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Interoperability & Data Integration

Good afternoon, I am here as a „black box'. I only see what goes into the box and what comes out of the box… At the U.S. Department of Commerce's (DoC) National Institute of Standards and Technology (NIST) researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating information into the electronic health record. We have developed software test tools[1] and a modeling application (an electronic representation of an international standard's information model[2]) which provides several important capabilities leading toward device interoperability[3].

Conformance testing is a key step leading to, although not guaranteeing, interoperability[4]. Sparked by involvement over the past several years of working with medical device domain experts and vendors who participate in Standards Development Organizations (SDOs), an approach to identify testable assertions derived from standards and constrained by important use cases was developed and continues to evolve. Such medical device- and healthcare-related standards include *Health Level 7*[5] (HL7), *ISO/IEEE 11073 Health informatics – Point-of-care medical device communication*[6] and *Personal health device communication*[7] (x73), and *ASTM F2761-2009 – Integrated Clinical Environment* (commonly referred to as ICE).

The black-box messaging test approach addresses how we define and get to a level of rigor that improves - if not (dare I say), *„ultimately assures' – given no optionality* - correct data exchange. In particular, verifying that physiological information derived and communicated from a source medical device (e.g., an infusion pump) or healthcare information system, to another medical device (e.g., a patient monitor) or healthcare information system that consumes or makes use of the data is syntactically and semantically correct. In other words, the structure of information exchanged within the healthcare system is compliant to a defined specification(s) and the information meaning conveyed and interpreted by the consumer is exactly the same and as intended by the source. Unfortunately, this „ultimate assurance' can only be a reality given more than technological solutions. The commitment to and consistent use of industry standards is essential. To achieve commitment and consistent use, buy in of key stakeholders is critical – perhaps first and foremost by the leadership, as well as information technology (IT), clinical engineering and users. Because the lead time for medical devices and systems is lengthy, vendors must become committed and actively involved in the near term, and users must begin to budget for and specify interoperable devices.

But since I'm from NIST, let me get back to and stick with what I know best - the technical side of things... The reality that medical devices need to communicate with tens, if not hundreds, of other devices of varying makes, models, and modalities - has large market and substantial healthcare implications. Acute point-of-care settings such as a hospital's intensive care unit, a patient's bedside, or personal telehealth location require each class of medical device to use the same terminology and data organization to seamlessly and reliably communicate physiological data. Healthcare communication standards that address plug-and-play medical device interoperability are critical. While

providing the groundwork to enable device communication, standards are developed in an open ended manner (and for good reason). It is my contention, through experience in software testing, that only until standards and defined specifications are constrained (ultimately removing all optionality to create *profiles*) that the desired "guarantee" of syntactic and semantic correctness can even begin to be achieved.

Conformance test methodologies are being employed by NIST via software test tools to help get closer to that "guarantee." These tools are publicly available and being used by the medical device industry to ensure that critical devices correctly implement the medical device standards. Consortia of medical device vendors have come together (and more are coming) to use such test methodologies to successfully meet a level of compliance to standards sufficient to achieve truly efficient interoperability. Correct implementation of standards lead to effective exchange of critical physiological data derived from the patient at the device and exchanged throughout the healthcare enterprise. As more and more devices are able to achieve "plug-and-play" capabilities, health caregivers are empowered to focus more on the patient, diagnosis, and treatment and less on the devices. The ability to reliably and effectively integrate data from a broad range of point-of-care devices will ultimately lead to a reduction in medical errors and the associated loss of life. From the buyers perspective, resources providing procurement guidance (and a level of assurance) of device interoperability is an essential need.

To enable device interoperability more rapidly, particularly from the health information technology side, identification of key use cases driving efforts to pilot and prototype medical device systems should be encouraged. In fact, several efforts are underway leading to interoperable medical device products showing up on the market. Such work must be performed in a cross-industry, consensus-based manner - with buy-in of appropriate and committed resources. Implementation guides and conformance profiles are key ingredients to articulate meaningful use requirements to device manufacturers and test system developers respectively. Additionally, articulation and guidance of such requirements lead to evaluation criteria necessary for users to make informed procurements.

Medical Device conformance leading to interoperability - based on standards and to a finer level constrained profiles with clearly and unambiguously defined assertions – will not happen overnight (and hasn't to date). Such work should be iterative in nature to provide feedback to SDOs and to establish „meaningful' criteria addressing key needs in our healthcare system of systems. With physiologic data primarily being derived at the medical device a process driven by meaningful use criteria cannot be put off to the future and must be identified today. Criteria called out specifically for devices to meet defined meaningful use priority areas should be established as soon as possible.

Supporting Information

Profiles focus, organize, and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards such as HL7 and x73. They provide precise definitions of how standards are constrained and may be implemented to meet specific clinical needs.

The Need for Conformance Test Tools

Conformance and interoperability testing of medical device data communication is essential leading to long term value propositions that include:

- Integrity of data – automatic population of all information systems – reducing medical errors
- Automating systems to capture clinical data into Electronic Health Records (EHRs) thus saving time for clinicians
- Access to patient data across devices and systems so custom communication interfaces can be eliminated thus allowing for best of breed and even plug-and-play devices
- Improving agility of enterprises to meet varied patient loads
- Improving life-cycle cost of ownership

To address real-world semantic interoperability the transfer of data must be (in many cases) near real-time data from a gateway to an Electronic Health Records (EHR) system in a rich, accurate, and consistent manner. To first show conformance that subsequently enables such interoperability, test tools that rigorously enforce defined specifications to facilitate safe and effective plug-and play interoperability are necessary.

Our approach for developing a test system to validate messages is based on constraining identified specifications. The validation is defined by assertions derived from the specifications and constraints placed upon the specifications. The premise at getting to any level of rigor is that specifications are complete (as possible) and constrain open ended assertions. The more well-formed, formal, and complete the specifications the greater level of rigor can be achieved by the test system.

It is unrealistic to assume all standards and specifications are correct or mature to a level of „complete'. However as specifications are implemented and a collaborative, iterative, feedback process occurs - so too can the rigor-level and coverage provided by the test tools via updates, enhancements and issue resolution. [Current tool development supports IHE-type work cycles - should we decide to consider different enterprise-level testing outside of IHE, other specifications as made available by the domain could be integrated in a similar manner into the test tooling.]

Based on the specifications and any constraints identified in those specifications, messages are validated by the test system which employs various test components. For example, an HL7 message derived from an infusion pump (or generated from the pump system or gateway) is evaluated against the HL7 standard for its syntax and semantics, the x73 standard for terminology, terminology co-constraints, and information model (i.e., the device object hierarchy), and the test case for any specific values or attributes.

[Medical Device Communication terminology is being mapped between SNOMED CT, LOINC, and x73 (MDC).]

In considering and developing our test approach one of the overarching goals is to achieve semantic interoperability – communicate medical device data using a single (or mapped if possible) unified nomenclature and semantic model that can be rigorously defined and enforced to facilitate safe and effective plug-and play interoperability.

Other consortia efforts, based on standards, approach similar objectives with a different perspective or slant. Examples include such standards as:

- ASTM F2751-2009 defining architecture for integrated clinical environment (ICE) (Medical Device "Plug-and-Play Interoperability Program, http://www.mdpnp.org/ICE.html) – focus: patient safety;
- IEC 80001 (ISO, Technical Committee 215 Health Informatics, http://www.iso.org/iso/catalogue_detail.htm?csnumber=44863) – focus: risk management (from an IT network perspective).

Key medical device terminology-led (including classification and coding standards) efforts include:

- NIH's National Library of Medicine Unified Medical Language System (UMLS – LOINC, http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html);
- Copenhagen, Denmark's International Health Terminology Standards Development Organization (IHTSDO – SNOMED CT, http://www.ihtsdo.org/snomed-ct/),
- ISO/IEEE 11073 Medical Device Communication Nomenclature (11073-10101, http://standards.ieee.org/findstds/standard/11073-10101-2004.html).

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