



## Health IT Standards Committee Clinical Operations Workgroup

### Medical Device Interoperability Hearing Summary

March 28, 2011

#### Meeting Agenda

#### Background

The [Health IT Standards Committee](#) is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. In developing, harmonizing, or recognizing standards and implementation specifications, the Health IT Standards Committee will also provide for the testing of the same by the National Institute for Standards and Technology (NIST).

The [Clinical Operations Workgroup](#) is tasked with making recommendations to the HIT Standards Committee on the role of EHRs and e-prescribing, clinical summaries, lab and radiology report functionality.

#### Announcements by the Chair/ Themes

- The next HIT Standards Committee meeting will take place in Washington DC on March 29<sup>th</sup>, 2011.
- Consumers and patients need interoperability to be made cheap and easy.
- Connectivity and setup are huge challenges in home environment.
- Providers see setup problems for device security when trying to achieve meaningful use.
- There are problems with non-standard vocabularies with medical devices.
- Payments and incentives don't pay for medical device interoperability fixes.
- Ensuring that remote patient identification is correct is a huge problem.
- EHR vendors are not able/focused on achieving full interoperability. Instead they are focused on standards for data intermediaries as the "middlemen" between the device and EHR. Patients and providers want data interface standards now
- Conflicting advice on stage 2 of Meaningful Use
  - Argument for Meaningful Use requirement that supports home health organization using remote monitoring
  - Not clear: what are the levers to encourage home health remote monitoring?

#### Questions for All Panelists and key themes in response

- Are there areas where standards are more mature or less mature?
  - Network connectivity standards are mature/ Standards around point of care integration are less mature.
  - Eliot Sloan- WAN (Network Wide Interface) unified with IHE PCD Device to Enterprise Communication Profiler is mature and allows unified data transfer/ Systems of Systems Engineering is not mature
  - Document exchange standards are mature, but highly dependant on use case

- Home health standards are brand-new in most cases
- What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?
  - Almost universal support amongst providers and consumers for better device to EMR data exchange standards
  - Automation of the data capture of vital signs into the EHR
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- What do you see as key barriers to effective use of health care devices to advance health and wellness?
  - Proprietary solutions and the variation in data exchange without standards.
  - Barriers to clinical documentation due to non-standardized data interfaces (both hardware and software)
  - Bandwidth limitations on interface performance
  - Each device should have a unique identifier within the network
  - FDA can address the device itself, but can't regulate interfaces.
  - Absence of remote monitoring requirement in Meaningful Use
  - Some interface standards have been declared proprietary
- 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?
  - Effective interoperable data interfaces
  - Each device should have a unique radio frequency ID along with unique identifiers
  - Devices would use "semantic interoperability" to promote automation
  - HITSP/IS77 (updated with the IHE PCD – Continua-WAN reconciliation) into Stage 2 requirements
  - Interoperability guidelines should be mandated through regulation and incentives along with standards.

### **Patient/Consumer Panel**

- Please comment on your needs and issues related to the use of health devices in managing health and wellness, in home care and remote health monitoring.
- What issues and requirements are most important for health care devices?
  - Reports on patient experience should include home monitoring (Stage 3)
  - Meaningful Use Stage 3 should be expanded to include electronic self-management tools for patients with high priority health conditions
  - Medicaid and Medicare should reimburse for telehealth (currently a barrier)
  - Data accessibility will be key to improved outcomes.

### **Provider Panel and Interoperability/Data Integration Panel**

- Questions related to Meaningful Use
  - How would device data in EHRs affect Stage 1 measures?
    - Patient blood pressure
    - Patient vital signs
    - Clinical Laboratory Test Results
    - Uploading Syndromic Surveillance data from devices can expedite reporting requirements.

- Medical Device Data can be used to provide data supporting attestation of quality measures (example: blood pressure measurements)
  - What device-related patient safety and/or quality issues should be measured or reported?
    - Device compliance
    - Medication error detection
    - Device fail-safes
- What is the impact of the recent FDA MDDS rule on device integration with EHRs?
  - Many hospitals are now considered “medical device manufacturers” thanks to MDDS rule.
  - There is still significant confusion as to what qualifies as a MDDS. Hospitals are determining what qualifies and the costs of registration and listing MDDSs, adherence to FDA Quality Systems Regulation (QSR), and adverse event reporting
  - This is an additional challenge when coupled with Meaningful Use, ICD 10 and 5010, and healthcare reform.
  - Significant additional liability costs if FDA pursues reports of an adverse event.
- How should integration of home and remote monitoring with EHRs be addressed?
- How should integration of regulated clinical devices with EHRs be addressed?
- Please consider comments on identification of devices related to use of EHRs
  - In supply chain management and other management processes
    - UDI can be useful in an FDA recall
    - Allows better tracking for supply chain management
    - Assists in investigation of adverse events
  - In safety processes including identification of recalled implanted devices
    - Eliot Sloan: FDA tracking should be required to be uploaded into EHR
      - Allows for complete disclosure of allergy/adverse events if loaded into EHR

### **Data Accuracy & Integrity Panel**

- What are the data accuracy and data integrity requirements for device data in EHRs?
  - Product metadata (data about devices)
  - Interoperability data (health data from devices)
  - What are the differences and similarities for patient-collected data vs. provider-collected data, and what are the requirements for both? d. Are there different accuracy and integrity requirements for patients or providers in different care settings, e.g. SNIF vs. Hospital vs. Home?
- What risks relate to device data accuracy and integrity?
- How does patient identification relate to device data in different care settings?
- Eliot Sloan (testifying on behalf of IHE-USA) called for adopting and specifying the IHE-PCD and Continua-WAN profiles for patient care and personal health applications, and Meaningful Use clinical practices and incentive thresholds

### **Device Security & Data Security Panel**

- What are the security requirements for devices in different care settings?
- How do existing security standards support network-enabled devices today?
- What network and connectivity issues relate to remote monitoring with intermittent connectivity?
  - Vendors recommend:

- In the clinical setting, we feel that some aspect of device interfacing in the Stage 3 requirements is reasonable, given the technology maturity, but allowing for the implementation challenges that still exist.
- In the home setting, our recommendation is that no Stage 2 requirements be considered and to re-evaluate prior to Stage 3.

### **Unique Device Identification Panel (UDI)**

- What are the requirements for unique device identification?
- How do they relate to the use of EHR technology? For providers vs. patients? For different care settings? 21
- To what extent are the standards for device identification used today by US providers of health care? Are there different patterns of use for consumer health and wellness devices vs. professional-use clinical devices? What issues arise from the use of multiple identification standards? How does device identification relate to patient identification?
- What device classification/nomenclatures are in use, and how do they relate to UDI?
- UDI was part of The FDA Amendments Act of 2007
  - The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number
- Reason for using a UDI, FDA can aggregate data on medical device usage in a standardized way
  - Identify safety signals
  - Ensures effective recalls
  - Supply Chain security, anti-counterfitting and tracking
  - Strengthens FDA Sentinel (ability to query data systems)
- Developing and Application of UDI
  - UDI code meets ISO 15459 standards
  - Manufacturer creates the code, which includes a Device Identifier and a Production Identifier
  - UDI applies to all layers of packaging and labels
  - Must be human readable and/or encoded
  - Identifies a series of standards (barcodes, RFID)
  - Products will then be registered in a Global UDI Database by: UDI; Make/Model, Unit of Measure; Contact information; GMFN Classification; Storage Condition; labeled allergens; FDA Premarket Authorization (510k or premarket approval); and FDA listing number.
- The Veterans Health Administration is incorporating UDI into their supply chain management