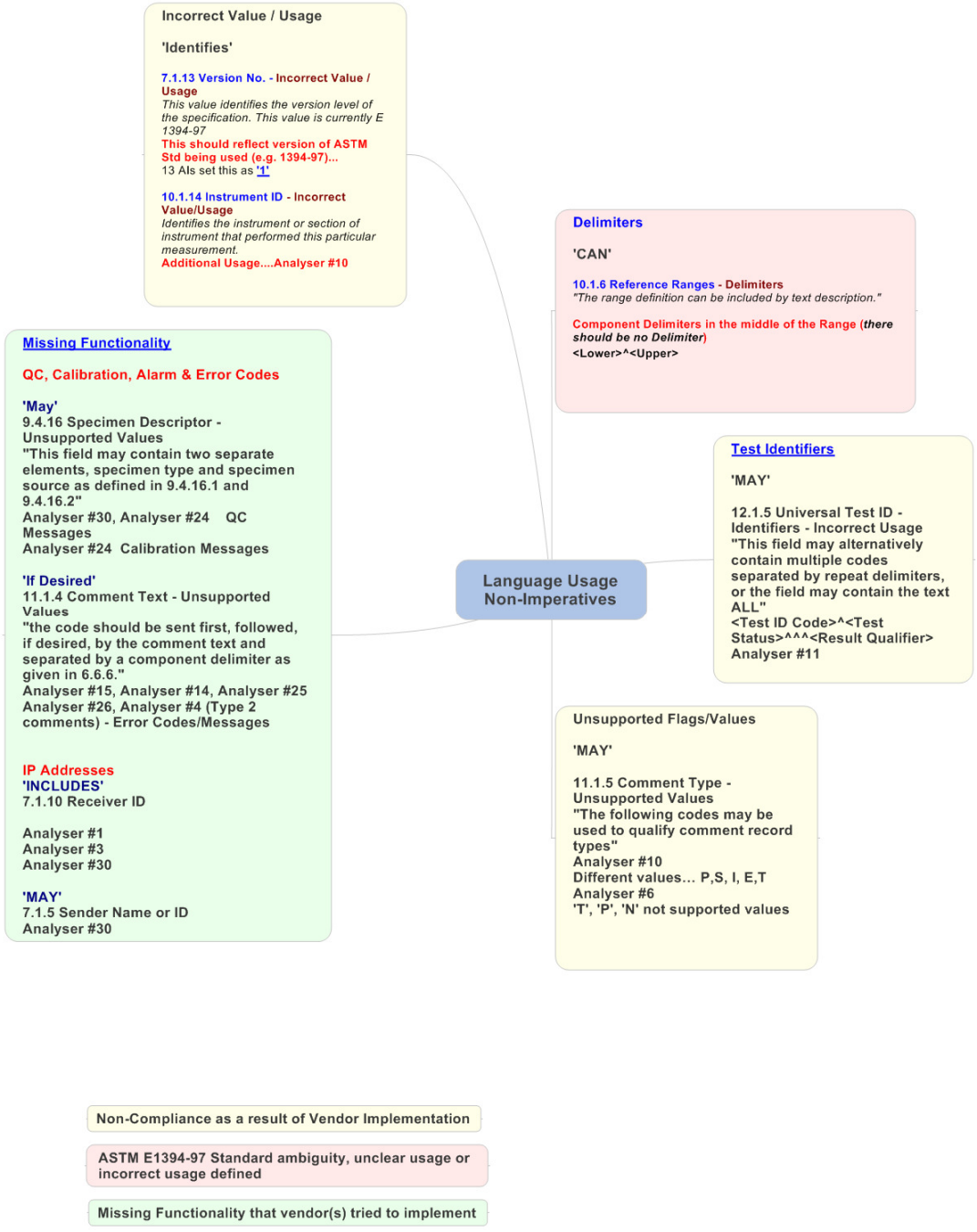

Figure 31 - The use of non-imperatives and non-compliance with ASTM E1394-97

Appendix E – Ethics Approval Process

E-1 Communications between Author and Ethics Committee

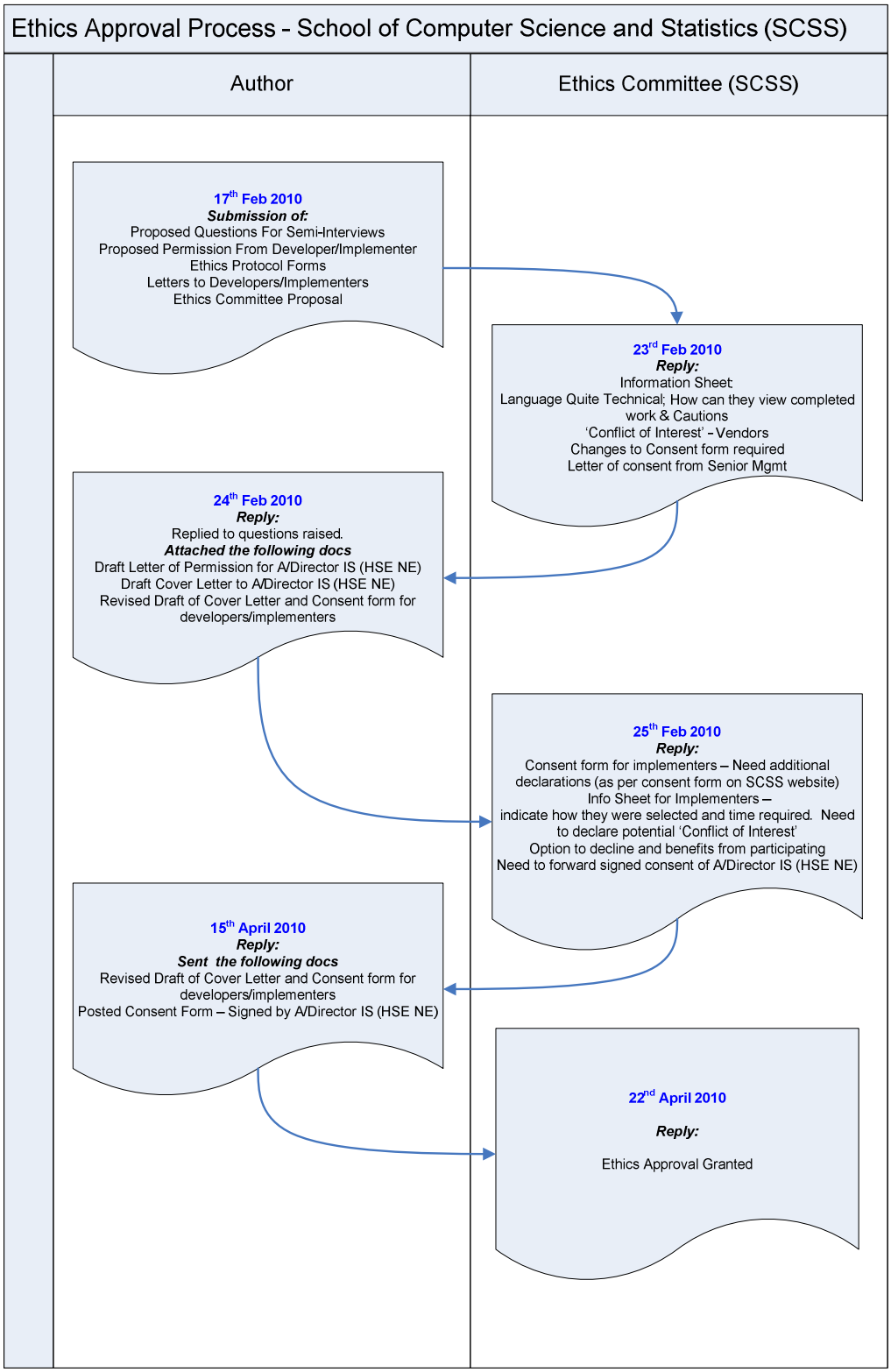

Figure 32 - Communication between Author and Ethics Committee

E-2 Ethics Committee - Proposal

Date: 3rd February 2010

To the Ethics Committee:

Dear Committee Member,

Project Title:

My project questions **is "An Investigation of the properties of a messaging standard that makes it useable but generally applicable"**

Purpose of Project:

The study will endeavour to identify:

- Compliance/Adherence with the ASTM standard
- Non-compliance/Issues
- Benefits from LIS Developers/Implementers point of view
- Issues from LIS Developers/Implementers point of view
- Ways in which the ASTM 1394-97 standard could have been improved
- What properties a standard must employ to ensure success and ease of implementation and integration of systems using same?

Gurguilo once commented that "Standards are only meaningful if implemented in a consistent and correct way" (Garguilo, J.J., Martinez, S., Rivello, R. and Cherkaoui, M. (2007) Moving Toward Semantic Interoperability of Medical Devices. High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability, 2007.). This research hopes to identify the properties of messaging standards that ensure that they are applied consistently and correctly by vendors; to ensure both patient safety and enhance interoperability between systems.

We anticipate that this research will offer insight into all of the questions posed at the outset and that the answers obtained will help in the future development of all lab messaging standards and possibly other messaging standards. SE is fundamental to successful implementation and successful support of projects.

Methods and Measurement to be used:

Detailed Case Study

A detailed case study of ASTM file output formats from all the Analytical Instruments, employing ASTM as their preferred messaging format, in the Cavan/Monaghan laboratories. We may wish to extend this study to include other hospital laboratories in the North East (i.e. Drogheda, Dundalk and Navan hospital laboratories). This study will look in detail at how each extract complies or differs from the ASTM 1394-97 Standard (ASTM, 1998). We will attempt to either get an actual anonymised ASTM extract directly from the Analytical Instruments (AIs), if and where possible, or to get the implementation manual for those AIs and subsequently determine the ASTM output file format.

Semi Structured Interview

We plan to carry out semi-structured interviews with one or more of the Laboratory Information Systems developers/implementers. These will be either conducted face-to-face or over the phone, depending on suitability to the respondents. These will consist of questions such as:

- What percentage of laboratory analysers currently employs ASTM 1394 as their messaging protocol/standard?
- From your experience, do manufacturers tend to use the same interpretation of the standard throughout all devices that they manufacture?
- Do manufacturers offer alternative messaging standards to ASTM 1394 (or non-standard approaches) on their analysers?
- Do you feel there are ways in which the ASTM 1394 standard should have been changed to make it more effective in terms of interoperability between systems (LIS-AIs)?
- In your view, what properties of the ASTM 1394 standard have helped make it successful?

Ethical Considerations:

We hope to conduct a face-to face interview with one or more LIS interface implementers. As part of this undertaking, we would like to make an audio recording of the interview to help facilitate analysis of the discussion. This recording will only be undertaken if the participant is in agreement with same.

All issues uncovered during the research will be reported in such a manner as not to imply directly or indirectly any issues pertaining with the vendors themselves; any issues will be reported in a anonymised fashion.

I hope this is to your satisfaction.

Thanking you.

Yours sincerely

_____

Brian Markey

Student ID: 08261186

E-3 Ethics Committee - Ethics Protocol

School of Computer Science and Statistics
Research Ethical Approval Form

Part A

Project Title: **"An Investigation of the properties of a messaging standard that makes it useable but generally applicable"**

Name of Lead Researcher (student in case of project work): Brian Markey

TCD E-mail: bmarkey@tcd.ie Contact Tel No.: 087 2656212

Course Name and Code (if applicable): MSc in Health Infomatics

Estimated start date: October 2009 Estimated end date: September 2010

Office Use Only
SCSS Ref No.: …….....……. Date Received: …….....……..……

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.

Signed: Brian Markey Date: 6th February 2010
Lead Researcher/student in case of project work

School of Computer Science and Statistics
Research Ethical Approval Form

Part B

Please answer the following questions.		*Yes/No*
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		No
Will your project involve photographing participants or electronic audio or video recordings?		Yes
Will your project deliberately involve misleading participants in any way?		No
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		No
Does your study involve any of the following?	Children (under 18 years of age)	No
	People with intellectual or communication difficulties	No
	Patients	No

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided an complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.

Signed: Brian Markey Date: 6th February 2010
Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

School of Computer Science and Statistics
Research Ethical Approval Form

Part D

If external ethical approval has been received, please complete below.

External ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: Date:
Lead Researcher/student in case of project work

Completed application forms together with supporting documentation should be submitted in hardcopy to the School's Research Unit, Room F37, O'Reilly Institute, and an electronic copy e-mailed to research-unit@scss.tcd.ie Please use TCD e-mail addresses only.

Application Check List

- The following documents are required with each application:

1. SCSS Ethical Approval Form
2. Participants Information Sheet
3. Participants Consent Form
4. Research Project Proposal
5. Intended questionnaire/survey/interview protocol/screen shots/representative materials (as appropriate)

E-4 Letter to A/Director of Information Services – HSE Dublin North East

To:

Michael Redmond

A/Director of Information Services – HSE Dublin North East

Date: 24th February 2010

RE: Permission to interview LIS Implementers/Developers in line with my dissertation "An Investigation of the properties of a messaging standard that makes it useable but generally applicable"

Dear Michael,

I wish to seek your approval to interview current LIS Implementers/Developers to the HSE North Eastern Area as part of my current research, **"An Investigation of the properties of a messaging standard that makes it useable but generally applicable".**

With regards to this research, I'm enclosing a copy of:

- My research Proposal
- Information Sheets for Interview Participants
- Proposed Interview Questions
- Interviewee Consent Forms

I would be grateful if you could sign the attached approval form.

Thanks and regards

_____

Brian Markey

Management Services

ICT HSE DNEA

E-5 Letter of Consent – A/Director of Information Services – HSE Dublin North East

Date: 24th February 2010

Michael Redmond
A/Director of Information Services
HSE Dublin North Eastern Area
Kells Business Park
Cavan Road
Kells
Co. Meath

To: Ethics Committee, Trinity College, Dublin.

Dear Committee Member,

This letter is to inform you that I give permission to Brian Markey of ICT, HSE Dublin North East to interview LIS Implementers/Developers to verify and obtain relevant new information in relation to the dissertation he is undertaking.

Yours sincerely,

Michael Redmond

_____

E-6 Cover Letter to Implementers/Developers

Project Proposal:

"An Investigation of the properties of a messaging standard that makes it useable but generally applicable"

Date: 10th April 2010

Dear Systems Developer/Implementer,

You are invited to participate in an interview which endeavours to assist my research in identifying the properties of the ASTM 1394-97 messaging standard that have made it successful and what failure/lack of features it may have.

You have been selected to partake in this study, due to your expert knowledge with regards the interfacing of Analytical Instruments (AIs) with Laboratory Information Systems (LISs) using this standard. It is hoped that the interviews will take around 30 minutes, but no more than 60 minutes to complete.

This study endeavours to identify:

- Compliance/Adherence with the ASTM 1394-97 standard by AI Manufacturers
- Any Non-compliance/Issues with the ASTM 1394-97 standard
- Benefits of the ASTM 1394-97 standard from LIS Developers/Implementers point of view
- Issues with the ASTM 1394-97 standard from LIS Developers/Implementers point of view
- Ways in which the ASTM 1394-97 standard could have been improved
- What properties a standard must employ to ensure success and ease of implementation and the integration of systems using same?

Please note that any quotations/references made pertaining to these interviews will be anonymised. There will be no reference to any locations, persons, system vendors/companies or particular hardware/software solutions.

To help ensure correct reporting and assist with analysis of same, I would like to make an audio recording of this interview. This interview will then be transcribed and analysed. Please indicate whether you are happy for me to also make this recording. You may request the recorder to be turned off at any point and that any request you make to withdraw the recordings will be respected.

I will forward to you by email/post a copy the proposed content (of the dissertation) pertaining to the interviews undertaken, for approval, prior to inclusion/publication of same. Any request for changes to be made or part/all of the content (relating to or obtained from your interview) to be omitted will be undertaken in accordance with your instructions.

Please note that participation is on a voluntary basis and you have the right to withdrawal from the interviewing process and/or request for any content (pertaining to your interview) to be omitted from the dissertation at any time, without fear of any form of penalty/reprisal.

I don't envisage any conflict of interest between this research and the potential benefit it may offer the HSE in terms of possible lower interfacing costs, as this is not involving any changes to the existing ASTM standard (or the LIS2A standard that has superseded it) but rather attempts to identify the key components of a successful messaging standard.

In recognition of their participation, all interviewees will receive a copy of the final dissertation in pdf format for their perusal.

If you are satisfied with my explanation for the use of the material I would be grateful if you would sign the attached form and if not thank you very much for taking the time to read this letter.

Please note that in the extremely unlikely event that illicit activity is reported to me during the interview, I will be obliged to report it to appropriate authorities.

Please do not name third parties. Any such replies will be anonymised.

Regards

Brian Markey

E-7 Letter of Consent from Implementers/Developers

Date: 3rd February 2010

To whom it may concern,

This letter is to inform you that I give permission to Brian Markey of ICT, HSE, DNEA to use information obtained from me [Name] in this interview and verified before publication to be used in relation to his dissertation.

- I allow recordings to be made of interviews conducted during this study.
- I understand that this means that I may request the recorder to be turned off at any point and that any request I make to withdraw the recordings will be respected.
- I understand that the recordings will be replayed solely by the researchers and not in any public forum.

Brian Markey will forward to me (the participant) by email/post a copy the proposed content (of the dissertation) pertaining to the interviews undertaken, for approval, prior to inclusion/publication of same. Any request for changes to be made or part/all of the content to be omitted will be undertaken in accordance with the participant's instructions.

Please note that participation in this process is on a voluntary basis and you (the participant) have the right to withdrawal from the interviewing process and/or request for any content (pertaining to your interview) to be omitted from the dissertation at any time, without fear of any form of penalty.

Please note that in the extremely unlikely event that illicit activity is reported to the interviewer (Brian Markey) during the interview, I will be obliged to report it to appropriate authorities.

Please do not name third parties. Any such replies will be anonymised.

<u>DECLARATION OF PARTICIPANT:</u>

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.

- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- If the research involves viewing materials via a computer monitor, I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I have received a copy of this agreement.

Name of Participant (Printed Name) [Name]_____

Signature of Participant _____

Date _____

Name of Researcher (Printed Name) BRIAN MARKEY

Signature of Researcher _____

Date _____

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