



**Written Testimony
Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International**

**To
Healthcare IT Standards Committee
Clinical Operations Workgroup**

**For
Medical Devices
Barriers and Enablers for Medical Device Interoperability
March 28, 2011
Washington, DC**

On behalf of Health Level Seven International (HL7), we wish to thank the Clinical Operations Workgroup of the Healthcare IT Standards Committee for this opportunity to contribute to the Interoperability & Data Integration panel and to provide testimony on the hearing for medical devices.

For nearly twenty-five years, HL7 has contributed to the creation of standards for the interoperability of healthcare information. As a not-for-profit, ANSI-accredited standards development organization, HL7 is dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. In this way, we support clinical practice as well as the management, delivery and evaluation of health services.

To this end, HL7 enables the exchange of information for patient care, public health, and medical research for more than 95% of healthcare systems. As an international body, HL7 also support the interoperable exchange of healthcare data in nearly forty countries worldwide. Our membership includes over 500 companies representing over 90% of the world's vendors of health information systems as well as the developers of medical devices.

During the last decade, HL7 has provided both the standards and the technical framework for electronic health records, for personal health records and for support of medical research in regulated and in non-regulated environments. Since the passage of the HITECH legislation and the establishment of Meaningful Use guidelines, HL7 has been the fundamental enabler for information exchange.

HL7 has continued to develop and refine these processes through harmonization and collaboration, both in the US and globally. We have been the principle nexus for collaboration among standards bodies, including IEEE and ISO, and have ongoing working relationships with IHTSDO and LOINC, as well as with IHE and Continua. Today, existing and emerging interoperable, standards-based solutions for connecting devices to EHRs are predicated on HL7 v2 messaging. More critically, both regulated and non-regulated devices are supported by multiple working groups within HL7.

Themes/Questions

All Panels – General Questions

1. What is your experience with health care devices and device interoperability? Have you experienced specific problems where standards might contribute to solutions?

Experience

- For over 10 years, the HL7 Health Care Devices Working Group has provided the primary collaboration center for medical device informatics standards development, by enabling the context for coordination and collaboration between IEEE, ISO, IEC, IHE and other groups.
- HL7 version 2 messaging is the primary open standards-based (i.e., non-proprietary) method for communicating device data to enterprise applications such as an EHR/EMR
 - Today, the IHE PCD profiles enabled a single common specification between vendors providing true interoperability, albeit with the same HL7 messaging base.
 - In addition, the ISO/IEEE 11073 semantics provide solutions for the needed semantic interoperability
- The HL7 Conformance Working Group develops specifications that enable rigorous message profiling and strong validation testing, including for those needed for both Version 2 & 3
- Open Health Tools, for which HL7 is the principle resource, builds upon this process, to support strong validation activities, including Tools from NIST, the Messaging Workbench, as well as specifications leveraged by the IHE PCD
- Specific examples of these specifications include
 - Use of an "ORU" message to communicate near-real-time device data
 - Use of an "ORU" with special high-priority trigger to communicate medical device alarm information
 - Use of "RGV" to send 5-rights validated program data sets to infusion pump servers
 - Use of "ADT" for managing patient identity
- HL7 version 2 provides the messaging backbone for conveying remote / home acquired device data across a Wide Area Network (WAN) to monitoring / hospital services, including, for example, the Continua-IHE WAN Interface.
- HL7 Clinical Document Architecture (CDA) enables Personal Health Monitoring & Reporting that is now used by Continua. In addition, CDA supports the bridge from ISO/IEEE 11073 (Continua) personal health device context both to EMRs and to Health Information Exchanges. Perhaps most importantly, CDA supports mappings from ISO/IEEE 11073 semantics to SNOMED and LOINC terminology.
- While these systems are in production today, with many more planned for this year. HL7 has been the non-proprietary technology in use for 10+ years. Today, IHE PCD HL7 v2-based profiles are shipping in 13 products from 9 companies. The number is growing weekly.

Solutions

The prevailing problems with successful adoption of device standards are more political and social than they are technical. Nonetheless, the prevailing terminology specifications, which are sparse, need to be enhanced. This will result in more effective syntactic integration of the existing standards, but dramatic improve semantic interoperability. This should lead to simplified process and reduced costs for mapping and for integration. While the efforts of Continua and IHE are valuable for achieving interoperability, both regulatory authorities and device manufacturers often fail to enforce interface

standards. We believe that more uniform application of existing standards would speed both adoption and alleviate costly process for device integration.

In addition, the device data requirements for EHR integration and reporting must be more clearly articulated. When available, the existing standards should be applied to solve the data requirements that are often overlooked. End-users must define their business and workflow requirements and actively participate in the specification of data needs. The HL7 Clinical Interoperability Council is but one step in the right direction.

2. Are there areas where standards are more mature or less mature?

In general, exchange and transport standards are mature. The requirements for seamless interoperability are not always articulated by healthcare providers. When their needs are made known, application to existing systems can be slow. Both IHE and Continua are working effectively to reduce barriers, but solutions for hospital and other acute care environments often lag behind.

The binding of vocabulary standards to transport standards needs to be accelerated. HL7 is actively pursuing this course with both IHTSDO (SNOMED-CT) and LOINC. While the standardization has been augmented by collaboration between device vendors and the clinical community, implementation has been slow.

Finally, integration of data from devices in the ambulatory environment must become interoperable with electronic record systems in hospital and Emergency Department settings. This is particularly critical as we attempt to reduce the total cost of care, not just the component relevant to the clinician.

3. What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?

The data must be delivered to the point of care. Context-aware implementation is more meaningful as data overload becomes a barrier to the quality of care. Increasingly, this will be predicated upon decision support algorithms that integrate device data into the clinical guidelines. HL7 Clinical Document Architecture (CDA) has become increasingly adopted for high level quality analytics and should prove valuable in the decision support process.

4. What do you see as the key barriers to effect use of healthcare devices to advance health and wellness?

As in the response to Question 3, simply providing the data to the EHR is insufficient. The data must be parsed and managed in the way that is most useful to the clinician. Unabated data streams are a distraction in almost all settings. In addition, the exchange of data should be bidirectional. The care record should inform the devices about important clinical requirements and trigger messages for supporting device management. Ventilators and infusion pumps immediately come to mind in the acute care setting, but the EHR should inform the behavior of increasingly “smart” devices in the ambulatory setting as well.

5. If you could wave a magic wand to effect one change to enable more effective and widespread use of healthcare devices, what would that be?

As stated above, the much of the technology is already available to improve patient care. The standards must be deployed in the acute and ambulatory settings with seamless data exchange. The

magical change to help realize that process would be to better align regulatory policies, care incentives (including reimbursement), and clinical adherence to clinical guidelines. Unfortunately missing from this equation is the contribution of the patient. Healthcare literacy is a significant component of patient compliance and this must be accelerated if the value of many devices is to be realized.

Interoperability/Data Integration Panel

8. What data about devices is need in EHRs?

In legal terms, all device data should be delivered to the EHR. From a more practical perspective, HL7 has learned that caregivers share much in both workflow and business requirements for data. At the same time, there are inherent conflicts about what must be known by the clinician as compared to the requirements of the technical expert. Technical device data (including serial number, reagent lot number, operator ID and time stamp information) may be critical to a lab technician for quality control, but the caregiver probably only needs to know the value of the blood sugar.

In practical terms, the 80/20 rule would significantly drive the quality of care. We should not delay the requirements for device data implementation because all of it is not readily available. The standards needed to achieve the 80/20 goal already exist. Requirements for standards implementation do not. For example, the standards to inform a device about the system time already exist. Requiring the device makers to use that standard to set the device clock has never been enacted.

9. Questions related to Meaningful Use

a. How would device data in EHRs affect Stage 1 measures?

This would have its greatest impact on quality measures. Quality is not “knowing” that the clinician has ordered a beta-1C-hemoglobin, quality is verifying that the blood sugar is better controlled.

b. What device-related patient safety and/or quality issues should be measured or reported?

Those that reduce morbidity and mortality (based on published evidence) first. Those that reduce the cost of healthcare secondly.

10. What is the impact of the recent FDA MDDS rule on device integration with EHRs?

HL7 specification both support and are deployed by regulated and non-regulated systems, medical device systems, and non-medical device systems. HL7 standards provide data integration for systems classified as an MDDS as well as systems that are not classified as such.

11. How should the integration of home and remote monitoring with EHRs be addressed?

This requires two answers, one procedural and one technical. Much as subjective, patient-originated information is specifically identified as such in a clinical history, home and remote monitoring data should be given a unique location in the EHR.

From a standards perspective, this has been cited in HITSP technical notes TN905 and IS77. The use of the HL7-based Continua-IHE WAN interface and the CDA-based PHM Report both support this level of data integration.

12. How should integration of regulated clinical devices with EHRs be address?

This is largely out of scope from an HL7 perspective. In general, however, the purpose for regulation of a medical device or intervention is patient safety. While HL7 has no specific standards for such use, we support the application of existing standards to this functionality.

13. Please consider comments on identification of devices related to use of EHRs?

a. In supply chain management and management process

HL7 has several solutions although our collaboration with GS1 provides the most effective standards application instance.

b. In safety processes including identification of recalled implanted devices

HL7 specifications provide the needed capabilities to ensure proper association of devices and patients. The binding and unbinding of patient level data is not sufficiently enforced. This needs to be enhanced on both policy and regulatory levels.