

1. Introduction

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1.2 PURPOSE

This document contains the specifications for Version 2.4 of the Health Level Seven (HL7) Standard for electronic data exchange in all healthcare environments, with special emphasis on inpatient acute care facilities (i.e., hospitals). It summarizes the work of a committee of healthcare providers (i.e., users), vendors and consultants established in March 1987 on the occasion of a conference hosted by Dr. Sam Schultz at the Hospital of the University of Pennsylvania. Its participants, who represent users as well as vendors, share a common goal of simplifying the implementation of interfaces between computer applications from different, and often competing, vendors. This committee, which subsequently became known as the HL7 Working Group, endeavors to standardize the format and protocol for the exchange of certain key sets of data among healthcare computer application systems. Meetings are held approximately every four months in scattered locations throughout the United States. HL7 sanctioned national groups also exist in many other countries outside of the United States including Australia, Canada, China, Finland, Germany, India, Japan, Korea, New Zealand, Southern Africa, Switzerland, Taiwan, The Netherlands, and the United Kingdom.

This document is being presented to interested parties. It is a status report that is periodically published to solicit the involvement of the broadest possible group of participants as this protocol is being put into use. Comments are solicited on all aspects of the Standard.

This effort is expected to yield a balloted standard that is open to **all** who develop healthcare data processing systems. As the Standard has been put into production, experience has been gained and is reflected in this latest revision.

There have been two parallel efforts since the publication of Version 2.2. First, Version 2.3 represents an evolutionary change over Version 2.2 that was published in December 1994. Version 2.3 is the result of more than two years work, and thousands of hours of volunteer effort by active HL7 members since the publication of Version 2.2. Its primary goals include maintaining backward compatibility with Version 2.2, correcting errors discovered after the publication of 2.2, and extending the Standard within the format and context of Version 2.2.

HL7 is operating under formal bylaws and balloting procedures. These procedures are modeled on the balloting procedures of other relevant healthcare industry computer messaging standards organizations (e.g., ASTM) and are designed to conform to the requirements of the American National Standards Institute (ANSI). HL7 is participating in ANSI's Healthcare Informatics Standards Board (HISB). In June 1994, HL7 became an ANSI Accredited Standards Developing Organization. Version 2.2 of HL7 was accepted by ANSI as an accredited standard in 1996 and HL7 Version 2.3 received ANSI approval in May of 1997. Version 2.3.1 received ANSI approval in April of 1999. Version 2.4 is being submitted to ANSI for similar consideration.

HL7, as an organization, has experienced significant growth over the last several years. Currently, HL7's membership consists of approximately 2000 members in all membership categories and regularly attracts 400-500 members and non-members to each of its three yearly meetings. As of 1998, HL7 had documented several hundred healthcare provider organizations that have implemented computer interfaces based on the HL7 Standard. It is possible for a healthcare provider institution to use HL7 without actually being an HL7 member through a member vendor or through outright purchase of the Standard without joining HL7.

1.3 BACKGROUND

The term "Level 7" refers to the highest level of the Open System Interconnection (OSI) model of the International Organization for Standardization (ISO). This is not to say that HL7 conforms to ISO defined elements of the OSI's seventh level. Also, HL7 does not specify a set of ISO approved specifications to occupy layers 1 to 6 under HL7's abstract message specifications. HL7 does, however, correspond to the conceptual definition of an application-to-application interface placed in the seventh layer of the OSI model.

In the OSI conceptual model, the functions of both communications software and hardware are separated into seven layers, or levels. The HL7 Standard is primarily focused on the issues that occur within the seventh, or application, level. These are the definitions of the data to be exchanged, the timing of the exchanges, and the communication of certain application-specific errors between the applications. However, of necessity, protocols that refer to the lower layers of the OSI model are sometimes mentioned to help implementors understand the context of the Standard. They are also sometimes specified to assist implementors in establishing working HL7-based systems.

The HL7 Working Group is composed of volunteers who give their time on a personal basis or under sponsorship of their employers. Membership in the HL7 Working Group has been, and continues to be, open to anyone wishing to contribute to the development and refinement of Level 7 Interface Standard for network technology in healthcare.

The Standard currently addresses the interfaces among various systems that send or receive patient admissions/registration, discharge or transfer (ADT) data, queries, resource and patient scheduling, orders, results, clinical observations, billing, master file update information, medical records, scheduling, patient referral, and patient care. **It does not try to assume a particular architecture with respect to the placement of data within applications but is designed to support a central patient care system as well as a more distributed environment where data resides in departmental systems. Instead, HL7 serves as a way for inherently disparate applications and data architectures operating in a heterogeneous system environment to communicate with each other.**

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If we consider the multitude of healthcare information systems applications as well as the variety of environments in which healthcare is delivered, it is evident that there are many more interfaces which could benefit from standardization. The interfaces chosen were considered to be of high priority by the members participating in the standards writing process. HL7's intent is to prepare a complete standard for these interfaces, built on a generic framework that is sufficiently robust to support many other interfaces. This Standard has been put into production and is being used as a basis for extending the existing interface definitions and also adding other definitions.

It is expected that one result of publishing this specification will be the recruitment of more Working Group members with special interest in some newer and not yet fully specified areas. Some of the areas that have already been identified are:

- a) decision support
- b) additional specific ancillary departments
- c) information needs associated with healthcare delivery systems outside of the acute care setting

The above notwithstanding, the Working Group members feel that the interfaces addressed here are sufficient to provide significant benefit to the healthcare community.

This document is structured as follows. The balance of this chapter contains a rationale for developing the Standard, the goals of the Standard, and issues that have been considered by the Working Group pertaining to scope and operational approach. It is hoped that this will help the readers understand the basis for decisions that have been made in developing the Standard. Subsequent chapters specify, respectively:

- a) overall structure for all interfaces including a generalized query interface
- b) patient administration (admission, discharge, transfer and registration)
- c) order entry
- d) patient accounting (billing) systems
- e) clinical observation data, such as laboratory results, that are sent as identifiable data elements (rather than display oriented text)
- f) a generalized interface for synchronizing common reference files (master files)
- g) medical information management
- h) patient and resource scheduling
- i) patient referral messages for referring a patient between two institutions
- j) patient care messages that support communication of problem-oriented records, and to provide functionality for the implementation of clinical pathways in computer information systems

1.4 NEED FOR A STANDARD

The organization and delivery of healthcare services is an information-intensive effort. It is generally accepted that the efficacy of healthcare operations is greatly affected by the extent of automation of information management functions. Many believe that healthcare delivery agencies that have not automated their information systems are not able to compete effectively in the healthcare market of the 1990's.

In the past two decades, healthcare institutions, and hospitals in particular, have begun to automate aspects of their information management. Initially, such efforts have been geared towards reducing paper processing, improving cash flow, and improving management decision making. In later years a distinct focus on streamlining and

improving clinical and ancillary services has evolved, including bedside (in hospitals and other inpatient environments) and “patient-side” systems (in ambulatory settings). Within the last few years, interest has developed in integrating all information related to the delivery of healthcare to a patient over his or her lifetime (i.e., an electronic medical record). It has also been envisioned that all or part of this electronic medical record should be able to be communicated electronically anywhere as needed.

It is not uncommon today for the average hospital to have installed computer systems for admission, discharge, and transfer; clinical laboratories; radiology; billing and accounts receivable, to cite a few. Often these applications have been developed by different vendors or in-house groups, with each product having highly specific information formats. As hospitals have gradually expanded information management operations, a concomitant need to share critical data among the systems has emerged. Comprehensive systems that aim at performing most, if not all, healthcare information management are in production by selected vendors. These systems may be designed in a centralized or a distributed architecture. Nevertheless, to the extent that such systems are truly complete, their use would mitigate the need for an external data interchange standard such as HL7.

There are, however, many pressures on an institution to develop or acquire individual departmental applications on a modular basis. One source of such pressure is the special departmental needs that may not be addressed well (or perhaps at all) by a comprehensive vendor (i.e., so called “best-of-breed”). Another is the need to evolve the overall systems environment of a hospital through a series of incremental, departmental decisions rather than in a single, revolutionary acquisition. These pressures could be met by an environment containing a comprehensive system supplemented by departmental systems, or one consisting entirely of separate and discrete systems.

Network technology has emerged as a viable and cost-effective approach to the integration of functionally and technically diverse computer applications in healthcare environments. However, these applications have developed due to market structure rather than through a logical systems approach; they are therefore often ad hoc and idiosyncratic. At the very least, they do not possess a common data architecture and their combined data storage actually constitutes a highly distributed and severely de-normalized database. Extensive site-specific programming and program maintenance are often necessary for interfacing these applications in a network environment. This occurs at considerable expense to the user/purchaser and vendor while often keeping vendor staff from other initiatives such as new product development. The need for extensive site-specific interface work could be greatly reduced if a standard for network interfaces for healthcare environments were available and accepted by vendors and users alike.

Finally, the lack of data and process standards between both vendor systems and the many healthcare provider organizations present a significant barrier to application interfaces. In some cases, HL7 becomes an effective template to facilitate negotiations between vendors and users but cannot, by itself, serve as an “off-the-shelf” complete interface.

In summary, it is important that both vendors and users not be faced with the problem of supporting incompatible transaction/communications structures. Instead, a framework must be developed for minimizing incompatibility and maximizing the exchange of information between systems. It is proposed that HL7 can act as a superstructure in this environment to facilitate a common specification and specifications methodology. It is indeed both practical and economical to develop, and commit to, standard interfaces for computer applications in healthcare institutions.

1.5 GOALS OF THE STANDARD

The specifications of this Standard were developed in accordance with **a priori** specified goals. Future extensions of the Standard should also support these goals.

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HL7's purpose is to facilitate communication in healthcare settings. The **primary goal** is to provide standards for the exchange of data among healthcare computer applications that eliminate or substantially reduce the custom interface programming and program maintenance that may otherwise be required. This primary goal can be delineated as a set of goals:

- a) the Standard should support exchanges among systems implemented in the widest variety of technical environments. Its implementation should be practical in a wide variety of programming languages and operating systems. It should also support communications in a wide variety of communications environments, ranging from a full, OSI-compliant, 7-level network "stack" to less complete environments including primitive point-to-point RS-232C interconnections and transfer of data by batch media such as floppy disk and tape.
- b) immediate transfer of single transactions should be supported along with file transfers of multiple transactions.
- c) the greatest possible degree of standardization should be achieved, consistent with site variations in the usage and format of certain data elements. The Standard should accommodate necessary site-specific variations. This will include, at least, site-specific tables, code definitions and possibly site-specific message segments (i.e., HL7 Z-segments).
- d) the Standard must support evolutionary growth as new requirements are recognized. This includes support of the process of introducing extensions and new releases into existing operational environments.
- e) the Standard should be built upon the experience of existing production protocols and accepted industry-wide standard protocols. It should not, however, favor the proprietary interests of specific companies to the detriment of other users of the Standard. At the same time, HL7 seeks to preserve the unique attributes that an individual vendor can bring to the marketplace.
- f) while it is both useful and pertinent to focus on information systems within hospitals, the long-term goal should be to define formats and protocols for computer applications in all healthcare environments.
- g) the very nature of the diverse business processes that exist within the healthcare delivery system prevents the development of either a universal process or data model to support a definition of HL7's target environments. In addition, HL7 does not make a priori assumptions about the architecture of healthcare information systems nor does it attempt to resolve architectural differences between healthcare information systems. **For at least these reasons, HL7 cannot be a true "plug and play" interface standard.** These differences at HL7 sites will most likely require site negotiated agreements.
- h) a primary interest of the HL7 Working Group has been to employ the Standard as soon as possible. Having achieved this, HL7 has also developed an infrastructure that supports a consensus balloting process and has been recognized by the American National Standards Institute (ANSI) as an Accredited Standards Organization (ASO).
- i) cooperation with other related healthcare standards efforts (e.g., ACR/NEMA DICOM, ASC X12, ASTM, IEEE/MEDIX, NCPDP, etc.) has become a priority activity of HL7. HL7 has participated in the ANSI HISPP (Health Information Systems Planning Panel) process since its inception in 1992.

1.6 HISTORY OF HL7 DEVELOPMENT

The HL7 Working Group has met approximately every three to four months since March 1987 to develop and review this specification. The group is structured into committees to address each of the functional interfaces under development, with additional committees to address the overall control structure and various administrative aspects of the group. These committees have the responsibility to author and maintain the chapters in the HL7

Interface Standard. In addition, from time to time various special interest groups are formed within HL7 to develop ideas and sponsor particular perspectives that are not covered by any single existing committee. If a special interest group's activities warrant and a new chapter is considered necessary, they may petition the HL7 Technical Committee Chair and the Executive Committee to form a Technical Committee.

In the initial three meetings, a Version 1.0 draft Standard was prepared covering the overall structure of the interfaces, ADT, order entry, and display-oriented queries. Although the patient accounting system was recognized as very important, the time frame did not allow it to be addressed in the first draft. This draft was presented to a Plenary meeting of the overall group in Tyson's Corner, VA, on October 8, 1987.

Version 2.0 was prepared subsequent to Plenary I in Tyson's Corner and presented at Plenary II in Tucson in September 1988. Since Plenary II, editing and revisions for Version 2.1, 2.2, 2.3, 2.3.1, and 2.4 have been ongoing and the Working Group has grown to nearly 400 individuals, far exceeding its original size of 12 and the following has been accomplished:

- a) specifications for the various functional areas have been refined and expanded.
- b) formal liaison was developed with several other standards efforts: the ANSI HISPP (Healthcare Information Standards Planning Panel) for the coordination of healthcare standards efforts that has since been replaced by the ANSI HISB (Healthcare Information Standards Board), the ASC X12N group for external EDI Standards, the ASTM E31.11 group for Clinical Data Exchange Standards, the ACR/NEMA DICOM group for standards relating to imaging and other aspects of Radiology Information Systems, and the IEEE P1157 group for medical data interchange (MEDIX).
- c) the generic control structure was modified, on the basis of comments, to be adaptable to a wider variety of communications environments and to facilitate cooperation with other standards groups.
- d) a chapter on the interface to a patient accounting system has been added.
- e) a chapter on the reporting of ancillary results, clinical trials, product experience and waveform data has been prepared, harmonized with the ASTM 1238-91 Standard and with the direct, active participation of members of the ASTM E31.11 committee.
- f) a chapter with a set of transactions to support the synchronization of master files between related information systems has been added.
- g) a chapter on the interface to applications that support medical record functions including transcription management, chart location and tracking, deficiency analysis, consents and release of information.
- h) a chapter on messages to support the communication of various events related to the scheduling of appointments for services or for the use of resources has been added.
- i) a chapter defining the message set used in patient referral communications between mutually exclusive healthcare entities has been added.
- j) a computerized data dictionary of all data elements and other message components has been created. Appendix A contains cross references and other information generated from this electronic data dictionary.
- k) inconsistencies and mistakes which were discovered in the previous Versions 2.0, 2.1, 2.2 and 2.3 of the Standard have been addressed and documented in Version 2.3.1.

- l) extensive additions have occurred in the Order/Entry and Clinical Observations chapters to include data element oriented results, pharmacy orders and administrations interface.
- m) message acknowledgments have been extended to include a separate enhanced mode that defines the “accept acknowledgment.” While this mode of acknowledgment has always been allowed, it is now obvious how HL7 supports any environment when intermediaries exist in the network with implicit time delays (such as store and forward services, “Interface Engines” that perform fan out services, etc.). Immediate acknowledgments are available to release the sending system from the need to resend the message.
- n) distinctions have been documented between the HL7 abstract message definition which is purely a level 7 (application level) definition vs. the HL7 encoding rules for converting an abstract message into a string of characters that comprises an actual message. These encoding rules are actually a suggested potential alternative where a fully defined level 6 (presentation level) definition does not exist (e.g., ISO’s ASN.1 Basic Encoding Rules (BER)).

1.7 OVERVIEW

This section contains a description of the conceptual basis of the HL7 Standard, the approach to accommodating intra-site variations and evolutionary changes, and the way it has been structured in order to accommodate varying current and future communications environments.

1.7.1 HL7 encoding rules

Message formats prescribed in the HL7 encoding rules consist of data fields that are of variable length and separated by a field separator character. Rules describe how the various data types are encoded within a field and when an individual field may be repeated. The data fields are combined into logical groupings called segments. Segments are separated by segment separator characters. Each segment begins with a three-character literal value that identifies it within a message. Segments may be defined as required or optional and may be permitted to repeat. Individual data fields are found in the message by their position within their associated segments.

All data is represented as displayable characters from a selected character set. The ASCII displayable character set (hexadecimal values between 20 and 7E, inclusive) is the default character set unless modified in the MSH header segment. The field separator is required to be chosen from the ASCII displayable character set. All the other special separators and other special characters are also displayable characters, except that the segment separator is the ASCII Carriage Return character.

(1) There is nothing intrinsic to HL7 Version 2.4 or ASTM 1238 that restricts the legal data set to the printable ASCII characters. The former restriction was imposed to accommodate the limitations of many existing communication systems. Some existing systems would misinterpret some eight-bit characters as flow control characters instead of data. Others would strip off the eighth bit.

(2) The European community (EC) has a need for printable characters (for example, the German oe, the French accent grave) that are not within the above-defined restricted data set. The personal computer market accommodates these alphabetic characters by assigning them to codes between 128 and 256, but it does this in many different ways. ISO 8859 is a 256-character set that does include all of the needed European letters and is a candidate for the European standards group. Where the Europeans define an eight-bit character set specification, HL7 will accept this data set in environments that require it, and can use it without complications.

(3) Multi-character Codes:

(a) UNICODE - When communicants use UNICODE, and all characters are represented by the same number of bytes, all delimiters will be single characters of the specified bytes length, and the Standard applies just as it does for single-byte length, except that the length of the characters may be greater than one byte.

(b) JIS X 0202 - ISO 2022 provides an escape sequence for switching among different character sets and among single-byte and multi-byte character representations. Japan has adopted ISO 2022 and its escape sequences as JIS X 0202 in order to mix Kanji and ASCII characters in the same message. Both the single- and multiple-byte characters use only the low order 7 bits in JIS Kanji code with JIS X 0202 in order to ensure transparency over all standard communication systems. When HL7 messages are sent as JIS X 0202, all HL7 delimiters must be sent as single-byte ASCII characters, and the escape sequence from ASCII to Kanji and back again must occur within delimiters. In most cases the use of Kanji will be restricted to text fields.

There are other parts of the JIS X series that support Katakana (JIS X 0201/ISO IR 13), Romaji (JIS X 0201/ISO IR 14) and Kanji (JIS X 0208/ISO IR 87) and JIS X 0212/ISO IR 159) that can be used in HL7 messages in the same manner as JIS X 0202.

(c) In the case that a single country uses conflicting rules for representing multi-byte characters, it is up to the communicants to ensure that they are using the same set of rules.

The encoding rules distinguish between data fields that have the null value and those that are not present. The former are represented by two adjacent quotation marks, the latter by no data at all (i.e., two consecutive separator characters.) The distinction between null values and those that are not present is important when a record is being updated. In the former case the field in the database should be set to null; in the latter case it should retain its prior value. The encoding rules specify that if a receiving application cannot deal with a data field not being present, it should treat the data field as present but null.

The encoding rules specify that a receiving application should ignore fields that are present in the message but were not expected rather than treat such a circumstance as an error. For more information on fields and encoding rules, see Section 2.6, "Fields," and 2.10, "Message Construction Rules."

1.7.2 Local variations

The HL7 Standard is intended to standardize data interchanges, not the underlying applications systems. This means that there will be a wide variety in the manner in which the Standard is applied in different institutions.

The requirement to support diversity within the Standard is addressed in these ways:

- a) The only data fields that are required in the abstract messages are those necessary to support the logic of the relationships among the messages or their basic purpose. Many other fields are specified but made optional.
- b) There are provisions within the specifications to add messages or portions of messages that are local to an institution. The conventions used for this are intended to prevent conflict with future versions of the specification.

1.7.3 Evolutionary changes to the standards

All standards must evolve as the applications they support change and as a result of experience using them. In recognition of this, the Standard includes a protocol version ID in all messages.

New transactions or data elements will be added to operational HL7 environments as a result of changes in the Standard or due to changes in the local implementation as permitted within the Standard. It is important that these changes be implementable at a site without requiring all communicating applications to upgrade simultaneously. The special provisions in the Encoding Rules for dealing with fields that are not present or unexpected are very important here. Because of them, new fields can be added first to the sending or source system; the receiving system will ignore the new fields until it has been updated to use them. Often, these rules also facilitate changing the receiving system first. Until the sending system is changed, the receiving system will find the new data field 'not present' and deal with this according to its rules for data not present.

Similarly, the HL7 Encoding Rules support changes in data field sizes. Fields are found within the message by examining separators, rather than by an offset. Changing the size of a field does not change the procedure used to detect subsequent fields.

1.7.4 Applicability to file transfers (batch processing)

Although the HL7 Standard is defined in terms of the client-server (remote operation) model, its standards are equally applicable to file transfers. One or more messages may be encoded according to the Encoding Rules, grouped in a file and transferred using external media, FTAM, FTP, Kermit, or any other file transfer protocol. Responses may be grouped in a file and similarly transmitted. Chapter 2 provides the general mechanisms for the batch transmittal of HL7 messages.

1.7.5 Relationship to other protocols

A great deal of consideration has been given to the relationship between the HL7 Standard protocol and other protocols. There are three questions:

- a) what is the relationship between the HL7 protocol and "lower layer," service protocols? In strict accordance with the ISO OSI model, HL7 should not replicate features of these protocols. This can even be construed to require HL7 to avoid replicating certain ISO layer 7 functionality contained in the Service Elements.

However, it is the goal of the HL7 group to support healthcare communications in a wide variety of communications environments, including many that are not as complete as ISO will be one day.

- b) what is the relationship between the HL7 Standard protocol and other applications protocols? Protocols of interest include the ASC X12 Standards for Electronic Document Interchange, the ASTM 1238-88 Standards for laboratory data reporting, the ACR/NEMA DICOM Standards for imaging and other aspects of Radiology Information Systems, and the IEEE P1157 Standards for Medical Data Interchange (MEDIX).
- c) what is the relationship between the HL7 Standard and various proprietary healthcare protocols in use today?

1.7.5.1 Lower layer protocols

The HL7 Encoding Rules are substantially different from the ASN.1 Basic Encoding Rules (BER) documented in CCITT X.409 and X.209 and ISO 8825 or those employed in LU6.2 or RPC. This is because:

- a) by definition, the HL7 encoding rules will be applied where the environment does not include software to do encoding. Without such software, the burden on applications programmers to develop messaging software that conforms to those encoding rules is onerous.
- b) the encoding rules of these protocols depend on the assumption that lower level protocols provide transparency (i.e., all character codes can be transmitted without being changed by and of the lower levels). This assumption is often not met in the communications environments that must serve HL7 for the interim. The techniques that might be used to implement transparency in the Lower Level Protocol are difficult to implement in some present-day applications environments.

The notation chosen to document the message formats in the HL7 Standard is not the Abstract Syntax Notation1 (ASN.1) Basic Encoding Rules (BER) defined by ISO.

Contrary to other high level communications environments, there is no notion of association separate from the sending of the message from client to server and the response. This seems appropriate to the client-server model.

Whenever HL7 is applied in a networking environment, addressing will be an issue. This is equally true when it is applied on ISO Standards networks or proprietary networks. Although the Standard does not specify how this addressing will occur, it does provide certain data fields that will be of value in determining addresses. The fields *MSH-5-receiving application*, *MSH-6-receiving facility*, and *MSH-11-processing ID*, are located in the header of all HL7 messages. *MSH-6-receiving facility* is intended for environments where multiple occurrences of the same application are being run on the same computer system or on the same network on behalf of different institutions or other organizational entities. *MSH-11-processing ID* is used where various versions of essentially the same application may reside on the same computer for different purposes. See *HL7 table 0103 - Processing ID* for recommended values.

HL7 does not standardize all values for *MSH-5-receiving application* and *MSH-6-receiving facility* at this time because there are so many variations in place in existing systems and because different kinds of environments (e.g., different countries) may have different required code sets. However, we strongly encourage the use of the HL7 suggested code sets where they are defined and we recognize that movement toward more standardized codes is essential for seamless communications.

1.7.5.2 Other application protocols

The Working Group has given considerable attention to the relationship of the HL7 protocol and other protocols. A considerable liaison effort is underway. This is described below:

- a) ACR/NEMA DICOM. The HL7 Working Group maintains an on-going liaison with the ACR/NEMA DICOM working group. HL7 and ACR/NEMA DICOM are both members of ANSI's HISB.
- b) ASC X12 Standards for Electronic Document Interchange. ASC X12 is a family of standards that provides both general and specific descriptions for data interchange within a number of industries. The HL7 Encoding Rules are modeled on the X12 standards, although there are differences. The HL7 Standard needs to accommodate online exchange of individual transactions on LANs. This difference, and certain applications issues, is responsible for the variance from X12. X12 has recently decided to follow the UN/EDIFACT encoding rules for all X12 standards produced in 1995 or later. X12N transactions that facilitate the transfer of healthcare claims and

remittance information as well as benefit coordination, enrollment and verification are enjoying dramatically increased use. HL7 has elected to assume that all new business transactions between institutions regarding the interchange of claims, benefits, or other financial information are the responsibility of ASC X12N, the insurance subcommittee of X12.

In February of 1994, HL7 and X12 signed an agreement to “improve coordination efforts and have identified that technical issues must be harmonized. Both groups agree to migrate to the appropriate level of resolution of potentially overlapping work by utilizing user and standards communities’ and anticipated healthcare reform requirements.”

- c) ASTM 1238.94 Laboratory Data Reporting. An active liaison effort between the ASTM committee and the Working group has resulted in minor changes in the ASTM specification to enhance compatibility, changes in the HL7 control specifications to enhance compatibility, and the development of the entire Ancillary Data Reporting chapter, developed jointly by the committees and built on the ASTM Standards. This liaison has extended to the point where both groups now have the permission to freely use the contents of each others standards efforts “in whole” within their own published standards.

Some distinctions are more in the terminology chosen than the actual message content. For example, the ASTM “sub-field delimiter” is generally used to separate repetitions of homogenous values. It is called a “repetition separator” in HL7. HL7 and ASTM are both members of ANSI’s HISB.

- d) IEEE P1157 (“MEDIX”). The MEDIX committee has defined an application-level protocol similar in scope to HL7 but built strictly on the ISO protocol stack, up to and including the Remote Operation Service Element (ROSE). HL7 varies from this approach by the decision not to depend on ROSE nor use the ASN.1 BER syntax notation. Despite the difference in approaches, the HL7 Working Group has regular liaison with the MEDIX committee. The Working Group has devised a format for the HL7 Standard that is relatively independent of the encoding rules chosen and easily translated into the ASN.1 notation. The transactions defined in this manner should be directly transferable to the MEDIX effort, and transaction messages encoded using the HL7 scheme should be translatable to transactions encoded using the BER. This should facilitate the creation of gateways between the HL7 and future environments.

In addition, HL7 and MEDIX have agreed on a course for convergence. This will occur within the HL7 abstract message definitions. MEDIX has further agreed to use the HL7 abstract message definitions as defined in Version 2.1 as a starting point for the MEDIX message definitions.

HL7, IEEE, and X12 are ANSI approved standards developers.

1.8 THE SCOPE OF HL7

It is useful to understand both what HL7 is and what it is not. This chapter, up to this point, represents some effort to give the reader an overall understanding of HL7 by looking at purpose, history, and some of its overall features and architecture. It is also of value to understand the “edges” or limitation of HL7. While HL7 can, and routinely does, provide a considerable service in everyday use today, there are certainly many areas of healthcare system integration that HL7 does not address or addresses with what may prove to be an inadequate or incomplete solution.

Many of these topic areas are being worked on today by HL7 and will, hopefully, appear in latter versions of this balloted Standard. Some others of these topics may never be addressed by HL7 because they are being addressed

by some other standards body. Still other areas may never be addressed by HL7 due to a lack of interest, or at least available energy by its members.

In any case, it is certainly useful for the analyst to understand what these boundaries are and to then either choose to solve them in some other way or to merely ignore them if they are deemed not sufficiently important. The following features listed in this section may well be best served by the participating applications themselves. However, it is possible to conceive of an architecture that expects these features to be present in the messaging standard itself. These potential deficiencies are included to give the reader a complete view.

1.8.1 A complete solution

HL7 is not, in itself, a complete systems integration solution. The issue directly addresses the so-called goal for “plug-and-play.” There are several barriers in today’s healthcare delivery environment that make it difficult, if not impossible, for HL7 to create a complete “plug-and-play” solution. Two of these barriers include: a) the lack of process conformity within healthcare delivery environments and b) the resulting requirement for “negotiation” between users and vendors.

There is little, if any, process conformity within healthcare delivery environments. As a consequence, healthcare information solutions vendors are required to create very flexible systems with a very wide range of data and process flow options. HL7 attempts to address the superset of all known process (i.e., trigger) and data (i.e., segment and field) requirements. In doing this, it has attempted to be “all things to systems and users.”

In fact, there is no one user nor any system that users would elect to use that would use all that HL7 attempts to offer. This “excess” of features typically requires some level of “negotiation” to take place between a user and his/her vendors to come up with the set of triggers and data items necessary to affect the solution for the user. In effect, this creates a unique use of the Standard at that site. The current version of HL7 has no intrinsic way to tailor a pre-determinable view of the Standard for each possible use. Future versions of HL7 will likely address this shortcoming.

A true integrated healthcare information systems solution addresses an integrated database, or at least what appears to be a virtual integrated database. In fact, however, as a practical matter, information solutions still need to be installed and operated in environments where no other, or only a subset of other, systems are available. In any case, all systems today are designed and implemented to process using their own local copies of data.

HL7, to this date, has not attempted to prescribe the architecture, functionality, data elements or data organization of healthcare applications. Rather, HL7 has attempted to accommodate all application requirements that have been brought to its attention by volunteers willing and able to address them.

Future versions of HL7 may choose to alter HL7’s historic approach to these issues. Recent efforts by HL7 and other ANSI Standards Developers to produce Data Meta Models have created a framework that both standards and applications developers can use as a common basis for defining and using both data and data organizations. Widespread acceptance of these concepts may allow HL7 and other Standards Groups to be more prescriptive in their approach with a smaller set of choices that must be made when interfaces are implemented.

For now, however, users should be aware that HL7 provides a common framework for implementing interfaces between disparate vendors. In all cases, if an existing application interface is not available, HL7 reduces (but does not eliminate) the time and cost required to implement an application interface between two or more healthcare information systems. If a user chooses to implement a set of homogeneous solutions from a single vendor, HL7 is typically not necessary nor even applicable.

1.8.2 Protection of healthcare information

HL7 Version 2.4 is largely silent about the issues of privacy authentication and confidentiality of data that pass through HL7 messages. HL7 makes no assumption about the ultimate use of data but rather assumes that both source and destination applications provide for these requirements. In addition, HL7 does not, at this time, specifically specify what, if any, encryption method should be used when transporting HL7 - based messages between two or more systems. At this time, HL7 users should familiarize themselves with legal and professional requirements for these topics.

1.8.3 Department of Defense (DOD) requirements for systems security and robustness

HL7 Version 2.4 does not attempt to support DOD Security Divisions (A, B, C, D) and Classes (1, 2, 3). If a user requires these features, they will have to define their own structures to support these classifications and insure a uniform implementation across multiple systems in an enterprise.

1.8.4 Enforcement of organizational security and access control policies

HL7 Version 2.4, itself, does not provide for the enforcement of a provider organization's security and access control policies. There are no messages specifically defined, at this time, that affect the movement of data based on an organization's security and access control policies in conjunction with message content information that identifies the users of the message data and the organization's policies for that user's authorization to access that data. Systems implementors may want to reference relevant ASTM standards and IOM recommendations on this topic.

1.8.5 Security classifications (markings) and users authentication and identification

HL7 Version 2.4 does not, at this time, attempt to address DOD requirement for marking or access control labels that are associated with data objects. This particular method might be one way of supporting both IOM and JCAHO recommendations for providing different levels of data confidentiality and authentication of both producers and consumers of confidential data.

1.8.6 Roles and relationships

HL7 Version 2.4 does not, in itself, attempt to define or even support the implicit and explicit relationships between persons such as patients, physicians, providers, etc. It is possible that current data modeling efforts by HL7 and other standards developers will, in the future, result in HL7 assuming this responsibility.

1.8.7 Accountability, audit trails and assigned responsibility

HL7 Version 2.4 does not attempt to define typical transaction processing features such as audit trails. A feature such as an audit trail may well be needed to successfully implement both a robust and security auditable environment. This feature could also support verifying that a given action is performed by individuals who are also responsible. A user may decide that these features are necessary in their integrated environment.

1.8.8 Central, unified hardware, software controls for security and trusted continuous protection

HL7 Version 2.4 does not attempt to support hardware and software security controls, nor does it provide means to insure continuous protection of data from unauthorized changes. Such a feature may be useful in limiting access to certain types of data to devices and/or users, based on device type or location. Certain DOD requirements and IOM recommendations may require users to implement these on their own and/or rely on specific applications vendors to support this requirement.

1.8.9 Uniform data definition and data architecture

HL7 Version 2.4 does not include an explicit data model or composite data dictionary. However, extensive work has taken place within the HL7 Working Group to produce a data model for Versions 2.2 and 2.3. While these models have not been formally balloted, they are available on the HL7 web server. Future versions of HL7 may also include a balloted data model and composite data dictionary.

1.8.10 Controlled disclosure, notification of disclosed information as protected and tracking exceptions of protected health information

HL7 Version 2.4 is silent on supporting the controlled disclosure of protected health information where HL7 is the vehicle of the disclosure across multiple systems in a healthcare delivery system. It is also silent on messages that notify a user that requested information is protected and messages to track allowed exceptions that may take place at the discretion of potentially, but not certified, authorized users (e.g., a physician in the emergency room).

1.8.11 Tracking of corrections, amendments or refusals to correct or amend protected health information

HL7 Version 2.4 does not provide messages to support the tracking of corrections, amendments or refusals to correct or amend protected health information. These messages would support the process to verify, challenge and ultimately correct inaccuracies discovered in protected health information. Users needing such messages may need to define custom messages to support this requirement.

1.8.12 Disclosure of disidentified health information

HL7 Version 2.4 does not have specific messages to disclose “disidentified” health information. Disidentified data is data that does not reveal the identity of the person or care provider(s) (either organizations or individual licensed practitioners or both). While it may be possible to support this need with existing HL7 messages, it would create an unexpected message with missing required patient identification.

1.8.13 Ensuring and tracking data source authentication and non-alterability

While HL7 Version 2.4 does support an electronic signature for chart completion transactions, it does not, in general, support an electronic signature that is also tied to relevant applications to insure the authentication of the source or arbitrary health data and a prohibition against the alteration of data that has been electronically signed.

1.8.14 Tracking input validation

HL7 Version 2.4 does not provide messages for tracking the validation (or lack of validation) of data from its source (human or machine).

1.8.15 The longitudinal health record

HL7 Version 2.4, itself, is silent on the actual logical and physical construction of the patient longitudinal health record. While it is certainly possible to build the currently-identified major components of such a record using existing HL7 messages, there is no formal attempt on the part of HL7 to define just what the exact message sequence and content should be to describe this record. Other organizations such as ASTM, CPRI and the IOM have published on this subject. It is not the intent of HL7, at this time, to formally define message sequences and structures to directly create the longitudinal health record across multiple information systems within (or outside of) a healthcare delivery system.

1.8.16 Integration of the health record

HL7 Version 2.4 is silent on messages to support the integration of a patient's health record across multiple delivery entities (or outside of) a healthcare delivery system. This would also include messages to insure central control and integrity of information that was "merged" between multiple delivery entities.

1.8.17 Data, clock synchrony

While HL7 Version 2.4 makes significant use of time and date stamped data, it does not support a set of transactions to insure that synchronization of the electronic clocks with the various computer systems of the enterprise's heterogeneous computing environment.

1.8.18 Intersystem database record locking and transaction processing

HL7 Version 2.4 makes no attempt to provide messages that could support the coordination of database activities across multiple information systems in a heterogeneous computing environment. Users who want to operate their multiple systems as a distributed database environment must provide their own message support or rely on a database vendor's facilities (e.g., Oracle, Sybase, etc.).

1.8.19 Operations, process and other "local" support

As stated in Section 1.8.2, "Protection of healthcare information," above, process and operations variations are a primary barrier to HL7 providing a complete solution. Serious attempts are being made to give HL7 the ability to support operations and process variability in a future revision. At this time, however, (Version 2.4), operations and process variability is a major reason why HL7 is implemented in a slightly different form at each and every site. This includes issues such as business and clinical practice rules, clinical and operation processes, staging and continuity of process steps, protocols, resource/utilization requirements, quality assurance requirements, cost management, comprehensive master file and code tables, etc.

1.8.20 Interface engines

The so-called Interface Engine has grown into a popular implementation and operation tool for HL7 and other message-based interfaces over the last several years. Interface engines, per se, however, are not an a priori consideration in the design of HL7. HL7 makes no assumption about the existence of an Interface Engine at a particular HL7 site. Hence, there also are no defined HL7 messages to directly communicate with and control the operations of Interface Engines. This might be of particular use when the Interface Engine assumes an applications architecture role as a dynamic filter and arbitrator of information based on dynamic rules defined by delivery systems.

1.8.21 Rules engines

As a close practical application of an Interface Engine in the topology of healthcare interfaces, rules engines are becoming increasingly popular. HL7 does not have, at this time, specific messages to define and control the rules that might be dynamically associated with an Interface Engine. This might include, but is not limited to: Create and modify patient therapeutic or diagnostic protocols; Activate clinical or operational processes (e.g., conditional orders, critical paths, etc.); Cancel or hold active clinical processes; Notify appropriate users of a state or condition.

1.8.22 Infrastructure based applications

A number of applications and information delivery methods exist within the healthcare delivery environment that can be closely identified with the “infrastructure” that ties together disparate systems. These applications include, but are not limited to:

- Robust and Integrated Scheduling
- Point of Service Support
- Prompts Alerts and Reminders
- Concurrent Data Surveillance, Metrics and Analysis
- Concurrent Decision Support
- Outcome Tracking
- Tracking of Patient (i.e., customer) Expectation and Satisfaction
- Problem Lists

These, and probably others, could be well served by the use of healthcare data during and very close to the action of transferring information between healthcare information systems. HL7, at this time, has very little or no message functionality that directly supports these uses of healthcare data.

1.8.23 Support for secondary clinical records

HL7 Version 2.4 does not provide specific messages to support partial replication (i.e., extraction and subsequent merger) of a patient’s demographic and clinical records. This process has been identified by the IOM, JCAHO and others as an emerging requirement for the maintenance and practical use of an electronic health record system. HL7 may provide more explicit support for this concept in the future as organizations such as ASTM and CPRI develop specific definitions and requirements for this functional activity and healthcare vendors start to include this type of functionality within their individual clinical record solutions offerings.

1.9 REFERENCE DOCUMENTS

1.9.1 ANSI standards¹

ANSI X3.30	1985 Representation for calendar date and ordinal date
ANSI X3.4	1986 Coded character sets - American National Standard code for information interchange (7-bit ASCII)
ANSI X3.43	1986 Information systems representation of local time of day for information interchange
ANSI X3.50	1986 Representations for U.S. customary, SI, and other units to be used in systems with limited character sets
ANSI X3.51	1986 Representations of universal time, local time differentials, and United States time zone references for information interchange

1.9.2 ISO standards²

ISO 5218	1977 Information Interchange-Representation of Human Sexes
ISO 1000	1981 SI Units and Recommendations for the use of their multiples and of certain other units
ISO 2955	1983 Information processing-Representation of SI and other units in systems with limited character sets
ISO 8072	1986 Network Standards
ISO 8601	1988 Data elements and interchange formats - information interchange (representation of dates and times)
ISO 8859	1988 Information Processing- 8-bit single-byte coded graphic character sets
ISO 8859/1	1988 Information Processing-Latin Alphabet No. 1
ISO 8859/2	1988 Information Processing-Latin Alphabet No. 2

¹ Available from American National Standards Institute, 11 West 42nd Street, New York, NY 10036

² Available from ISO 1 Rue de Varembe, Case Postale 56, CH 1211, Geneva, Switzerland

ISO 8859/3	1988 Information Processing-Latin Alphabet No. 3
ISO 8859/4	1988 Information Processing-Latin Alphabet No. 4
ISO 8859/5	1988 Information Processing-Latin/Cyrillic Alphabet
ISO 8859/6	1988 Information Processing-Latin/Arabic Alphabet
ISO 8859/7	1988 Information Processing-Latin/Greek Alphabet
ISO 8859/8	1988 Information Processing-Latin/Hebrew Alphabet
ISO 8859/9	1988 Information Processing-Latin Alphabet No. 5
JAS2020	A subset of ISO2020 used for most Kanji transmissions
JIS X 0202	ISO 2022 with escape sequences for Kanji

1.9.3 Codes and terminology sources

ACR	Index for Radiological Diagnosis, Revised 3rd Edition
CPT4	Current Procedural Terminology ³
CAS	USAN 1990 and the USP dictionary of drug names ⁴
EUCLIDES	European standard for clinical laboratory data exchange ⁵
Home Health	Home Healthcare Classification System (Virginia Saba, EdD, RN, Georgetown U. School of Nursing, Washington DC)
HIBCC	Standard for electronic business data interchange
ICCS	Commission on Professional and Hospital Activities

³ Available from American Medical Association, P O Box 10946, Chicago, IL 60610

⁴ William M. Heller, Ph.D., Executive Editor. Available from United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

⁵ Available from G. De Moor, M.D., Dept. of Medical Informatics 5K3, State University Hospital Gent, De Pintelaan 185, B 9000 GENT, BELGIUM

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ICD-9	International Classification of Diseases, 9th Revision
ICD9-CM	International Classification of Diseases, Clinical Modification Manual of Clinical Microbiology ⁶
NANDA	North American Nursing Diagnosis Association, Philadelphia PA
NDC	National drug codes ⁷
NIC	Nursing Interventions Classification, Iowa Intervention Project. U. of Iowa
NLM	Unified Medical Language ⁸
Omaha System	Omaha Visiting Nurse Association, Omaha NE
Read	Clinical Classification of Medicine ⁹
SNOMED III	Systemized Nomenclature of Medicine ¹⁰
WHO	Drug Codes ¹¹
UMDNS	Universal Medical Device Nomenclature System ¹²
FDA K10	Device Codes Device and analyte process codes ¹³
LOINC	Laboratory Object Identifier and Numerical Code

⁶ Available from American Society for Microbiology, 1913 Eye St., NW, Washington, D.C. 20006.

⁷ Available from the National Drug Code Directory, FDA, Rockville, MD, and other sources

⁸ Available from National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894

⁹ Available from James D. Read, MB, ChB, DRCOG, MRCGP, General Medical Practitioner, Park View Surgery, 26-28 Leicester Rd., Loughborough, Leicestershire LE11 2AG.

¹⁰ Available from American College of Pathology, Skokie, IL

¹¹ Available from INTDIS, P O Box 26, S-751 03 Uppsala, Sweden

¹² Available from ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462

¹³ Available from Dept. of Health & Human Services, FDA, Rockville, MD 20857

1.9.4 Other applicable documents

ASTM E31.12 Draft Dec 1990 - A Standard Specification for Representing Clinical Laboratory Test and Analyte Names *Draft*¹⁴

ASTM E1467-91 Standard Specification for Transferring Digital Neurophysiological Data Between Independent Computer Systems¹⁵

ASTM E1394 A Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems¹⁶

ASTM E1381 Standard Specification for the Low-level Protocol to Transfer Messages between Clinical Instruments and Computer Systems¹⁷

McDonald CJ, Hammond WE: Standard formats for electronic transfer of clinical data. *Annals of Internal Medicine* 1989; 110(5):333-335.

International Union of Pure and Applied Chemistry/International Federation of Clinical Chemistry. *The Silver Book: Compendium of terminology and nomenclature of properties in clinical laboratory sciences.* Oxford: Blackwell Scientific Publishers, 1995.

LOINC Committee. Logical Observation Identifier Names and Codes. Indianapolis: Regenstrief Institute and LOINC Committee, 1995. c/o Kathy Hutchins, 1001 West 10th Street RG-5, Indianapolis, IN 46202. 317-630-7433. Available via FTP/Gopher ([dumccss.mc.duke.edu/standards/HL7/termcode/loinclub](ftp://dumccss.mc.duke.edu/standards/HL7/termcode/loinclub)) and the World Wide Web (<http://dumccss.mc.duke.edu/standards/HL7/termcode/loinclub/>)

Forrey AF, McDonald CJ, DeMoor G, Huff SM, Leavelle D, Leleand D et al. Logical Observation Identifier Names and Codes (LOINC) database, A public use set of codes and names for electronic reporting of clinical laboratory test results. *Clin Chem* 1996; 42:81-90.

UB-92 National Uniform Billing Data Element Specifications as developed by the National Uniform Billing Committee, November 5, 1997. National Uniform Billing Data Element Specifications as adopted by the Florida State Health Claims Review Committee, 2nd Revision, December 19, 1993.

UB-82 Recommended Billing Instructions.

¹⁴ Available from Arden Forrey, Ph.D., 4916 Purdue Ave., NE, Seattle, WA 98105

¹⁵ Available from American Society for Testing and Materials (ASTM) 1916 Race St., Philadelphia, PA 19103-1187.

¹⁶ Available from American Society for Testing and Materials (ASTM) 1916 Race St., Philadelphia, PA 19103-1187

¹⁷ Available from American Society for Testing and Materials (ASTM) 1916 Race St., Philadelphia, PA 19103-1187

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1.11 SUGGESTIONS AND COMMENTS

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