A Development of HL7 Middleware for Medical Device Communication

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Abstract

An efficient middleware has been developed to support medical device communication. HL7 is known to be best international standard to facilitate clinical device data transfer to information systems in hospital. In this study, we developed a middleware with capability of receiving data from mCare 300 Vital signs monitoring device and converting to HL7 data type format.

1. Introduction

Continuous patient care requires increasingly voluminous amounts of electronic data. Patient information includes administrative data, therapeutic and diagnostic data, and is superimposed with complex data such as electrocardiogram (ECG). In hospital environment, it is necessary to extract and gather heterogeneous data from distributed information systems. In addition, patient care also requires including point-of-care (POC) information from medical devices. Thus, clinical data integration becomes a critical solution to collect, store and manage high quality data for clinical studies and researches. Because of gathering medical data being well suited for medical research, it should acquire not only numeric and/or textual data (administrative data, pharmaceutical data), but also complex data intermixed with encrypted structure given by commercial purposes.

Most POC devices such as physiological monitors are microcomputer based. POC device is designed to support standardized display as a standalone unit to adapt various industrial specifications. However, the absence of standards for medical device communications greatly stymied the acceptance and automated clinical data management. To overcome such hindrances, Institute of Electrical and Electronic Engineers (IEEE) developed Medical Information Bus (MIB) standards and 1073 committee was established. Automated data capture directly from medical device is now possible using IEEE 1073 communications standard [1-3].

The OpenECG network was created in 2002 when the need for universal standard to reduce medical errors, support cost containment, and promote interoperability [4-6]. However, standards alone do not guarantee interoperability. First, standardization efforts barely keep up with the innovation driven by medical device industry. Secondly, implementing standards is costly and time consuming. Finally, testing conformance to interoperability standards frequently involves diverse software components from different medical device manufactures, and information system integrators.

Nowadays, critical patient data is often interspersed in multiple data storage systems. Data can even reside in different systems from different vendors, and these systems also employ different versions. A healthcare delivery organization is to achieve a unified view of patient information despite these variances. In this regard, HL7 is highly recommended for organizations that seek interoperability between internal systems and external data from public healthcare agencies. HL7 messaging standard will improve quality, efficiency and effectiveness of healthcare delivery and sharing medical information [7-9]. The Integrating Health Enterprise initiative (IHE) proposed an implementation framework so called integration profiles in healthcare enterprises. An integration profile leverages health informatics standards to facilitate integration of heterogeneous system in clinical workflows. The use of specific standards is documented in an integration statement that declares the capability of specific product to support an IHE integration profile. For example, the IHE Cardiology technical framework (IHE Card-TF) defines*: "specific implementations of established standards to achieve integration in cardiology"* [10, 11].

Because many vendors manufacture different medical devices, and most medical devices are designed respective commercial specifications, thus resulting in unstandardized data format. To integrate various forms of data efficiently, developing a

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middleware is indispensable step for facilitating medical information transfer to electronic medical record (EMR) system in HIS. Clinicians are anxious to include bio-signal such as ECG to accomplish functional goals of EMR. The aim of this study is to develop middleware which can connect to commercial monitoring devices in order to transmit ECG signal and vital signs together with patient demographics. Then data packets from monitoring devices are parsed to extract HL7 compatible data. We have developed a middleware that consist of a set of library functions to support data transmission from medical devices to arbitrary information systems.

2. Materials and Methods

2.1. mCare 300 Monitoring Device

Spacelabs Healthcare mCare 300 patient monitoring device is selected for implementing middleware. The monitoring device generates four kinds of data– numeric (e.g., heart rate), system parameters, alarm status, waveform (e.g., ECG), and the device is configured as a server for middleware implementation. Port number 1472 is used to transmit data in real-time from the device externally to authorized information system. Data transmission is accomplished in packet of 29 bytes, which is described in Table 1.

In Table 1, the key and data layer parts indicate what kind of raw data and data. For example, the key is 0x01 which means the output data is waveform data. And the waveform data are store in 24 bytes within data layer part according to commercial specifications.

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Table 1. Packet transmission structure.

Field Name	Description	Field length
Sync	0x55	1byte
Key	Define data layer	1byte
Data Layer	Raw data in decimal number	24byte
CRC	0x18	1byte
CNT	0~255	1byte
Ext	0xFF	1byte

Within 250Hz sampling frequency, the mCare 300 provides 125 waveform data packets, and 20 status packets per second. Moreover, the device also provides waveform data of lead I, lead II, lead III, lead V, SpO2, Respiration, IBP wave, and CO2 wave [12, 13].

2.2. System architecture

The middleware can connect to medical devices through LAN interface. For interoperability of various medical data, middleware receives raw data from medical device, converts to HL7 data, and creates unsolicited observation message ORU^R01 in order to send message to HIS based on HL7 interface engine (Figure 1). Because HIS consists of various clinical subsystems, integrating data is necessary in order to improve patient services, optimize resource management, and support decision-making [7-9]. In Figure 1, middleware components collect raw data from medical devices, convert raw data according to HL7 standard. Then, middleware components send HL7 messages to HIS.

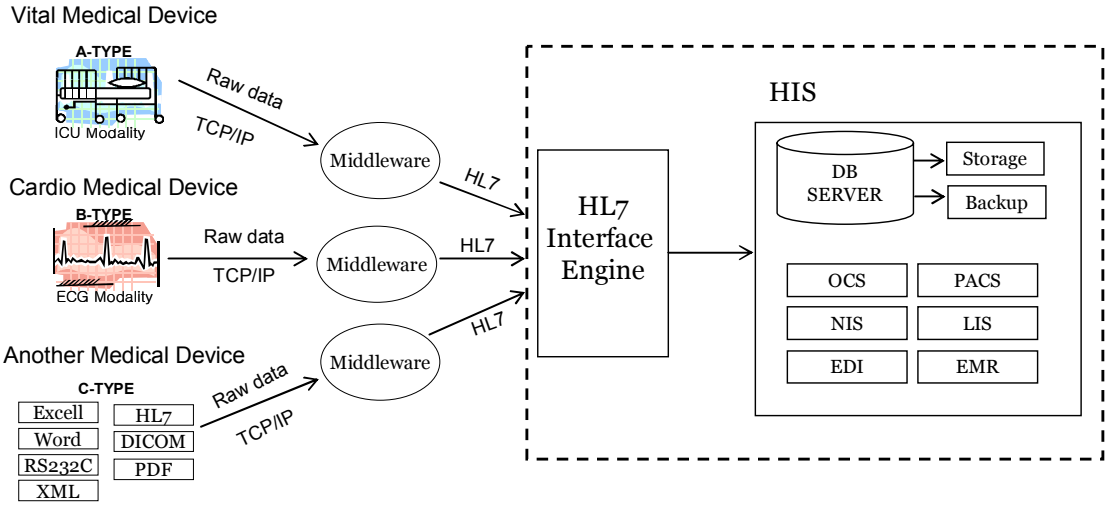

Figure 1. System architecture.

2.3. HL7 standard

Health Level 7 (HL7) is designed to support communication requirements frequently needed especially in clinical settings. HL7 follows the conceptual definition of application interface model in the seventh layer of the OSI. The purpose of HL7 is not to provide a networking solution but to support "plug-and-play" functionality when integrating two or more computer systems into a unified hospital information system. HL7 also allows the use of trigger event at several different levels of data. The trigger event is real-word event. For example, an observation of patient (e.g., ECG waveform data is available, may cause the requirement for that observation data to be sent to another information systems. When mCare300 is ready to dispatch, a set of 125 waveform data packets is turned into a HL7 compliant transaction set required for sending structured clinical data from one computer system to another. A common use of these transaction sets will be to transmit observations and results of diagnostic studies from the producing system (e.g., clinical laboratory system) to the ordering system (e.g., HIS order entry). Observations can be sent from producing systems to clinical information systems and from such systems to other systems that were not part of the ordering loop, e.g., an office practice system of the referring physician for inpatient test results ordered by an inpatient surgeon. HL7 also provides mechanisms for registering clinical trials and methods for linking orders and results to clinical trials and for reporting experiences with medical devices [14]. The transaction sets permit the transmission of clinical observations including (but not limited to) clinical laboratory results, measures of patient status and condition, vital signs, intake and output, severity and/or frequency of symptoms.

There are two modes to transmit observation data.

- In the solicited mode, a user requests a set of observations according to criteria transmitted by the user. The sending system responds with existing data to satisfy the query (subject to access controls). Queries do not elicit new observations by the target system, they simply retrieve old observations.
- The unsolicited mode is used primarily to transmit the values of new observations. It is the mode used by producing services to return the values of observations requested by an ordering system. A laboratory system, for example, would usually send the results of an AM electrolytes to the ordering HIS via the unsolicited mode.

Consequently, we used Unsolicited Observation Message within trigger even R01 (ORU^R01) to transmit ECG raw data. The ORU^R01 message consists of:

- The OBX segment which is defined an observation segment. OBX is used to transmit one or more observation results.
- The OBR segment serves as report header in the clinical report.
- The PID segment includes patient information such as patient name, patient ID, etc.
- An order record (OBR) at the next level with one or more observation records (OBX), followed by the specimen information (SPM) and one or more observations (OBX) directly associated with the specimen.

Table 2. Unsolicited Observation message structure.

ORU^R01	Unsolicited Observation Message
MSH	Message Header
[{SFT}]	Software Segment
{	PATIENT_RESULT begin
[	PATIENT begin
PID	Patient Identification
[PD1]	Additional Demographics
[{NTE}]	Notes and Comments
[{NK1}]	Next of kin/Associated Parties
[	VISIT begin
PV1	Patient visit
[PV2]	Patient visit – Additional Information
]	VISIT end
]	PATIENT end
{	ORDER_OBSERVATION begin
[ORC]	Order Common
OBR	Observations request
[{NTE}]	Notes and comments
[{	TIMING_QTY begin
TQ1	Timing/Quantity
[{TQ2}]	Timing/Quantity Order sequence
}]	TIMING_QTY end
[CTD]	Contact data
[{	OBSERVATION begin
OBX	Observation related to OBR
[{NTE}]	Notes and comments
}]	OBSERVATION end
[{FT1}]	Financial Transaction
[{CTI}]	Clinical Trial Identification
[{	SPECIMEN begin
SPM	Specimen
[{OBX}]	Observation related to Specimen
}]	SPECIMEN end
}	ORDER_OBSERVATION end
}	PATIENT_RESULT end
[DSC]	Continuation Pointer

HL7 compliant waveforms consist of an OBX triplet for each of 12 ECG channels for both median and rhythm data on each channel. The three OBX

segments include timing, channel definition, and waveform data [14].

Table 3. OBX-3-Observation identifier.

Observation	Suffix	Data Type
Timing information	TIM	TS
Channel Definition	CHN	CD
Waveform Data	WAV	NA or MA
Waveform annotation	ANO	CE

In Table 3, each waveform channel in recording contains timing, channel definition and digital series data. The category of waveform result transmitted in a given OBX segment is determined by the Observation ID suffixes.

A waveform result contains 12 channels of digital waveform data. The Observation Sub-ID is used to logically associate the TIM, CHN and WAV category OBX segments which pertain to a given channel in the result. Each Observation Sub-ID group must contain one TIM, one CHN and one WAV category segment. The TIM category result segment must precede the WAV category result segment in that group (Table 4 through Table 7 in Appendix). According to HL7 messaging control specifications, we have developed HL7 library for middleware using Visual C++. In this library, we used parsing algorithm and validate before constructing HL7 messages [14 - 17].

3. Results

3.1. HL7 middleware

The middleware is composed of two parts: converting and creating HL7 message components.

The converting component connects to a medical device through TCP/IP as client. This component receives binary data from the device, selects waveform data according to commercial specifications, and then converts waveform data into an array of numbers. After converting, the array of numbers is transferred to create HL7 message component.

When the created HL7 message component receives the number array, the component initiates numeric array data type (HL7 specific data type for waveform data). Eventually, ORU^R01 message object is invoked to handle data such as date time, data type and actual data of waveform (Figure 2).

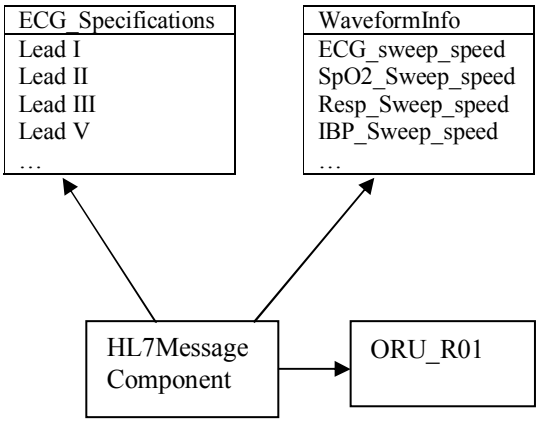

Figure 2. The create HL7 message component.

In Figure 2, creating HL7 message component contains two objects that are called ECG_Specifications and WaveformInfo objects. Objects can handle waveform data and waveform parameters from monitoring device. In addition, the HL7 message component refers to HL7 messages package to get ORU_R01 message structure, and then gives ORU_R01 as output message.

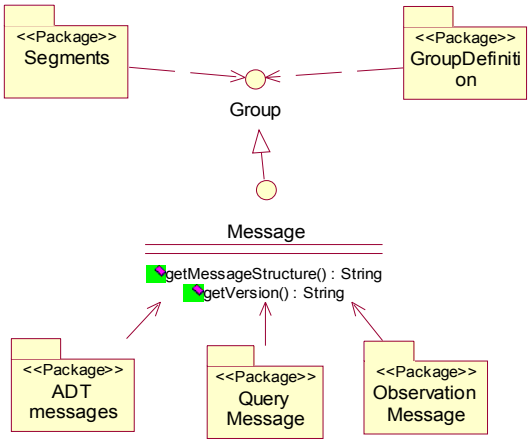

Figure 3. The HL7 message structure

In the HL7 middleware library we have developed 62 ADT messages including 7 Query messages and 10 Observation messages. Those message objects will be used to create HL7 messages for patient administration, query, and patient observation results (Figure 3 and Figure 4, respectively). Figure 3 presents HL7 message structure. An object name "Group" interface defines HL7 group structure that is an array or a list of segments. Another object name "Message" interface defines HL7 message structure in a manner similar to "Group" object. HL7 segment is an array of

data types (Type interface defines HL7 data type). Additionally, type contains two types of data type such as Primitive data type and Composite data type. Composite data type is group of primitive data type. In HL7 standard, primitive data type is smallest object that handles information.

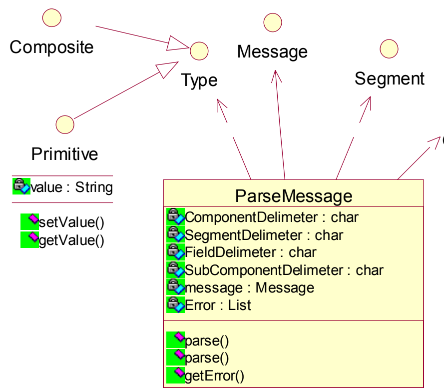

Figure 4. The mechanism of parsing and validating HL7 message.

3.2. Transaction between middleware and medical device

The HL7 messaging middleware is designed to facilitate communication from POC devices to arbitrary information system. When the connection is ready, mCare 300 device starts transmitting waveform data packet, data status, and so on to client using port 1472.

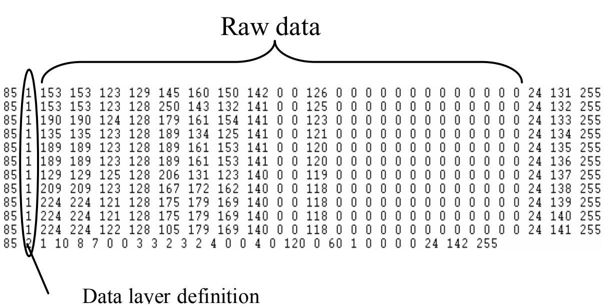

Figure 5. The received data packet displayed in decimal.

In Figure 5, the middleware can recognize if waveform data exist or other relevant information follows such as data layer definition key.

The middleware receives transmitted packet from mCare 300 device, and parses out to store the packet into data objects according to the proprietary specifications defined by mCare 300. During every interval per second, the middleware receives 125 waveform data packets and 20 status data packets.

The HL7 message component has createOBX object that allows system to create OBX segment within waveform data. Similarly, createORU object also allows to create unsolicited message ORU^R01 and sends to other information systems.

We have tested the middleware for converting waveform data and creating HL7 unsolicited message ORU^R01. In Figure 6, the HL7 message is ORU and trigger event R01 with HL7 version 2.5. The message will be sent to the other information systems through HL7 Interface Engine. The Patient ID is 34003200, and patient name Mr.John Q Doe, Jr. The channel category result defines data channel by number and specify a label (waveform source) for each channel. The channel sensitivity for ECG is given 1mV, and sampling frequency is 250Hz.

The waveform category result may be transmitted in either "channel-block" (unmultiplexed) format using numeric array data type. In this experiment we used numeric array data type with 20 samples.

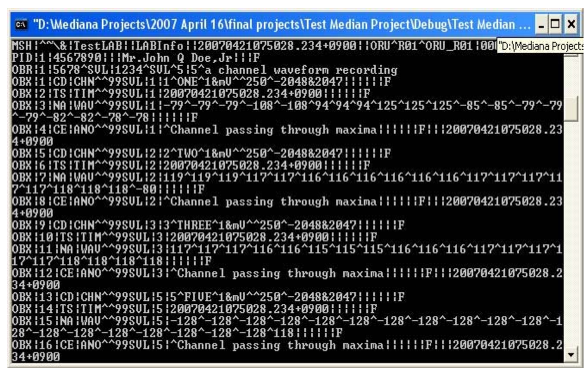

Figure 6. HL7 message generated via middleware.

In order to transfer data from one to another information system, the middleware selects data from data object, converts and makes an unsolicited message according to HL7 standard (Figure 6).

4. Discussion

Hospital information systems these days are increasingly heterogeneous in nature. Systems are implemented using disparate databases, different communication protocols, and various data standards. Hospital information systems are also used to meet various clinical requirements with different levels of expertise. As a result, interoperability among a variety of information needs manifests interesting challenges. Once the interoperability problem is solved, the

development of standardizing vital signs (ECG waveform data, SpO2 waveform data, etc.) greatly simplified to make corresponding HL7 messages.

In a typical intensive care unit (ICU), a patient may be connected to one or more vital-sign monitors, multiple infusion pumps and a ventilator. Each of medical devices has the ability to capture volumes of data, available multiple times per second, on a per patient basis. Today, medical devices are implemented as case-by-case applications, communicating only with the monitor to which it is connected, with no plug-and-play interoperability. The IEEE 1073 Medical Device Communication Working Group defines a set of standards to enable medical device communication. (ISO 11073 is identical standard with IEEE 1073.) The standards will enable acute and continuing care devices to interoperate and electronically capture and process their data to optimize healthcare delivery and improve patient safety and clinical efficacy. To address this critical need, the IEEE 1073 Working Group is developing extended standards for medical device communications and the Integrated Health Enterprise (IHE) Patient Care Devices (PCD) Domain is developing a framework for the integration of medical device related information into EMR. In other words, IHE Patient Care Devices Domain suggested integrated profiles using HL7 standards (HL7 messages version 2.x, and version 3.0) for exchanging clinical information among information systems. The result of these efforts will provide clinicians with the ability to easily link patient connected medical devices to a single monitoring device or a computer network, thus facilitating the efficient exchange of medical device and vital signs data throughout the healthcare enterprise.

In this approach, the interoperability is achieved by physically transferring the information through electronic media such as floppy disks or magnetic tapes. In this case, middleware provides health care professionals access to real-time and stored physiological data from most healthcare networking. In our middleware package, this mode of interoperability means that data (in a known format) has to be transferred from one system to another by HL7 messages. However, the focus is only on the content and structure of information exchange that are implemented with available vital signs monitoring device (Spacelabs Healthcare mCare300). Using HL7 standard is necessary for interoperability. Typically, this type of interoperability requires the use of the same type of data formats, but the medical devices are manufactured by different data specifications. As a result, the interoperability is significantly limited.

Thus, middleware can provide health care professionals access to real-time and stored physiological data from any network connection. All vital sign data can be stored and retrieved to and from EMR. In addition, the physiological monitoring and assessment software allows for real-time collection, storage, transmission, surveillance, and management of vital sign data from supported medical devices. Vital sign and patient data is made available on any workstation connected to the network or Internet allowing health care providers at the point of care to receive supplementary medical services from health care professionals located off-site.

This study offers features for digital recording and interpretation and the possibility to transfer a digitally stored ECG to hospital information system within mCare 300 Vital Signs Monitoring device. However, current LIS are interfaced to a variety of automated instruments, allowing LIS to receive numerical test results in the real time sent by instruments for reviewing, collection. Often those instruments are typically connected to a concentrator functioning as an intelligent controller to monitor in real time the signals from multiple instruments, consolidate and pre-process data where needed and forward the data to the laboratory and hospital information system. Therefore, we are going to add more functions that can interpret the other medical devices and then implement to embedded system in the near future.

5. Conclusion

We have developed and implemented HL7 compliant middleware. The preliminary results are found to be satisfactory and encouraging. A given set of proprietary data formats are successfully converted into interoperable standard using HL7, which can be transmitted to any information systems in general. We will continue this experiment in order to accomplish a general-purpose interfacing facilitator to deal with many different kinds of patient care devices to appear from medical industry. We hope that the middleware library package will be evolved to become an embedded software that can be used in ubiquitous healthcare devices such as wearable vital signs monitor.

Appendix

Table 4. TIM HL7 Attribute.

SEQ	LEN	DT	OPT	ELEMENT NAME	Source
1	4	SI	O	Set-ID OBX	HL7 Segment ID
2	2	ID	R	Value Type	Constant "TS"
3	250	CE	R	Observation Identifier	Component 1 "93000&TIM" Component 3 "CPT4"
4	20	ST	R	Observation Sub-ID	Channel number 1, 2, etc
5	26	TS	R	Observation Value	HL7DATETIME-Standard
11	1	ID	R	Observation Status	REPORTSTATUS-Standard

Table 5. CHN HL7 Attribute.

SEQ	LEN	DT	OPT	ELEMENT NAME	Source
1	4	SI	O	Set-ID OBX	HL7 Segment ID
2	2	ID	R	Value Type	Constant "CD"
3	250	CE	R	Observation Identifier	Component 1 "93000&CHN" Component 3 "CPT4"
4	20	ST	R	Observation Sub-ID	Channel number 1, 2, etc
5	65536	CD	R	Observation Value	
11	1	ID	R	Observation Status	REPORTSTATUS-Standard

Table 6. CD – Channel definition.

Component	Sub-Component	DT	ELEMENT NAME	Source
1		CM	Channel Identifier	
1	1	NM	Channel Number	Channel number 1, 2, etc
	2	ST	Channel Name	Channel number 1, 2, etc
2		CM	Waveform Source	
	1	ST	Source name 1	Lead name (I, II, etc)
3		CM	Channel sensitivity/units	HL7WAVECHNSENSITIVITY
	1	NM	Channel sensitivity	
		ST	Unit of measure identifier	
5		NM	Channel Sampling frequency	WAVESAMPLERATEBASE
6		CM	Minimum/maximum Data values	
	1	NM	Minimum data value	HL7WAVEMINVALUE
	2	NM	Maximum data value	HL7WAVEMAXVALUE

Table 7. WAV HL7 Attributes.

SEQ	LEN	DT	OPT	ELEMENT NAME	Source
1	4	SI	O	Set-ID OBX	HL7 Segment ID
2	2	ID	R	Value Type	Constant "NA"
3	250	CE	R	Observation Identifier	Component 1 "93000&WAV" Component 3 "CPT4"
4	20	ST	R	Observation Sub-ID	Channel number 1, 2, etc
5	65536	NA	R	Observation Value	Waveform – HL7RhythmLeadxx where xx is the lead or Waveform – or HL7MedianLeadxx where xx is the lead
11	1	ID	R	Observation Status	REPORTSTATUS - Standard

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