Medical Device Interoperability and Data Integration to Clinical Information Systems

Medical Device Data Alignment

John R. Zaleski, PhD

Aligning and synchronizing data from disparate medical devices can be an impediment to interoperability with electronic medical record systems (EMR). While some medical devices support open standards-based data communication, like Health Level Seven (HL7), many medical devices still do not.

Even when medical devices support open standards, terminology and units of measurement may not be consistent across medical devices. Devices that perform the same function may have different parameters and use different terminology.

While to some this may seem a small issue, each medical device represents a data silo with a unique data model. This model's terms and definitions must be aligned with a common data model to ensure that information derived at the point of care from any medical device, irrespective of vendor, conforms to common definitions employed by the clinical staff.

Healthcare professionals require a unified representation of information to effectively support patient care. This paper discusses the problem of medical device data alignment and its impact on clinical information system (CIS) implementation.

Introduction

Many medical devices produce data using common messaging formats, such as HL7. Many more medical devices communicate using vendor-proprietary formats and syntax. Medical Device Data Systems (MDDS) are chiefly employed to translate data from a proprietary medical device format to one that is standard.

Medical device data often require translation to this common format from their proprietary formats, and then require an alignment to a common vocabulary prior to acceptance within a receiving CIS or electronic medical record system (EMR). For example, mechanical ventilators developed by competing manufacturers can have parameters that differ in definition from one to the other.

The differences can include the omission of fields, the lack of common operating modes, differences in units of measure, and differences in terms of protocols for query and retrieval of data. These differences make it difficult to support plug-and-play usage of different brands unless the appropriate translation is in place that allows for interpreting parameters from one device to the other.

Even when medical devices support open standards, terminology and units of measurement may not be consistent across medical devices.

Medical devices, in effect, become silos whose data are not easily shared or conveyed to the CIS or EMR unless significant translation of terminology is performed. Not unlike the Tower of Babel of Biblical fame, data in silos raise barriers to communication that impede the usability of data even when measured on the same patient. As described by Richards et al.:[1]

"The Babelization of medical data in proprietary formats and silos is the primary barrier to innovation and clinical research ...Each device has

About the Author

John R. Zaleski, PhD, CPHIMS, is chief technical officer and vice president of clinical applications at Nuvon, Inc., Philadelphia, PA. E-mail: jzaleski@nuvon.com

its own unique proprietary communication protocol, unique physical connectors, unique data format, unique terminology and units of measurement for the same parameter, varying frequencies of data output, and clocks on each device that are not set to the same time."

The term "Babelization" is a reference to the biblical account of the Tower of Babel as reported in the Book of Genesis:[2]

"1 The whole world had the same language and the same words.

4 Then they said, "Come, let us build ourselves a city and a tower with its top in the sky..."

6 The LORD came down to see the city and the tower that the people had built.

The Tower of Babel (Pieter Bruegel the Elder, c. 1563), a metaphor for the challenges existing in medical device semantic interoperability today.

7 Then the LORD said: If now, while they are one people and all have the same language, they have started to do this, nothing they presume to do will be out of their reach.

8 Come, let us go down and ... confuse their language, so that no one will understand the speech of another.

9 So the LORD scattered them from there over all the earth, and they stopped building the city.

10 That is why it was called Babel, because there the LORD confused the speech of all the world."

Piecemeal separation of information is anathema to large enterprise interoperability, in which patients need to be transferred around the hospital.

Unified Terminology, Medical Device Time Alignment and MDDS

A recent Healthcare Information and Management Systems Society (HIMSS) *Daily Insider* publication[3] commented on the final U.S. Food and Drug Administration (FDA) ruling on MDDS and the impact on medical device connectivity.

Several key and salient points relate to the FDA's position on the integration of medical device data into EMR systems:

1. Piecemeal integration leads to silos and separation of information. Piecemeal separation of information is anathema to large enterprise interoperability, in which patients need to be transferred around the hospital. This increases the difficulty in sharing patient information as they roam or are moved from department to department.
2. Silos are often unable to deliver real-time patient data reliably to centralized information systems, implying that the absence or lack of data synchronization to ensure the latest time-aligned data may be absent.
3. Vendor-dependent solutions lead to internal battlegrounds. By targeting enterprise-wide solutions that meet the scalable and flexible needs of the institution and allow for expansion and growth, the market would drive towards those solutions that meet the needs with most flexibility. In other words, a process of applied standards and preferential use will help this process greatly.

As hospital systems migrate away from piecemeal, homegrown medical device connectivity implementations and employ commercial, off-the-shelf MDDS, standards become even more important. This is because these commercial systems are intended for use with a wide variety of medical devices, eschewing the proprietary data formats that require time and effort to mold into the required formats of commercial EMR systems.

MDDS that can overcome these proprietary data restrictions help to solve the Babelization problem among multiple disparate medical devices. The Integrating the Healthcare Environment (IHE) initiative has undertaken the effort of creating a terminology mapping for patient care devices (PCDs)[4] through their Rosetta Terminology Mapping (RTM) profile.

An example of terminological data alignment

as applied to mechanical ventilation was published by the IHE's Rosetta Terminology Mapping Ventilator Task Group.[5]

The objective of this effort is to:

"... [harmonize] nomenclature terms and specify the appropriate units-of-measure and enumerated values permitted for each numeric parameter to facilitate safe and interoperable communication between devices and systems."

For example, medical device data from a particular device (say, a mechanical ventilator; Table 1) may report on a parameter such as respiratory rate using the parameter name (also termed "unified code" in some circles) RR. A second medical device, also monitoring the same patient, may report on a similar function using a different parameter definition, fR.

Because these medical devices are autonomous, they are not likely to report the same parameter at the same time interval. Table 2 shows time interval reporting for the two devices from Table 1, Brand X and Brand Y.

The simple example in Tables 1 and 2 illustrates that data originating from multiple devices may not be aligned in parameter terminology (semantics) or in time. To allay confusion and to ensure a common report that will feed the EMR, it is necessary to align these data in the form of a unified output. Such an alignment might appear as shown in Table 3.

Medical Device	Description	Parameter (Unified Code)	Unit of Measure (UOM)
Mechanical Ventilator: Brand X	Respiratory Rate	RR	{breaths} / min
Physiologic Monitor: Brand Y	Respiratory Frequency	fR	{breaths} / min

Table 1. Differing Parameter Definitions in Two Medical Devices

Time	Physiologic Monitor	Mechanical Ventilator	Unit of Measure (UOM)
T0		RR = 20	{breaths} / min
T0 + 30 sec	fR = 15		{breaths} / min
T0 + 60 sec		RR = 18	{breaths} / min
T0 + 90 sec	fR = 17		{breaths} / min
T0 + 120 sec		RR = 20	{breaths} / min

Table 2. Differing Patterns of Parameter Reporting in Two Medical Devices

Data Alignment Recognition Through Meaningful Use

One objective expressed by the U.S. Office of the National Coordinatior for Health Information Technology (ONCHIT) in its Stage 2 Meaningful Use criteria[6,7] is to achieve standardization among data formats in an effort to foster intersystem compatibility, thus facilitating the ease of sharing information across multiple disparate systems.

In order to produce a normalized, uniform and de-conflicted set of outputs, data are aligned so as to ensure proper association with a common set of unified codes that can be processed by the receiving CIS or EMR. In the example described previously using the respiratory rate parameter, separate devices produced the same parameter value but the value was expressed both in different time intervals and in different terminology.

Aligning on common terminology, parameters, and definitions is often identified with the term semantic. The alignment of data elements from different medical devices we will term "semantic interoperability."

A more complex illustration of this occurrence is expressed in the data of Figure 1. In this illustration a subset of parameters from two different devices are listed. Several parameters have syntactical differences but share lexical commonality; while others share the same definition—both in terms of syntax and lexical definition.

Often, different types of medical equipment will produce similar parameters that will differ in how they are expressed semantically and syntactically. At other times, medical devices that perform similar functions will produce parameters that overlap and parameters that are entirely unique to the vendor's brand of medical equipment.

Time	Physiologic Monitor	Mechanical Ventilator	Unit of Measure (UOM)	Common Definition (Semantic Synchronization)	Unified Output
T0		RR = 20	{breaths} / min	Resp Rate	Resp Rate = 20
T0 + 30 sec	fR = 15		{breaths} / min	Resp Rate	Resp Rate = 15
T0 + 60 sec		RR = 18	{breaths} / min	Resp Rate	Resp Rate = 18
T0 + 90 sec	fR = 17		{breaths} / min	Resp Rate	Resp Rate = 17
T0 + 120 sec		RR = 20	{breaths} / min	Resp Rate	Resp Rate = 20

Table 3. Alignment of Medical Devices Brand X and Brand Y

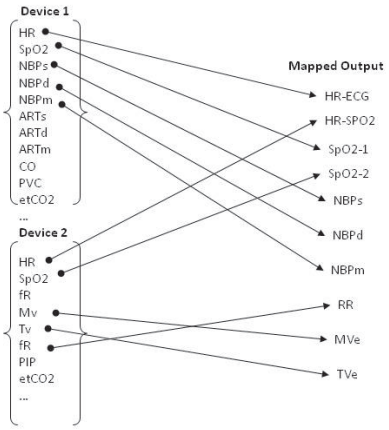

Figure 1. Mapping data from two medical devices that support equivalent functions to a common lexicon for clinical use.

Semantic Interoperability and the Semantic Web

To achieve common data alignment, the use of common parameter naming conventions and common definitions for what a given parameter means is required. The alignment of data architectures through open standards exists in some cases, most notably for physiological monitors.

However, one reason behind the many interoperability problems in healthcare is the number of semantic challenges that limit the interaction among the many disparate data sources and, hence, limit the ability to perform true integration of data.

To achieve common data alignment, the use of common parameter naming conventions and common definitions for what a given parameter means is required.

One possible model for semantic interoperability is the semantic web and the resource description framework (RDF). A seemingly esoteric and highly technical area, semantic interoperability and the semantic web relate to the methods of linking the web of data through a structured and well-defined framework.

The original vision for the semantic web is ascribed to Tim Berners-Lee.[8] For those unfamiliar with the term semantic web, the World Wide Web Consortium (W3C) website[9] is a good primer.

Semantic interoperability includes more than simply aligning the names and definitions of parameters: It also involves establishing a common context in which the use of the term is comparable across systems.[10]

Uschold and Gruninger[11] introduced their definition of the "gold standard" of semantic interoperability back in 2002, stating that "informally, two agents are semantically integrated if they can successfully communicate with each other." The authors defined complete semantic integration as:

"The idea is that agents have never met before. The only access to the meaning of another agent's terms is via the axioms of that agent's ontology. That is, there is no access to what the human agent designer had in mind ... Successful exchange of information means that the agents understand each other and there is guaranteed accuracy."

Furthermore, inconsistencies or misunderstandings in nomenclature can also have an impact on functional understanding. As Chatburn[12] writes:

"Confusion about nomenclature leads to confusion about clinical application, which adversely affects patient care ... on any given day you could walk into an intensive care unit anywhere in the world and observe a patient ... panic stricken and struggling to breathe, even though connected to a state-of-the-art intensive-care ventilator, because some clinician has failed to understand the capability of the machine and has an incomplete or inaccurate paradigm of ventilator mode functionality."

This leads us back to the point that when medical device data are communicated, regardless of device, the parameters must have precisely the same meaning, units of measure, and context. It follows that if medical device data are to be used for management and intervention, then clarity and accuracy of the data in the context intended with a specific patient are essential for patient care management.

Therefore, retrieving data from medical devices for the purpose of patient care management, research, or interventional guidance will require adherence to common terminology, common contexts for data consumption, common reporting characteristics, and common temporal (and time difference) reporting.

In the short-term, MDDS can assist with this problem by providing the mechanism by which the medical devices report according to these common and standardized mechanisms.

Apollo			Aespire 7100 / Aestiva 7900		
Parameter	Description	UOM	Mapped Parameter	Mapped Parameter Description	Mapped Parameter UOM
HAL-CONC	Halothane Concentration	mL	HAL-FLW	Halothane Concentration	mL/hr
ENF-CONC	Enflurane Concentration	mL	ENF-FLW	Enflurane Concentration	mL/hr
ISO-CONC	Isoflurane Concentration	mL	ISO-FLW	Isoflurane Concentration	mL/hr
DES-CONC	Desflurane Concentration	mL	DES-FLW	Desflurane Concentration	mL/hr
SEV-CONC	Sevoflurane Concentration	mL	SEV-FLW	Sevoflurane Concentration	mL/hr
AWP	Airway Pressure	mbar	AWP	Airway Pressure	cmH2O
PPLAT	Plateau Pressure	mbar	PPLAT	Plateau Pressure	cmH2O
PEEP	Positive End-Expiratory Pressure	mbar	PEEP	Positive End-Expiratory Pressure	cmH2O
PIP	Peak Inspiratory Pressure	mbar	PIP	Peak Inspiratory Pressure	cmH2O
TV	Tidal Volume	mL	TV	Tidal Volume	mL
TV-IN	Inspiratory Tidal Volume	mL	TV-IN	Inspiratory Tidal Volume	mL
MV	Minute Volume	L/min	MV	Minute Volume	mL
RR	Respiratory Rate	/min	RR	Respiratory Rate	1/min
CO2-EX	Expiratory CO2	%	CO2-EX	Expiratory CO2	%
O2-EX	Expiratory O2	%	O2-EX	Expiratory O2	%
O2-IN	Inspiratory O2	%	O2-IN	Inspiratory O2	%
SET-TV	Tidal Volume Setting	mL	SET-TV	Tidal Volume Setting	mL

Table 4. Parameter mapping between two different brands of anesthesia machine taken from an implementation of medical device integration at a large, multi-entity hospital system.

Long term, medical devices must be able to join the health information technology environment in a manner similar to electronic medical record systems.

These approaches will, by necessity, require standardized messaging, such as the Integrating the Healthcare Enterprise's (IHE's) patient care device[13] (PCD) transactions; and involve transactions based on simple, more readable representations such as representational state transfer-like (REST)[14] interfaces.

Practical Lessons Learned

What practical impact would common data alignment have? A typical activity undertaken during the process of integrating medical devices in the OR of a hospital with anesthesia information management system (AIMS) is the verification and validation of data transmitted from anesthesia and physiologic monitors into the enterprise's AIMS.

The process of taking the data from machines and translating into a commonly acceptable format for AIMS usually involves the MDDS vendor, hospital IT, clinical personnel (anesthesiologists and certified nurse anesthetists), and EMR vendor personnel. In enterprises in which many different brands of anesthesia machines exist, the time required to align parameters from the several disparate medical devices can be significant.

The need to validate parameters from the various anesthesia machines and monitors, and the importance associated with achieving accurate interpretations and mapping of these parameters into end-user AIMS can consume a great amount of effort and time. This cannot be understated in terms of clinical importance.

Long term, medical devices must be able to join the health information technology environment in a manner similar to electronic medical record systems.

For those planning to integrate data from medical devices, project plans should take this data alignment process into account. Alignment and verification of data from medical devices can easily consume weeks of effort. The amount of time needed depends on the number of different medical device types and the number of different AIMS in existence.

Clinical staff provide an essential contribution to the validation process and the team performing the integration. Their review of machine settings and machine data, and their assessment of the accuracy of what is being shown on the device versus what is being recorded in AIMS is critical to the usability of the data.

Alignment and verification of data from medical devices can easily consume weeks of effort.

Because different medical devices can report different parameters or parameters with different syntax and units of measure, disambiguating these differences becomes a necessary aspect of integration testing before

such systems can be used on live patients.

Table 4 illustrates two brands of anesthesia machines often used in operating rooms: the Draeger Apollo and General Electric Aespire class anaesthesia machine. Parameter mapping occurs as part of the process of validating inbound data to the anesthesia information management system (AIMS), and the table lists some of the parameters mapped between the two machines with the aid of IT, clinical, and vendor teams supporting the implementation of an AIMS rollout at a multi-entity hospital system.

Conclusion

The interoperability of medical devices with health information systems involves far more than physical connectivity and download of medical device data. To ensure the usability of data from medical devices, it is necessary to ensure common context of reported data, which implies terminology alignment and time synchronization of outbound data to CIS and EMR.

Given that these data are used for intervention with patients, it is important for the enterprise to require that medical devices—regardless of brand—communicate data in the same way (terminology, frequency) and support common functions that can be interpreted by any health information system. Data alignment activities should be taken into account in the rollout of all MDDS implementations and can consume a significant amount of the implementation team's time. ■

References

1. **Richards R, Zaleski JR, Peesapati S.** Liberating Medical Device Data for Clinical Research: An Architecture for Semantic and Temporal Harmonization. Second AMA-IEEE Technology Conference; Boston, MA. Oct. 16-18, 2011.
2. **Bible.** *Genesis 11.* United States Conference of Catholic Bishops. Available at: www.usccb.org/bible/genesis/11. Accessed Aug. 22, 2012.
3. **Carr M.** Agility Through Regulation. *HIMSS 2012 Daily Insider.* Feb. 21, 2012.
4. **IHE.** PCD Rosetta Terminology Mapping. Integrating the Healthcare Enterprise. Available at: http://wiki.ihe.net/index.php?title=pcd_rosetta_terminology_mapping#details. Accessed Aug. 22, 2012.
5. **Wikipedia.** IHE Rosetta Terminology Mapping Ventilator Task Group Wiki. Available at: http://wiki.ihe.net/index.php?title=pcd_rtm_ventilator#rosetta_terminology_mapping_.5brtm.5D_ventilator_task_group. Accessed Aug. 22, 2012.
6. **iHealthbeat.** CMS Releases Quality Measures for MU Stage 2 Proposed Rules. 2012. Available at: www.ihealthbeat.org/articles/2012/4/10/cms-releases-quality-measures-for-mu-stage-2-proposed- rules.aspx. Accessed Aug. 22, 2012.
7. **Kocher R, Roberts B.** Meaningful Use of Health IT Stage 2: The Broader Meaning. Health Affairs Blog. March 15 2012. Available at: http://healthaffairs.org/blog/2012/03/15/meaningful-use-of-health-it-stage-2-the-broader-meaning/. Accessed Aug. 22, 2012.
8. **Medicinfotech Web Log.** One Man's Quest for Data Alignment & The Semantic Web. Available at: www.medicinfotech.com/2011/12/one-mans-quest-for-data-alignment-the-semantic-web/. Accessed Aug. 22, 2012.
9. **W3C.** Semantic Web Standards. World Wide Web Consortium. Available at: www.w3.org/standards/semanticweb. Accessed Aug. 22, 2012.
10. **Kalfoglou Y.** Cases on Semantic Interoperability for Information Systems Integration: Practices and Applications. Information Science Reference, 2010.
11. **Uschold M, Gruninger M.** *Creating Semantically Integrated Communities on the World Wide Web*. Eleventh International World Wide Web Conference; Honolulu, HI. May 7, 2002.
12. **Chatburn RL.** Classification of Ventilator Modes: Update and Proposal for Implementation. *Respiratory Care*. 2007;52:3.
13. **IHE.** Integrating the Healthcare Enterprise Patient Care Device Domain. Available at: www.ihe.net/pcd/. Accessed Aug. 22, 2012.
14. **IBM.** RESTful Web Services: The Basics. International Business Machines. Available at: www.ibm.com/developerworks/webservices/library/ws-restful/. Accessed Aug. 22, 2012.