Clinical Operations Workgroup
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Medical Device Hearing
Testimony to HIT Standards Panel

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Thank you for the opportunity to provide testimony on this important topic. The Department of Veterans Affairs (VA) is a strong supporter of the Health Information Technology for Economic and Clinical Health (HITECH) Act and the work of the Health Information Technology (HIT) Standards Committee. VA is focused on providing patient-centric health care that facilitates evidence-based decisions for individual Veterans and their families, patient populations, clinicians and those managing healthcare delivery systems. VA fully endorses the need to further device interoperability standards enabling the exchange of clinical information.

VA appreciates the opportunity to express its views and looks forward to providing oral testimony for the *Data Accuracy and Integrity Panel.*

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?**
   Standards enable interoperability which in turn enables automation, improves efficiency and quality because it eliminates repetitive and error-prone activities (e.g. manual entry). For instance, if clinicians manually enter device results into a flow sheet, there is a risk of not including an important piece of information—or taking valuable time away from the patient. If the device was interfaced to the electronic health record (EHR), these risks could be minimized. The limiting factor is the level of standards adoption and the maturity of some devices.

   End-users have various problems accomplishing automation of medical device. However, standards could help ensure that medical devices report their results automatically to the Electronic Health Record System (EHRS) or nursing flowsheets. Standards may help manage personalized device configuration (e.g., a patient is moved from one ventilator to another and the configuration is

automatically uploaded from the previous device to the current device), ensuring that the medical device data is associated with the correct patient and the necessary clinical documentation automatically added to the patient's record.

Standardization opens up the possibility of remote access, creating semi-automated feedback loops (e.g., rules around blood pressure and medication drips in an ICU), decreases in teaching time due to the numerous interfaces currently available , and decreases costs associated with developing communication protocols.

2. **Are there areas where standards are more mature or less mature?**
   The standards dealing with ventilator modes terminology/nomenclature and those dealing with managing device configuration are in their very early stages of development.

   The standards dealing with integrating medical devices with nursing applications and EHRS are very mature. These standards enable automatic documentation of procedures and medical device observation reporting. Real-time standards for device integration, Institute for Electrical Engineers (IEEE/IEC 11073), are in place but mostly implemented to enable single-vendor integrated solutions.

   It is important to distinguish between the state of standards and the state of standard adoption. Adoption of standards, especially standard-based nomenclature/terminology, is still limited across the industry as whole though industry leaders are making progress in this area.

3. **What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?**
   Meaningful use of electronic data hinges upon real time, quality data, that will drive positive clinical outcomes and improve patient safety. Those standards that allow for the interconnecting and synchronization of these devices are most relevant.

   The emphasis of Meaningful Use is to enable the adoption of EHRs; any work intended to enhance the usefulness of these products is relevant to the overall adoption of EHRs in the United States. In this case, the ability of devices to report their observation and configuration automatically, resolving the issue of human error, would be relevant. This would require networked devices to use standards-based messaging and terminology in a secure way (i.e. user

authentication, transport level security) to communicate with EHRs and other Health Information Technology (HIT) systems. Ideally these devices would exchange information bidirectionally with the EHRS providing for orders and configuration to flow from the EHRS to the device, and results and configuration revisions (including patient assignment) to flow from the device to the EHRS.

4. **What do you see as key barriers to effective use of health care devices to advance health and wellness?**
   Barriers include precision of the observations measured by devices, the importance of meaningful alarms, and the ability to configure, manage, and locate a device. Viewing the current limitations from a standards-based interoperability stand-point the main barriers revolve around common standards that are implemented consistently. Medical devices use either proprietary protocols or standards-based protocols with local or manufacturer-specific extensions (i.e., proprietary terminology). Even those vendors who use standards have a choice of standards and terminology, thus providers have a complex task of integrating multiple vendor devices into their EHRS.

   Consistent adoption of standards, including terminology, would remove some of the barriers. A major impedement to adoption is the need to map the clinical parameters from the various devices and systems from different vendors to the chart. When a new device is hooked up or reconnected, the logistics of associating the device to the correct patient are not trivial. Additionally some advanced functionality of systems is protected by intellectual property laws and cannot be incorporated into standards. Unlike information systems, medical devices often undergo a longer product lifecycle--they take longer to upgrade and modify, not only because of they are regulated products, but because they consist of both hardware and software. Therefore designing, developing and testing a new or revised medical device version requires more time than an information system. A final barrier is that many legacy medical devices do not support a standardized output format.

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?**
   The magic wand would upgrade all the old, stand-alone devices to become networked and to be able to communicate bidirectionally with the EHRS in the enterprise using standard terminology and protocols. A single messaging protocol or interoperability profile that includes the best practices in security, real-time, and asynchronous communication is needed. Practitioners would be notified by medical alarms only for those conditions that are truly dangerous for

that patient. The magic wand would also affect products under development to be built from the ground up on standard terminology. The idea of a proprietary parameter or protocol would be eliminated.

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14. What are the data accuracy and data integrity requirements for device data in EHRs?

Accuracy and integrity requirement are identified and allocated at the time of acquisition. Generally, Health Level 7 is the messaging standard for communication between components of the Electronic Health Record. VA endorses compliance with international standards Institute for Electrical Engineers (IEEE EMBS 11073) and International Organization for Standardization (ISO-TC215) Health Care Informatics WG7 Devices. The Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing and transmitting information in medical imaging. The DICOM standard is also known as a National Electrical Manufactures Association (NEMA) standard, and as ISO standard 12052:2006. I nterfaces are required both on the EHR and device side when purchasing devices. VA has recommended all device-generated data include metadata for audit purposes including security, record actions, and health information exchange and system information (e.g., user and patient IDs, Date/Time Stamps, Type of Action).

a. Product metadata (data about devices.

VA's core EHR, Veterans Health Information Systems and Technology Architecture (VistA), provides a module supporting all options necessary for establishing and maintaining a comprehensive preventive maintenance program for devices. VA prefers that metadata be provided; and is working to further define metadata requirements.

b. Interoperability data (health data from devices)

A Medical Device Data System (MDDS) is a device intended to provide one or more of the following uses:

- The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices. For example, this would include software that interrogates a ventilator every 15 minutes and transfers information about patient CO2 levels to a central patient data repository.

- The electronic storage and retrieval of medical device data, without altering the function or parameters of connected devices. For example, this would include software that stores historical blood pressure information for later review by a healthcare provider
- The electronic display of medical device data, without altering the function or parameters of connected devices. For example, this would include software that displays the previously stored electrocardiogram for a particular patient.
- The electronic conversion of medical device data from one format to another format in accordance with a preset specification. For example, this would include software that converts digital data generated by a pulse oximeter into a digital format that can be printed.
- Examples of medical device data systems that would be used in the home are systems that periodically collect data from glucose meters or blood pressure devices for later review by a healthcare provider.

c. **What are the differences and similarities for patient-collected data vs. provider-collected data, and what are the requirements for both**?
For VA, data entry by patients is primarily through the My Health***e***Vet web portal. The My Health***e***Vet *Agreement to Terms & Conditions* that users agree to , discusses Access, Entry and Use of Information within My Health***e***Vet and states that, "Information entered by you in Health***e***Vet does not update or in any way replace information in official VA records. For example, changes made to your address, phone number or other demographic information within Health***e***Vet will not update information in VA systems and cannot be used as a change of address system. You must contact your local VA facility to perform any official business or make corrections or changes to any of your information."

My Health***e***Vet users have complete control over the information in their My Health***e***Vet Personal Health Record. Self-entered data may be shared through printouts or through VA Blue Button downloads. Data printouts and VA Blue Button outputs clearly define the source of user entered data as "self-entered". At this time, no self-entered data is written back to any VA system.

d. **Are there different accuracy and integrity requirements for patients or providers in different care settings, e.g., SNIF vs. Hospital vs. Home?**

- VA is a comprehensive health care system providing multiple levels of care. Throughout the VA's health care system, a mature and highly integrated

electronic health record is used; the health record is located within the Veterans Health Information Systems and Technology Architecture (VistA), which includes 100+ applications[1]. Requirements are developed for all care settings and the devices used. Below are some general statistics:

- 5.74 million total unique patients treated in FY (09)
- 152 VA hospitals
- 791 community-based outpatient clinics (CBOCs)
- Over 308,300 VA employees in pay status
- Nearly 115,000 HCPs rotating through VA (FY 09)

From a patient-safety, medical record and medico-legal perspective there are no differences. The frequency and detail of data needed may differ across care settings, however the need for precision of data accuracy and integrity does not change.

Data Accuracy & Integrity Panel, continued

14. What risks relate to device data accuracy and integrity?

Some risks include:

- Devices being purchased and implemented to create data similar to existing EHR applications without any effort to standardize concepts or integrate records in the EHR.
- Incomplete device data naturally leads to incomplete health records and documentation which in turn could affect the provider's ability to measure quality and perform outcomes research. This has patient safety and medicolegal implications.
- Matching a patient to a new device or restoring to an existing device is not trivial, incorrect matches can result in unintended consequences. It is important that protocols and safety checks are evaluated, implemented and redesigned as situations occur that compromise the accuracy, reliability and overall quality of the data.

15. How does patient identification relate to device data in different care settings?

Assuming this question is aimed at interoperable devices, then the data produced by devices (configuration and measurements) through its interface

[1] "VA Stats at a Glance", Produced by the National Center for Veterans Analysis and Statistics (008A3) , Veteran Population as of 09/30/10; VA Employ Pay Status Count 09/30/10; Veterans Affairs Site Tracking (VAST) 01/11/11; NCA as of 09/30/10; Office of Budget; Health Services Training Report FY09 ; * Includes Medical Care Cost Fund (MCCF)

must be assigned to the correct patient. In some settings (e.g. acute care) where the patient is assigned to a bed, the bed location is sometimes used to help associate a patient with a device (e.g., the bed location is associated with the device[s]; the patient is associated with the bed.)

Other devices rely on information from the hospital registration system or on user-entered information to identify the patient at the point of care, directly on the device. If the patient identification is not selected from a list based on the registration information, it is likely to be entered using a barcode reader or keypad on the device.

Within the VA electronic health record, the VA Master Veteran Index (MVI) plays a key role in identity management and serves as the authoritative system that assigns a unique identifier to an active patient and establishes a framework enabling the linkage of all records, from different systems, about a person from VA systems to that enterprise identifier. The MVI currently holds over 17 million unique patient entries and provides a longitudinal view of the person's record. VA depends on this functionality to provide care to all our patients. The MVI enables VA to:

- Uniquely identify an individual throughout health care processes through use of the Integration Control Number (ICN);
- Enable the identification of that patient within the computer system and facilitate selection of the correct patient record; and
- Facilitate the correct identification of patients for data exchange among sharing partners.

VA's MVI uses the ICN as the unique Universal Healthcare Identifier (UHID) and adheres to these national standards:

- American Society for Testing and Materials (ASTM) standard E1714 for Universal Health Care Identifier
- Object Management Group (OMG) Personal Identification Service (PIDS) standard
- VHA provides guidance to assure that health care software applications and systems adhere to VHA health care identity management requirements.