Semantic Data Alignment of Medical Devices Supports Improved Interoperability

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Abstract

Many medical devices used for treatment and therapy produce data that can be retrieved for clinical use, both for research and patient care management purposes. These patient care devices (PCDs) are distributed across the spectrum of care, from the operating rooms and intensive care units to medical surgical units and home-health devices. While much focus on interoperability over the past several decades has focused on the physical interaction with these medical devices, through the use of middleware and through manufacturer involvement within the interoperability communities, there still remain interoperability challenges in communication and interpretation of data from medical devices [1]. One area of evolving focus is semantic interoperability, involving the alignment on meanings and definitions of data, particularly from medical devices. The importance of retrieving data accurately from medical devices and interpreting data accurately is of critical importance to both care provider and patient. A discussion of semantic interoperability from the perspective of medical devices is introduced together with a summary of the work that has been done in recent years to align meanings and definitions of terms across medical devices.

Introduction

The challenges posed by disparate lexicons, operating modes and data communication mechanisms among medical devices performing the same or similar functions at the point of care can, at best, pose workflow challenges for hospital systems in terms of data alignment and, at worst, impact patient care. Data from medical devices are employed for therapy and decision making at the bedside, and while efforts are underway to remediate issues of data alignment disparities among medical devices, the challenge remains [2]:

"The majority of … devices use vendor-specific or proprietary nomenclatures and terminologies. As a result, even though information may be exchanged using standards-based transactions … semantic interoperability is not achieved until the content is mapped to a standard nomenclature. This mapping is often inconsistent and subject to loss of information (e.g. mapping from a specific term to a more generic term). Also given the lack of tooling, utilizing standardized medical device terminology in production systems is difficult and often cost prohibitive."

Taking a step back, and for those unfamiliar with the concept of medical device integration (MDI) or communication, involving extraction of data from point-of-care (POC) medical devices for the purpose of supporting therapy, intervention and patient care management. The Association for the Advancement of Medical

Instrumentation offered a definition in the AAMI White Paper 2012 [3]. Medical Device Integration falls within the purview of Medical Device Data Systems, or MDDS.

That definition: *"the ability of medical devices, clinical systems, or their components to communicate in order to safely fulfill an intended purpose."*

Medical device integration can be provided by certain medical device manufacturers, such as many physiologic monitoring and infusion pump manufacturers. Yet, the communication of medical device data from medical devices to electronic health record systems, data warehouses, and departmental clinical information systems is also provided by makers of middleware that support ubiquitous data communication from many different types of medical devices to these

receiving systems in many different formats. The most often used format is Health Level Seven (HL7) unsolicited observation report messaging—a standards-based transaction modality. Yet, as stated earlier, standards-based messaging does not necessarily imply consistent nomenclature.

Medical device integration software used for the sole purpose of communicating data for consumption by electronic health record systems falls into the regulatory category of a Medical Device Data System (MDDS). Medical Device Data Systems (MDDS) are hardware or software products that transfer, store, convert formats, and display medical device data. An MDDS does not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. MDDS are not intended to be used for *active patient monitoring* [4]. Examples of MDDS include:

- Software that stores patient data such as blood pressure readings for review at a later time;
- Software that converts digital data generated by a pulse oximeter into a format that can be printed; and,
- Software that displays a previously stored electrocardiogram for a particular patient.

The quality and continued reliable performance of MDDS are essential for the safety and effectiveness of health care delivery. Inadequate quality and design, unreliable performance, or incorrect functioning of MDDS can have a critical impact on public health.

Integrating data from medical devices is, more precisely, communication of data from patient care devices used for bedside physiologic monitoring, mechanical ventilation, anesthesia, oxygenation measurement, and similar devices. Data from medical devices are temporal in nature. That is, medical device produce data in one or more variables with time. Data can also be communicated nearly continuously, as in waveforms, or in discrete measurements separated by significant intervals in time. Data associated with a patient may be derived from multiple medical devices, requiring the fusion and interaction of multi-source data as well as multi-parameter data, which are then used to guide therapy or interventions.

Data extraction from medical devices can occur at different data collection frequencies, and as certain different medical devices do not normally communicate with one another as part of therapy, this implies that the data need to be aligned both temporally as well as semantically. Medical device data for the longest time has been isolated, trapped in silos, each having unique communication protocols, physical connections, non-standard or localized clock times, unique update rates, and unique terminology. Data cleaning, temporal and semantic alignment & harmonization are required for use in charting systems and to arrange for common interpretation of fields, units of measure and values. The conditioning of the data is extremely important for importation into electronic health record systems, where common alignment on timing, field mapping, and value conditioning is essential to ensuring proper posting and display of data. Research data warehouses also require similar conditioning to ensure numeric data are properly posted and interpreted.

As a result, medical device middleware has evolved to support the function of translating data from the proprietary, non-standardized formats prevalent with many medical devices today into a more standardized format, as illustrated in Figure 1. The role of the MDI middleware is to provide a common translator, or "Gateway" to take the proprietary data from the patient care medical device and relate it in a common or more standardized format to the recipient system of note. The usual preference for standardized communication is Health Level Seven (HL7). Yet, other formats and norms have developed over the years based on consensus established among medical device manufacturers, electronic health record system vendors, middleware vendors, health systems, and standards developing organizations (SDOs).

Figure 1: Basic function of medical device data system middleware: to extract data from medical devices, in whatever format provided (including proprietary) and transform to a more standardized format for consumption by third-party electronic health record systems or data warehouse.

Thus, while data can be translated into a common format for the receiving system (in this case, the EHR), the work of aligning on definitions of fields in the context of modes of the medical device and with respect to measurements or observations from the patient still remains, and oftentimes requires de-confliction effort between middleware and EHR system vendors to create customized flow sheets or charts to map the definitions of specific types of patient care devices in order to support their unique definitions. The effort involved in this effort can be significant, involving multiple individuals (clinical and information technology) and weeks of effort.

To address the issues surrounding semantic interoperability, the National Institute of Standards and Technology (NIST) has been engaged in an effort to create a standardized nomenclature surrounding patient care devices and their communication [5]. In the section that follows, an example of the type of semantic challenges will be discussed, together with current progress and future directions.

Methods

Example of the semantic mapping challenge

The effort surrounding the NIST effort at addressing the semantic interoperability challenges among patient care devices to interoperate based on aligning “observation

identifiers, units-of-measure and enumerations that vendors currently support on their gateways and how they plan to map these to the ISO/IEEE 11073-10101 nomenclature and its extensions" [6]. Yet, there are many medical devices that, as yet, do not employ gateways for common translation of data using the HL7 messaging standard. Yet, the role of the middleware is in both interpreting the proprietary data interface as well as performing the mapping. This poses a significant challenge. To illustrate the complexities involved in mapping and communicating data from disparate medical devices, it is worthwhile to draw upon an exemplar from the environment that is frequently used and of key significance. One of the key patient care devices used for therapy in intensive care units is the mechanical ventilator, used for respiratory support, intervention and patient care management. Two examples of mechanical ventilators employed frequently are the Draeger Evita and Puritan Bennett 840 models, both used invasively in adult critical care units (note: the Evita and the newest model, the V500, are also available for use in neonatal and pediatric intensive care units). Error! Not a valid bookmark self-reference. summarizes the modes of mechanical ventilation associated with these two mechanical ventilators. While, perhaps, the most obvious differences are in the general naming and differentiation of modes, it is able to map these to one another (for the most part). Some examples:

- Draeger Assist Control maps to Puritan Bennett Assist/Control breath-type.
- Draeger synchronous intermittent mandatory ventilation (SIMV) maps to Puritan Bennett SIMV breath-type.
- Draeger airway pressure release ventilation maps to Puritan Bennett BILEVEL breath-type [7].
- General volume and pressure control modes map to each other.

The challenges, per se, are not that there are not equivalent modes of operation (or similar), but that proprietary modes do exist and these translate into the requirement for different education on each ventilator type as well as an understanding of the variable output produced by these devices based on their respective modes of operation.

Table 1: Modes of mechanical ventilation of the Draeger Evita and Puritan Bennett 840 mechanical ventilators.

Draeger Evita XL [8]	**Puritan Bennett 840 [9]**
Volume-Controlled: • VC-CMV (continuous mandatory ventilation) • VC-AC (assist control) • VC-SIMV (synchronous intermittent mandatory ventilation) • VC-MMV (mandatory minute volume) Pressure-Controlled: • PC-CMV • PC-AC • PC-SIMV • PC-BIPAP m(biphasic positive airway pressure) • PC-APRV (airway pressure release ventilation) • PC-PSV (pressure support ventilation) • PC-HFO (high frequency oscillation – specific mode to neonatal ventilation) • PC-MMV Spontaneous/assisted: • SPN-CPAP/PS (continuous positive airway pressure / pressure support) • SPN-CPAP/VS (continuous positive airway pressure / volume support) • SPN-PPS (proportional pressure support) SPN-CPAP (continuous positive airway pressure)	Vent Type: Determines ventilation type • INVASIVE – endotracheal or tracheostomy (trach) tubes • NIV (non-invasive) – full face masks, nasal masks, infant nasal prongs, un-cuffed ET tubes Mode: Determines type of breath • A/C (assist/control) • SIMV (synchronous intermittent mandatory ventilation) • SPONT (spontaneous) • BILEVEL Mandatory Type: • PC (pressure control) • VC (volume control) • VC+ (volume control plus available only with volume ventilation when INVASIVE type) Spontaneous Type: • PS (pressure support) • TC (tube compensation) • VS (volume support) • PA (proportional assist) • NONE Trigger Type: • P-TRIG (pressure) • $\dot{V}$-Trig (flow)

Because some of the output fields are not defined across the different patient care medical devices, and the reporting of these output fields can vary based upon the mode or setting, a tailored flow sheet for charting purposes may be necessary. Alternatively, more generalized flow sheets which provide approximate definitions to support a "best-fit" across medical devices may be required to ensure that respiratory therapists working with multiple types of mechanical ventilators can both chart and receive data for managing their patients.

For instance, Table 2 shows a side-by-side comparison mapping of a subset of the output observations from these two mechanical ventilators translated into HL7 2.X standard format.

Table 2: A partial mapping of output variables between the Draeger Evita XL and the Puritan Bennett 840 mechanical ventilators.

Draeger Evita XL	**Puritan Bennett 840**
OBX||NM|SET-RR||15|/min	OBX||NM|SET-RR||10.0|/min
OBX||NM|SET-O2||21|%	OBX||NM|SET-O2||21|%
OBX||ST|VNT-MODE||Adults\IV - Invasive Ventilation\Mode IPPV/ASSIST/ACtoFlow	OBX||ST|VNT-MODE||CMV|
OBX||NM|SET-TV||540|mL	OBX||NM|SET-TV||0.50|L
OBX||NM|SET-PEEP||6|mbar	OBX||NM|SET-PEEP||5.0|cmH2O
OBX||NM|SET-APN-T||20|s	OBX||NM|SET-APN-IT||0.00|s
OBX||NM|SET-IEI||1| OBX||NM|SET-IEE||2.3|	OBX||NM|SET-IEI||1.00| OBX||NM|SET-IEE||3.17|
OBX||NM|MV||7|L/min	OBX||NM|MV||9.36|L/min
OBX||NM|SPO-MV||0|L/min	OBX||NM|SPO-MV||0.0|L
OBX||NM|TV||469|mL	OBX||NM|TV||0.52|L
OBX||NM|AWP||11|mbar	OBX||NM|AWP||13.0|cmH2O
OBX||NM|PIP||24|mbar	OBX||NM|PIP||23.0|cmH2O
OBX||NM|RR||15|/min	OBX||NM|VNT-RR||20|/min

The exercise of mapping output variables, once accomplished, can achieve a mapping of, perhaps 80%-90% of offered observations from patient care medical devices of the same type from different vendors. Yet, there are can be examples of variables that do not have equivalent mappings, and these will then need to be accommodated either as customized fields within the receiving system or simply ignored, depending on their importance to the clinical staff.

Mapping of Output Fields

Thus, as this example illustrates, the challenge of translating data from proprietary formats towards more standardized formats pertains not only to the physical collection of data and its translation, but also to the interpretation of data from complementary and competing medical devices. This point will be illustrated in reference to Figure 2 and Figure 3 below.

Data from different medical devices need to be mapped, as well. Many medical devices will create the same fields but in different formats or naming conventions. These need to be reconciled and mapped. For instance, here we have two different medical devices that both communicate heart rate, although the field on Device 1 corresponds to ECG measurement and that of Device 2 corresponds to pulse oximetry measurement. The medical devices themselves report these fields as "HR". Externally, the fields can be differentiated as "HR-ECG" and "HR-SPO2", respectively. These fields, thus, can be mapped to the EHR as distinct entities, despite the fact that the medical devices define the fields as the same variable "HR".

Similarly, each device reports a peripheral oxygen saturation measurement. These, too, can be mapped to distinct fields if desired, to provide differentiation and distinction between the two values. Clinically, there may be a desire to differentiate measurements by medical device, thus providing corroborating information on measurements from two different sources, such as peripheral oxygen saturation measurement from a left and right finger, or non-invasive blood pressure measurement from two different limbs.

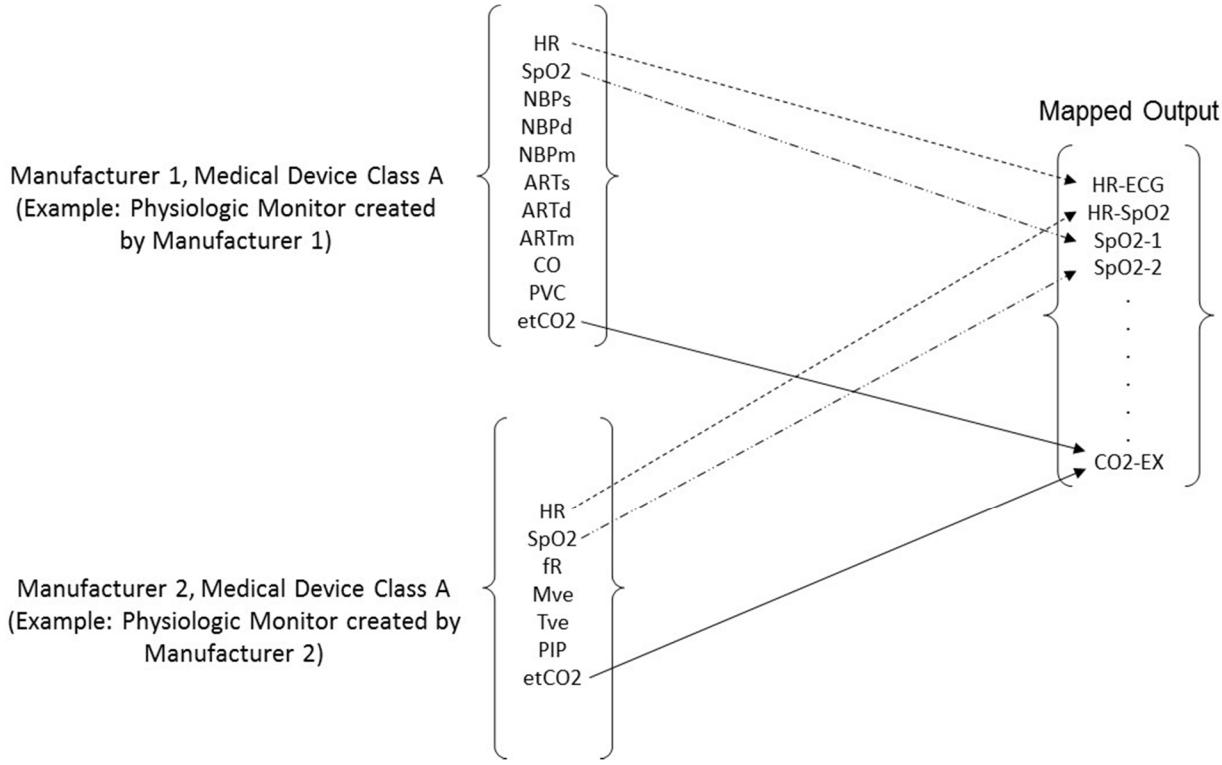

Figure 2: Mapping parameters from two different devices produced by different medical device manufacturers to parameters within the electronic health record system.

Management of medical device modes and the mapping of modes is also of key importance, particularly with mechanical ventilators and anesthesia machines. These types of devices are used to deliver therapy as well as monitor patient respiratory state and are, therefore, of critical importance to the welfare of the patient. Yet, certain different manufacturers of these devices provide for proprietary or exclusive modes that represent key features of the operation of the devices, but are inconsistent of not able to be interpreted one-for-one with other manufacturer device types that support similar or precisely the same functions in the healthcare environment. This can lead to the practice of approximating mode types for the purposes of charting in electronic health record systems, or omitting certain modes during the charting process in order to obtain a one-size-fits-all end user chart that is suboptimal in terms of clinical management but, due to limitations in

electronic medical record system capability, is unable to be accommodated due to customization. The impact on the clinician can range from increased clinician workflow burden (i.e., having to chart unmapped fields manually), to misinterpretation of settings or fields due to incorrect mappings. The resultant approximate mapping of modes, illustrated in Figure 3, results in an attempt to map common modes among manufacturers, but leave as orphan those modes that cannot be mapped across the medical device spectrum.

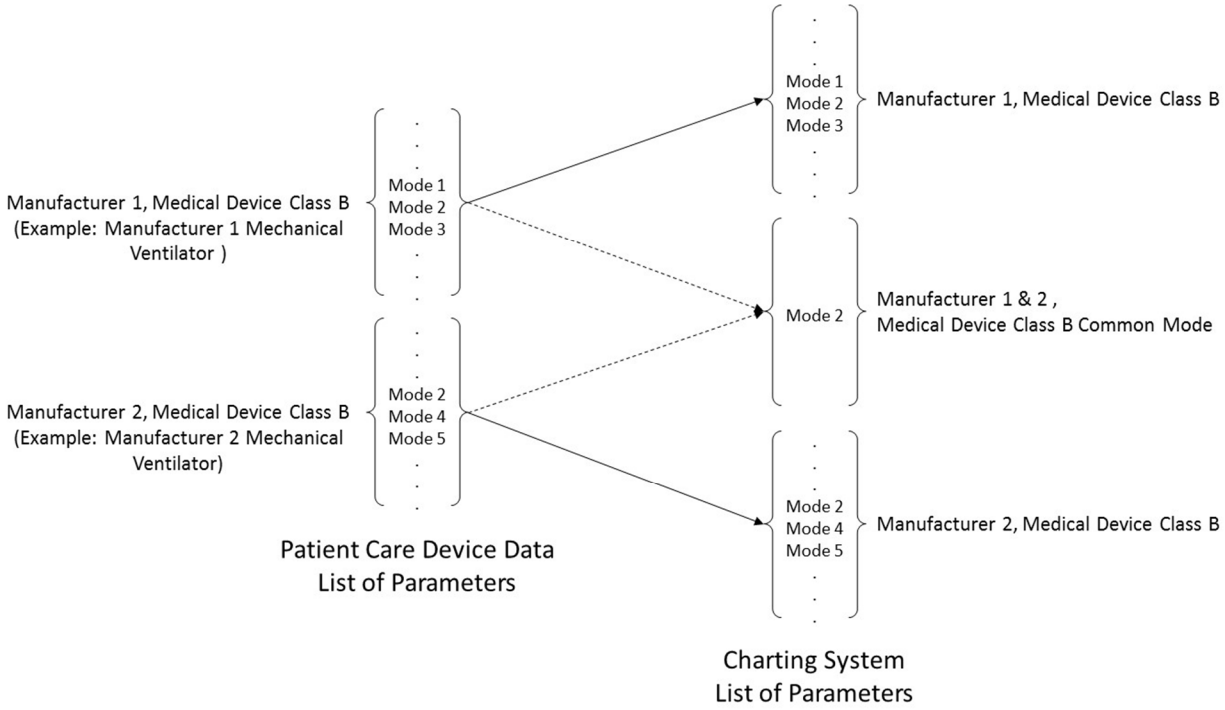

Figure 3: Mapping modes from two different medical devices produced by two different manufacturers. Medical devices are employed for same purpose with patients.

A common method of mapping that certain medical device middleware employ is a fixed mapping from the device data to a common format that can be received by electronic health record systems. Parameter observations from the patient care medical devices can be mapped to common unified codes, and these unified codes correspond to

accepted fields within the electronic health record system. As illustrated above, some parameter observations may have different names and units of measure based on device manufacturer preferences, yet are mapped to the same output parameter, as illustrated in Figure 3. The mapped output provides a lexicon or default which can then be reused with specific patient care medical devices and electronic health record system pairings, thus facilitating the implementation process of medical device integration within an enterprise.

Discussion

Over the past several years, The Rosetta Terminology Mapping Management Service (RTMMS), in partnership with the National Institute for Science and Technology (NIST), has adopted the RTM into a Harmonized Rosetta table containing allowed units of measure and normative mappings, observation identifiers and other enumerations together with their mapping to the ISO/IEEE 11073-10101 nomenclature and extensions [10]. Furthermore, the NIST-hosted RTMMS (http://rtmms.nist.gov) includes the harmonized (cross-device & manufacturer), "hRTM", or harmonized Rosetta Terminology Mapping. NIST is continuing to develop tools tied to the HL7 version 2 specification that provide for an automated set of testing capabilities to validate mappings and medical device output. NIST also works with SDOs and experts within the field to produce a more complete Domain Information Model (DIM), derived from the 11073-10201 standard to assist in the production of standardized terms consistent with the RTMMS, inclusive of unified codes and units of measure, body sites, and enumerations.

While the RTMMS effort is an important one and represents movement in the right direction, the implication is that there will be a middleware "gateway" to perform the translation from the proprietary to the aligned semantic interfaces required for equivalence between competing patient care devices.

Through the work of NIST both in terms of testing tools, improved Domain Information Model and cooperation of medical device vendors, there has been progress made towards the general alignment of medical device terminology. Yet, there is a lag between the progress of the standards organizations and the actual implementation

in the field. Many medical devices enjoy a 10 year or longer lifetime of operation within healthcare systems. As a result, the lag between current state of the art in terms of semantic alignment and adoption by a medical device manufacturer as a generally available product offering can be many years. As a result, hospital systems are left with the need to provide ad hoc or engineered solutions within their walls to accommodate the needs of clinicians. Wide scale or universal adoption of medical devices that conform to the RTMMS are years away. Hence, it is necessary for hospital systems to be cognizant of the challenges associated with medical device data alignment and to schedule sufficient time for clinical de-confliction of terminology or creation of alternate flowsheets and methods of workflow to meet both the clinical requirements and information requirements of the healthcare organization.

The use of pre-defined patient care medical device mappings facilitates the implementation of medical device integration with electronic health record systems, and speeds the time to go-live. Yet, the mapping approaches are still overlay methods on a larger issue: the generalized standard mapping of medical devices natively from the manufacturer. While a spotlight of standard semantics has received greater focus over the last several years, there is still the need for manufacturers to take on a more active role in terms of enabling easier mapping of raw data from the device to existing health record systems, particularly when coexisting with competing equipment from other manufacturers. While it is recognized that certain capabilities of medical devices are feature offerings providing for competitive differentiation, the process of adding new features must also be accompanied by the ability for ensure semantic interoperability. Again, many manufacturers understand this and are beginning to migrate towards more standardized implementations in terms of data semantics. Yet, as an industry and a community, there are significant gaps that will motivate this evolution over, perhaps, the next 5-10 years.

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