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HIT Standards Committee, Clinical Operations Workgroup
March 28, 2011, Washington DC
Public Hearing on
"Identification of Barriers and Enablers for Device Interoperability"
Provider Panel

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Background

Medical devices are essential sources of data for the EHR. However, in contrast to Information and Communication Technologies (ICT), most medical devices have been designed to operate as stand-alone devices and do not have standardized, interoperable electronic data interfaces. Currently, when mixed-vendor (heterogeneous) medical device integration is required, customized device interfaces must be developed, potentially with high cost, long development time, and incomplete functionality. The absence of interoperability presents significant barriers to the achievement of the national vision of using EHRs to transform healthcare. Furthermore, medical device interoperability is necessary to lay a foundation for the more comprehensive improvements in patient safety and quality that can arise from point-of-care clinical systems integration (i.e. for a single patient) incorporating rich data from medical devices:

Clinical system integration: It is important to frame medical device interoperability within the context of enabling clinical system integration. Integration of data from medical devices in order to improve EHR data quality (thus making outcomes research and powerful analytical applications possible) and to add error-resistance (prevention) to clinical care is the real goal: comprehensive interoperability is a key ingredient of effective, efficient, affordable integration.

Required functionality of data: A typical HIT perspective on the scope of medical device interoperability is the transfer of a subset of clinical data generated by devices to the EHR. The subset usually includes discrete data such as ECG-derived heart rate and systolic and diastolic blood pressure measurements, but usually excludes data such as ECG and blood pressure waveforms, alarm limits and status, and medical device configuration and management information. In addition, most medical devices today do not use a network time reference thereby introducing time inconsistencies into the EHR. The absence of the broader data set

significantly limits the opportunities to create contextually rich databases that can support meaningful clinical applications and research. Moreover, complete interoperability could enable the creation of integrated "error-resistant" medical systems to support advanced capabilities such as automated clinical device readiness assessment; physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; smart alarms; monitoring of device performance; plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; comprehensive data collection (such as a "black box recorder") for the analysis of near-misses and adverse events; enhanced disaster preparedness and response capabilities; and other innovations to improve patient safety, treatment efficacy, and workflow efficiency. [i]

Answers to "questions for panelists":

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

My experience with heathcare devices and interoperability has been in several domains: as clinician, researcher, standards developer, manufacturer, regulator, and health system device integrator.

1. Anaesthesiologist in clinical practice for over 20 years at multiple institutions
2. Medical device informatics fellowship as part of my academic training
3. Founded research program and lab at University of Colorado, which developed bedside clinical decision support tools using real-time comprehensive medical device and contextual data. Absence of device interoperability was identified as a major barrier to the development and adoption of our advanced clinical decision support applications
4. Served as Vice President of Medical Affairs of a medical device company
5. Served in the FDA Medical Device Fellowship Program
6. Founding Director of the Medical Device "Plug-and-Play" Interoperability Program (MD PnP) at the Center for Integration of Medicine and Innovative Technology (CIMIT) and the Massachusetts General Hospital. Since May 2004, the MD PnP program has convened hundreds of individual technical experts and corporate and governmental participants to lead the evaluation and adoption of standards and technology for medical device interoperability to support clinical innovation. The CIMIT MD PnP Lab, located in Cambridge, Massachusetts, provides a vendor neutral sandbox to develop and test medical device interoperability solutions. The MD PnP program is supported in part by grants from DoD/TATRC, NIH, NSF, NIST and CIMIT, and closely collaborates with the FDA and several medical device manufacturers. Program output has been placed in the public domain at www.mdpnp.org.
7. P.I. of newly awarded NIH/NIBIB Quantum grant to develop a "prototype healthcare intranet for improved health outcomes", with medical device interoperability at its core. This $10M grant has recently been adopted by the HHS ONC as a SHARP program affiliate.

8. Medical Director of Biomedical Engineering for Partners HealthCare System. A key responsibility is overseeing medical device-EMR integration strategy and implementation for Partners hospitals.
9. Co-Chair of FDA Workshop on Medical Device Interoperability (January 2010). [ii]
10. Co-Chair of FDA Prototype Regulatory Submission Working Group, an on-going activity to address the safety implications of interoperable medical device integration and define a regulatory pathway. (This is a follow-on to the FDA Workshop.)
11. Serve as chair of the Continua Health Alliance Use Case Working Group since its founding in 2006. Continua develops interoperable personal and tele-health devices and supports the development of enabling standards for personal health devices in IEEE 11073 PHD.
12. Standards: Most of the standards developed by the following committees address safety and performance of medical devices and are intended to support regulatory conformance.
    - 12.1. Chair of ISO Technical Committee 121 on anaesthetic and respiratory equipment (85 standards/26 countries).[iii] Leading a development effort to incorporate functional data interfaces in medical devices.
    - 12.2. User Vice Chair of ASTM committee F29 on anaesthetic and respiratory equipment
    - 12.3. Chair of ASTM Committee F29.21 Device in the Integrated Clinical Environment. Chaired development of standard F2761-09 "Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model"

Barriers related to medical device interoperability have surfaced in my scope of work in every role listed above. Here are several examples that provide insight into the limitations imposed by our current standards, technologies, and the systems that can(not) be created from them:

A. Barriers to clinical documentation: Partners Healthcare has been implementing a system-wide clinical documentation system, which was to include comprehensive medical device data acquisition. However, given the significant limitations of current medical device interfaces, we have had to markedly decrease the initial scope of data acquisition by reducing data types and by eliminating a number of widely used devices, such as infusion pumps. Due to the non-standardized handling of patient ID-to-device binding, we had to discard most clinical data acquired during in-hospital patient transport. Furthermore, key medical device data, such as alarm conditions, are not available beyond the patient monitoring gateway connection, and therefore cannot be included in the EMR.

B. Incorrect clock time: Cell phones and email programs obtain the correct time from the network using a time reference such as Network Time Protocol (NTP), but the clocks in most medical devices do not synchronize with the network. Consequently as the medical-device clock drifts, clinical data is exported to the EHR with an erroneous time stamp. These erroneous time-stamps may confound the interpretation of clinical events, undermine the

integrity of the EHR, and complicate the implementation of clinical decision support tools. (Interestingly, when the clock is rolled back each autumn ("fall back") some systems lose one hour of patient data.) Furthermore, there is a significant workload requirement for clinical engineers to manually change medical device clocks twice each year. This time-accuracy problem is one result of the inadequacies of medical device interfaces, and requires a standards-based solution to not only to use a network time reference, but also to handle synchronization errors, time management of intermittently connected devices, propagation of time on large networks of devices, etc. (Our MD PnP program has been researching the root causes of and potential solutions to this gap since July 2010 in preparation for an industry workshop.)

C. Interface performance: Even when using manufacturer-provided electronic data interfaces, data acquisition may be neither simple nor benign. For example, recently in our research lab, we discovered that under certain conditions an Intensive Care Unit lung ventilator shuts down and reboots (while ventilating) when prompted to communicate data to the EHR above a certain bandwidth limit. There are many anecdotal reports of similar – potentially hazardous - problems with implementing connectivity solutions in clinical environments. This is an example of the implication of gaps in clinical requirements (unspecified data bandwidth requirements), standards, and validation tests (to validate that medical devices will support clinical use cases).

D. Barriers to improving safety: The standards and interface technology ecosystem is too incomplete to support many needed innovations in patient safety. For example, we cannot interconnect medical devices from different manufacturers to improve the safety of medication delivery. Consider an example of a patient receiving an intravenous infusion of arthritis medication that may drop the blood pressure precipitously. If the monitored blood pressure drops, an alarm may sound at the nursing station, which will hopefully summon a nurse to stop or slow the medication infusion and examine and treat the patient. If the nurse is delayed or doesn't hear the alarm, the patient may be injured. Why can't hospitals be enabled to integrate a blood pressure monitor and an infusion pump to automatically stop the medication infusion and summon help when the blood pressure falls? This is one clinical example among many in which appropriately accurate and comprehensive medical device data and standardized interfaces could support the development of innovative applications.[iv] Additional examples are detailed in ASTM standard F2761-09 Annex B, AHIC Extension/Gap document on Common Device Connectivity, and HITSP TN905.

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

I would like to include in this document a rigorous analysis of the gap between available standards and the requirements for medical device interoperability, but that is difficult for the following reasons:

- There is no national-level compendium of clinical and technical requirements to inform medical device interface and interoperability standards development. This will require diverse clinical input, especially from clinicians and clinical engineers; and
- One cannot easily assess the utility of a standard by reading the published document – that requires implementation. But, there are virtually no public medical device interoperability reference implementations or verification and validation tools to use for gap analysis of requirements-to-standard.

Many current medical device interoperability activities are based on a least-common-denominator approach of using current standards and current vendor capability to down-select clinical use cases that can be implemented with existing standards. This leaves important, clinically meaningful capabilities out of scope and allows no room for improvement. In view of the importance of effective medical device interoperability, we should instead be forward-looking by following the industry standard methodology of product development, in which one begins with (clinical and functional) requirements to ensure that the results of the activities are meaningful. These requirements should be used to perform a gap analysis of the capabilities of current standards to enable innovative healthcare solutions. (NIST has been working on a project to develop gap-analysis methodology for medical device interoperability standards.)

Consequently, the MD PnP program is analysing what can be done with existing standards, and whether they can be improved or supplemented to facilitate innovative healthcare applications.

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

To some extent, this depends on the definition/scope of meaningful use. If we consider the vision of EHR technology, there is much more that can be done to improve the safety, quality, and effectiveness of healthcare. For example, there has been limited discussion to date in Meaningful Use documents, about the types of clinical data needed for improving the management of critically ill patients in the ICU, OR and ED. Critical care is expensive: it is responsible for approximately 25% of all hospital costs, or approximately 1% of the GDP. Enabling modest improvements in the quality and efficiency of critical care delivery could yield significant dividends.

Meaningful use of EHR technology requires more than medical device interoperability standards – it requires hospitals to function as medical device and HIT system integrators. Successful integration requires detailed knowledge of component interfaces and device and network behavior. Currently it may be difficult for healthcare delivery organizations to obtain important information about device and network interfaces and performance, thereby increasing the cost and introducing risk in the

integration project. Adoption of appropriate medical device interoperability standards could significantly help reduce the complexity and cost of integration.

4. What do you see as key barriers to effective use of health care devices to advance health and wellness?

A. Hospitals have had to become system integrators - diverting funds from the delivery of patient care. The scope and complexity of integration is rapidly growing as the clinical and economic value is recognized. Many hospitals lack resources and capabilities to perform this function competently now. Also, most vendors are reluctant to disclose complete device interface data.
B. There is a national shortage of clinical engineers with appropriate training in medical device informatics and HIT system integration. This challenge is amplified since many hospital IT departments have an incomplete understanding of the demands of clinical engineering, and vice versa.
C. Devices should be uniquely identifiable on the network and should bind patient ID to the data stream
D. The effectiveness of using medical devices to advance health and wellness will be greatly enhanced when applications can more completely interact with devices. For example, when a critically low blood glucose value appears in the EMR, an application should be able to stop the intravenous insulin infusion and alert the appropriate clinician. The ability to create and deploy these applications will empower the healthcare community to transform healthcare.

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

If medical devices were available with effective, interoperable data interfaces, hospitals could order the devices today and begin to build smarter, integrated clinical environments tomorrow. But, as in other domains, the whole of the integrated system should be greater than the sum of its parts. This requires medical devices to provide additional functionality via the electronic interface. For example, implementing the clinical scenario in section 4d above, requires that the insulin infusion pump have a "pause pump" feature, that can be accessed over the network (with appropriate safeguards). Achieving this level of system functionality will also require a significant level of standards coordination and the aggregation of comprehensive clinical and technical requirements.

I would also like to see a better pathway to resolve problems with device integration. The FDA can address problems with device safety and performance, but hospitals are on their own to assure the safety and performance of a system of heterogeneous medical devices and IT networks. A

procurement contract vehicle to encourage adherence to standards and disclosure of interface performance has been developed (see MD FIRE at www.mdpnp.org)[v] but we don't have the tools to adequately verify interfaces and diagnose system problems. We have a procurement carrot but the enforcement stick is more like a twig, in part because the assessment criteria (standards) are immature and not robust.

In conclusion, medical device interoperability should be advanced, by recognizing that medical devices are an integral part of a larger ecosystem that includes but is not restricted to the EHR. The fully integrated clinical environment will enable a transformation of healthcare.

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[i] http://mdpnp.org/MD_PnP_Program.html
[ii] http://mdpnp.org/FDA_Interop_Workshop.php
[iii] http://www.iso.org/iso/iso_technical_committee.html?commid=51984
[iv] http://www.aami.org/2011isc/Goldman%20_Systems_of%20_System.pdf
[v] http://mdpnp.org/uploads/MD_FIRE_Med_Device_Interop_Contracting_Requirements.pdf