



CENTER *for* MEDICAL INTEROPERABILITY

Comments to ONC 2016 Interoperability Standards Advisory November 6, 2015

The Center for Medical Interoperability (C4MI) welcomes the opportunity to comment on the 2016 Interoperability Standards Advisory and applauds ONC's continued efforts to advance standards-based interoperability throughout U.S. healthcare delivery.

C4MI is a 501(c)(3) organization led by health systems to change how medical technologies work together. We are solving the shared technical challenges health systems face in integrating medical devices, electronic health records and IT systems in a plug-and-play way. Our mission is to achieve two-way, plug-and-play interoperability by unifying healthcare organizations to compel change, building a centralized lab to solve shared technical challenges and pioneering innovative research and development. Our solutions will empower patients, healthcare professionals and the nation to optimize the use of health information.

We believe our mission and objectives are highly aligned with those of ONC, and we are pleased to offer the following perspective on the 2016 Interoperability Standards Advisory:

Interoperability Standards Advisory Scope

The Advisory Scope states that it focuses on:

“... clinical health IT systems’ interoperability ... includes electronic health information created in the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed”

and in the Introduction:

“identification, assessment, and determination of the ‘best available’ interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs”

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However, the 2016 Advisory does not recognize and integrate the many mature (“final” and in “production”) medical device interoperability standards that are used today by many commercially available systems, especially in the area of physiological or vital signs monitoring. These are arguably the richest sources of health information created during patient care. Though “vital signs” are identified, only LOINC is recognized in this Advisory, and the set of data that are supported represent a relatively small subset of the detailed standardized semantics that are available today from many medical devices and “gateway” systems.

The FDA in August 2013 recognized key standards that are used for medical device interoperability¹, especially in the ISO/IEEE 11073 family. These medical device interoperability standards are in wide use, including 25+ production systems for acute care medical devices that incorporate IHE Patient Care Device (PCD) profile specifications that leverage the IEEE 11073 semantic standards with HL7 v2 messaging.

C4MI Recommendation:

1. Recognize the same set of core medical device interoperability standards that are also recognized by the FDA and in broad use throughout the industry, namely:
 - ISO/IEEE 11073-10101 Nomenclature
 - ISO/IEEE 11073-10201 Domain Information Model
2. Recognize the IHE Patient Care Devices (PCD) “final text” profiles that support medical device data communication and are built on the ISO/IEEE 11073 standards identified in (1), as well as other mature standards included in the 2016 Advisory such as HL7 version 2.6, specifically:
 - IHE PCD Device-to-Enterprise Communication (DEC)
 - IHE PCD Point-of-Care Infusion Verification (PIV)
 - IHE PCD Alert Communication Management (ACM)
 - IHE PCD Implantable Device – Cardiac Observation (IDCO)

Recognition of the FDA Unique Device Identifier (UDI)

Section “I-R: Unique Device Identification” indicates that the UDI’s Standards Process Maturity is “Final”; however, C4MI staff have been involved in advancing the standardized use of the FDA UDI, including acting as editors of HL7’s UDI Implementation Guidance and related updates to various standards components, including Version 2, Version 3, CDA and FHIR. Based on the most recent standards activities, though, it is clear that many key implementation issues remain with the UDI and that its designation as “Final” is premature. We anticipate that there will be further changes to the underlying specifications and considerable implementation guidance development required before it can be considered for general use.

Note that C4MI recognizes the immense importance of the FDA UDI specification,

¹ See <http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf>.

especially as a key enabler of improving healthcare supply chain management and improving patient safety. As a result, we remain committed to working with the active standards organizations, especially HL7, to bring the specification and related guidance and implementations to where it is able to fully deliver on its intended objectives.

Additionally, there is currently no mandate to require electronic devices to communicate the UDI and it is unrealistic to expect clinical staff to manually enter the code.

C4MI Recommendation:

1. Indicate that the Standards Process Maturity is “draft” and not “final”; it is ready for DTSU or “trial implementation” but too many issues remain for it to be considered final;
2. Require the automatic reporting of the UDI from devices that also automatically report other results using standardized interoperability protocols like IHE PCD DEC or ISO/IEEE 11073 Personal Health Device (PHD).

Vital Signs, LOINC & Mapping Quality

Section “I-S: Vital Signs” identifies LOINC as the terminology of choice. Though this terminology is clearly the best for laboratory systems and devices, as well as acceptable for the relatively small number of vital signs semantics identified in other ONC specifications, it is wholly inadequate to represent the wealth of semantics available today from medical devices. The ISO/IEEE 11073 semantic standards (identified above) provide the granularity needed to represent medical device information and are in broad use for all standards-based medical device interoperability. In fact, studies in Europe showed that there can be a 40:1 ratio of a particular ISO/IEEE 11073 semantic to its LOINC or SNOMED-CT “equivalent.”

Recent efforts have been made to map a core set of 800+ terms from ISO/IEEE 11073 to LOINC. Though this effort is applauded and recognized as needed in some use contexts, it is also a possible source of degraded data quality and ultimately risk to patient safety – especially when the information is acquired from safety critical medical devices. In fact, it is widely recognized that mapping from one terminological system to another is challenging at best. For this reason, during the recent ISO/TC 215 Health Informatics meetings in Bern, Switzerland a new preliminary work item was advanced, “Terminology Resource Map Quality Measures (MapQual),” reflecting the recognition by international experts that understanding even how to measure mapping quality is an undeveloped area of study.

Note also, this mapping from ISO/IEEE 11073 to LOINC is in the initial stages and is not normative. It has yet to undergo any serious peer review effort as would happen in the development of a normative standard such as HL7 or IEEE. This future work is currently under consideration by the IEEE 11073 standards committee.

C4MI Recommendation:

1. Medical device semantic standards ISO/IEEE 11073-10101 and ISO/IEEE 11073-10201 should also be recognized for representation of vital signs and general medical device acquired information;
2. When the use context necessitates the use of LOINC for vital signs information, the standardized semantic originally acquired from the device should also be maintained, thus helping ensure the proper interpretation of the concept and providing the information needed for forensic analysis.

Personal Health Device Interoperability Standards

Also included in the FDA recognized interoperability standards list mentioned above are a series of ISO/IEEE 11073 interoperability standards for personal health devices. These are also based on the core semantic standards mentioned above, but are focused on the generally less complex equipment increasingly being utilized for post-acute care, chronic care and wellness. Given the increasing need to address health and wellness outside of the clinical context and to ensure the seamless flow of this information to clinicians when needed, these standards represent the best, most mature option for the industry.

As is true for the other ISO/IEEE 11073 standards mentioned above, the PHD standards are also broadly implemented nationally and internationally and have been integrated into many telehealth and mHealth platforms.

C4MI Recommendation:

1. Include the ISO/IEEE 11073 PHD personal healthcare device (PHD) standards in the Advisory.

C4MI looks forward to continuing to contribute to this effort. To discuss any of our recommendations, please contact Todd Cooper at todd@center4mi.org. Thank you.