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A quiet success story in the laboratory: survey of 30 implementations of the ASTM 1394-97 standard for analyser interfaces.

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Abstract

In 1991 the American Society of Testing and Materials (ASTM) introduced the first version of a standard called ASTM E1394-91 for communication between centralised clinical analysers and host systems. For nearly 20 years this low key standard has been used as the basis for analyser host communications. A minor revision of the standard (ASTM1394-97) was published in 1998*.

This work gives a brief summary of the development of lab messages that led to the introduction and continued use of the standard. The authors also present a review and preliminary analysis of 30 implementations of ASTM E1394. The authors investigated 30 relevant analyser interfaces in order to identify the successful and unsuccessful features of the ASTM E1394-97 standard by assessing the compliance and non-compliance of the chosen implementations with respect to different features of the standard.

* E1394-97 has since been consolidated into the Clinical and Laboratory Standards Institute (CLSI) LIS2-A2 standard; while the clauses of the standard have remained virtually unchanged. The standard is still commonly referred to as ASTM 1394.

A majority of the implementations, averaging 94%, were found to comply with the ASTM E1394 standard; with the majority of non-compliance pertaining to attempts to provide for missing functionality not addressed by E1394-97. The authors also advocate a revision of the standard to enhance the quality of messages by use of standardised test identifiers, use of strong data typing and use of standards for addresses and measurements recorded within the message.

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 that 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. 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, 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).

1.2 Motivation for Study

There is currently a drive internationally to improve the quality of healthcare messages. Given the current interest in adopting and adapting messaging standards in Ireland and elsewhere, e.g. GP Messaging Standard (Health Information and Quality Authority, 2010), 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 vague parts, concepts or sections that could be misinterpreted.

1.3 Aims and Objectives of this Work

The aim of this work is to analyse a number of implementations of a successful messaging standard that has been widely implemented by vendors/manufacturers. called ASTM E1394-97 (ASTM, 1998). The purpose of the analysis is to:

- Discover the features of ASTM E1394 that has made it so successful.

- Establish whether these features also make ASTM 1394 a “good” standard.

This work attempts to answer these questions through a number of different routes.

Firstly, implementations of a number of ASTM E1394-97 interfaces by different Analytical Instrument (AI) vendors are 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.

1.4 Introducing ASTM E1394

In April 1991 the American Society for Testing and Materials (ASTM) developed two messaging standards for electronic messaging between AIs and LIS systems, E1381-91 and E1394-91 (Kataoka, 2010). The E1394 standard which was slightly revised (E1394-97) in 1998, 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.

2 Research Methodology

The primary research was conducted around a total of 30 ASTM 1394 interface specifications for centralised and non-centralised clinical analysers; 27 AIs and 3 Data Management Systems. These were evaluated in relation to the ASTM E1394-97 specification (ASTM, 1998).

Details pertaining to each implementation were initially recorded in individual worksheets within a Microsoft Excel spreadsheet. These were then summarised and analysed to ascertain compliance/non-compliance with ASTM E1394, by record type. Mind maps were then generated to further aid analysis of this information; see (Markey, 2010) for further details on this process.

3. Findings

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 1 below for graphical representation of compliances across all record types.

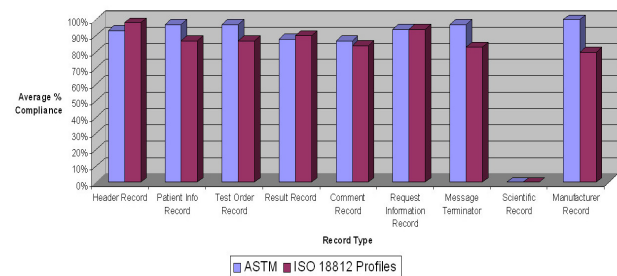


Figure 1 - ASTM E1394-97 and ISO 18812 Profiles Compliance per Record Type

3.1 ASTM Compliance

Header Record

A majority of the interfaces fully supported the 'Header Message' specification. Just a few inconsistencies were found; one not supporting the 'Escape Delimiter' and a few others supporting the use of IP addresses in the Sender (7.1.5) and Receiver (7.1.10) identifier fields. Also two-thirds of implementations incorrectly placed the software version number of their interface into the (standard used) 'Version Number' (7.1.13) field.

Patient Information Record

ASTM compliance within the patient record field was also high across all implementations. There were a couple of instances where an extra component for 'Age' and 'Age Unit' was added to the 'Birthdate' field (8.1.8). There were a couple of instances where information pertaining to different components of the 'Patient Name' (8.1.6) and 'Patient Address' (8.1.11) fields were concatenated into the first component of their respective field.

Test Order Record

The greatest deviation from the ASTM standard occurred in the Test Order Record, with almost 50% of the interfaces placed unsupported additional information 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. 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, while 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); placing their own test codes and other information in the fourth and subsequent components 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).

Result Record

There was also significant non-compliance within the 'Result Record'. There was incorrect use of delimiters within the 'Data or Measurement Value' (10.1.4) field. In addition there were a couple of instances where an unsupported second ('flags') component was used.

Half of all interfaces that supported the 'Reference Ranges' field (10.1.6), 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 results by the operator. One implementation supported the use of an additional 2 components.

There was also significant non-compliance with the use of the mandatory 'Result Status' field (10.1.9). These included vendors prohibiting the use of the field to others using their own codes or test error/status codes.

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).

Comment Record

Compliance across the 'Comment Record' was high with only three of the twenty-two analysers that supported this record using

un-supported values in the 'Comment Source' (11.1.3) field. Only one analyser used a completely different set of values for the 'Comment Type' (11.1.5), while another used an additional three unsupported values.

Request Information Record

There were only 2 deviations from the standard in relation to the 'Starting Range ID' (12.1.3); the first two components of the field to indicate the rack number and tube position of the sample in one instance, while in three other instances the location information was placed in the third and subsequent components of the field.

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.

There was also non-compliance in the 'Nature of Request Time Limits' (12.1.6) and the 'Request Info Status Codes' (12.1.13) fields.

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, while 2 analysers gave the option not to use one. It was also noted that one implementation chose to use the 'F' (last request for information processed) termination code flag in 13.1.3, rather than the 'N' (normal termination) flag.

4. Discussion

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 missing functionality in revisions of the standard:

- **Age for Infants** – ability to accurately record age in terms of months for infants.
- **Specimen Location/Position** – to identify location of specimen within an analytical instrument.
- **Network Address of Sender and Receiver** – to help further identify the Laboratory Information System/Data Management System or Analytical Instrument.
- **Barcodes for Specimens** – to further aid identification of specimen.
- **Support for Calibration / Error / QC and Training Messages.**

There were 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.

Other issues were identified pertaining to:

- **Misinterpretation of usage of the 'Version No' field (7.1.13).**
- **Concatenation of information** – where data pertaining to different

components were concatenated into a single string that was held in the first component of the given field.

- **Different Flags** – vendors choosing to use their own values/flags for given fields.
- **Additional Components** – vendors choosing to add additional components to given fields.
- **Use of Test Identifiers** – issues around use of local lab codes versus using standardised code sets.

A lack of strong data typing (Nadkarni et al, 1999) was also identified as a shortcoming of the ASTM standard. It was also acknowledged that there were a number of instances where external coding systems or standards could have been enforced to improve the quality of the messages; such as the Unified Code for Units of Measure (UCUM) code sets, (Schadow et al, 1999).

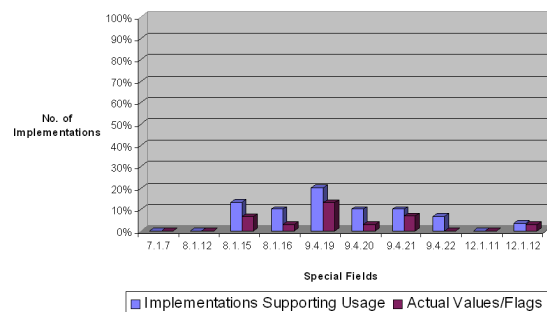


Figure 2 - Usage of 'Special' or 'Reserved' fields by vendors

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 2 above.

A further study was undertaken to determine whether language usage within the standard had contributed to the instances of non-compliance with the ASTM E1394-97 standard. It was found that the 'Reference Ranges' field (10.1.6) was the only one clause that caused confusion and ultimately one instance of non-compliance. Otherwise no instances of non-compliance could be deemed directly attributable to the use of language.

A closely related 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. It was found that there was a lack of clear guidelines pertaining to the usage of a number of fields. Also the use of a number of defined flags for the 'Result Abnormal Flags' field (10.1.7) seemed to have no logical meaning; such as "LL – below panic normal".

5. Conclusion

It was found that many features enabled ASTM E1394 to be so successful, namely:

- **A Small Control Group** – only the E31 group that developed the ASTM E1394 standard and the subsequent AI vendors that employed it had control over its implementation. All subsequent implementers had to follow the AI manuals and couldn't further customise it to their specific environment.
- **Simple Message Structure and Format** – enabled it to be successful understood and used by vendors.
- **Use of Language** – In most cases imperatives were used to clearly indicate usage, with optionality kept to a minimum. This helped ensure that the use of language with the clauses had not resulted in any ambiguity in meaning and ultimately non-compliance by vendors.
- **Use of Standards (within Standards)** – While it was limited it was clear that the use of standards such as the ANSI X3.30 and X3.43 standards for the recording of dates and times within messages and the use of the ISO 2955 (ISO, 1983), for the recording of units of measurement, helped ensure uniformity among vendors.

These features have enabled ASTM E1394 to be a "good" standard as:

- The nature of the small control group limits the amount of localisation and as such helps to minimise the amount of non-compliance that exists among different implementations.
- The simple message structure and format make it easy to implement.
- The clear use of language helps minimise misinterpretation or ambiguity and once more ensures ease of compliance by vendors.
- The use of other standards helps ensure coherence/consistency in messaging among vendors.

Overall it has been a successful standard that is still widely used today in possibly up to two-thirds of all AI to LIS messaging worldwide.

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