HIT Standards Committee
Clinical Operations Workgroup
Medical Device Hearing
Department of Veterans Affairs – Veterans Health Administration
Office of Nursing Services – Nursing Informatics Submission
23 March 2011

THEMES/QUESTIONS FOR PANELS:

All Panels – General Questions

1) What is your experience with health care devices and device interoperability?
Some devices have overcome the interoperability issues that others seem to struggle with. For instance, most physiologic monitors can output data easily to any electronic health record (EHR) with relatively little work needed. Other devices are still a struggle, for example we would like to interface our balloon pumps with our Clinical Information System (CIS) but the vendor has to develop custom solutions which can be costly and time consuming. Having said that, many of the interoperability issues experienced following the implementation of our EHR in the Intensive Care Unit (ICU) were resolved due to close collaboration between the vendor and VA with a commitment to finding solutions.

The limiting factor is the level of standards adoption and the maturity of some devices. 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 must enter device results manually into a flow sheet, then they could benefit from standards and interoperability. Standards could help to ensure that medical devices report their results automatically to the EHRs or nursing Flowsheets. Standards may also 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 its results are automatically added to the patient's record.

And finally, consider that in the current marketplace vendors have no incentive to make their information systems interoperable with other systems. There is actually a disincentive to do so because non-interoperable systems force an enterprise to continue to expand with one vendor versus being able to seriously consider solutions from other vendors. This has been an ongoing problem for many years in the private sector, but it is now a challenge that the VA will also need to address as the multiple clinical implementation systems are installed in VA medical centers.

a. Have you experienced specific problems where standards might contribute to solutions?
Yes. As I indicated with the balloon pump, standards would require the vendor to adhere to specific guidelines on how the data is to be exported. Intravenous (IV) pumps are another example. There are efforts underway to develop reliable standards to link IV pumps to a patient, but each vendor is searching for their own solutions. This is an area where patient safety can be effected an only regulated standards should be allowed. Another issue, we have observed that the communication between those who create the standards, do not clearly communicate with the vendors, who develop the commercial off the shelf (COTS) systems. A liaison between the two would help in the development of a product that would meet the needs of both the end user (not impede workflow) and the leadership of the organization (seeking compliance with regulatory standards in care/delivery). This could decrease timelines for implementation.

Another example is in 2005, GI scope software (i.e. the software that takes pictures and makes the report, usually comes with the scope from the vendor) did not interface with our Computerized Patient Record System (CPRS), and as a result providers were instructed to "cut and paste" reports from the GI software into a CPRS note. Occasionally, the reports were pasted into the

wrong chart. The reports were being cut and pasted because of the need for timely access by multiple providers to the scope of results. The site investigated and found an error rate of at 2% of copying and pasting into the wrong chart. The site reviewed its processes to decrease the lag time between when the scope report was generated and when it was available in VistA imaging for review, thus decreasing/eliminating the need to copy and paste reports for timely access.

It is important to note that the VHA regularly issues Patient Safety Alerts which describe safety risks and how to correct them. They are posted on our intranet site as well as on the internet for the general population. We encourage other health systems to use what VHA findings to encourage knowledge sharing to help all improve the way care is delivered. Some examples of VHA patient safety alerts include:
(1) CPRS – Changing Medication Schedule may Leave Incorrect Medication Administration Times, Alert AL09-19
(2) Possible blood contamination in hemodialysis machines, Alert AL10-04
(3) Misidentification of patient resulting in delay of surgery, Advisory AD10-01

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

Physiologic monitoring in critical care areas is seen as being highly standardized. There is little debate about how to measure a heart rate, blood pressure or central venous pressure. Standards within an ICU are ever changing and I would consider these mature evidence-based practices that dictate change in processes in order to provide exceptional care of our Veterans.

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 (IEEE/IEC 11073) are in place but mostly implemented to enable single-vendor integrated solutions. We need to distinguish however 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 area.

The less mature standards are those related to devices. Technologic interfaces are a real problem because of the process to maneuver through multiple administrative layers to determine if interfaces are possible. For example, if a new device is available, the site wishing to us the device must first contact the vendor, the vendor must collaborate with the developer of the device then the developer of the device must determine if they are interested in allowing interface with their product. An opportunity for improvement would be to establish standards requiring companies in contract with a government agency, and who would like to remain in good standing on a vendor list, to agree to work with other vendors.

The standards dealing with ventilator modes terminology/nomenclature and those dealing with managing device configuration are in their very early stages of development also less mature.

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

Clinical practice standards are by far the most important area where standardization is most relevant to EHR technology. The workflow of the end users must be understood and well documented before an EHR and medical devices can be interfaced. You have to know why healthcare clinicians are doing what they are doing in order to interface devices into the workflow and then retrieve that data for import to the EHR. Most VHA Performance Measures are dependent on reliable data. The data monitored and extracted from the critical care monitors, assistance devices such as ventilators, balloon pumps, continuous cardiac output monitors and interventions of the nursing staff, populate into a computer information system (ERH) and validate compliance with the clinical practice standards.

Since the emphasis of meaningful use is to enable the adoption of EHRs, then 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 of relevant. This would require networked devices that use standard-based messaging and terminology in a secure way (i.e., user authentication, transport level security) to communicate with EHRs and other health information technology (IT) systems. Ideally these devices would exchange information in a bidirectional way with the EHRs providing for orders and configuration to flow from the EHRs and results and configuration revisions (including patient assignment) to flow from the device.

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

Any device that does not synchronize (sync) data directly into the EHR is a barrier and potential safety issue because data could be delayed in entry to the EHR or incorrect data could be stored. The flow of data from device to EHR should be spontaneous, effortless and 100% accurate as long as the patient identification is completed User friendly design for data entry and retrieval is also an important factor. The technology is available, however funding is a significant barrier. The education resources needed during implementation and staffing are other barriers. If these barriers could be resolved, we would be able to better leverage an organized process to acquire and implement the available healthcare devices which could result in improvement in wellness and health ultimately reducing cost and preventable hospitalizations. The process of manual entry of data derived from one device and entering it into another system is totally unacceptable and proven to result in erroneous, intentionally distorted or missing data.

Another key barrier is the reluctance and inability of users and clinicians to participate in standards activities. Often, they do not have the time available to participate in document development and reviews or attend standards committee meetings. As noted in a question #2 above, a liaison between the two would help in the development of a product that would meet the needs of both the end user (not impede workflow) and the leadership of the organization (seeking compliance with regulatory standards in care/delivery). This could decrease timelines for implementation.

A key barrier that is observed in effectively using health care devices to advance the health and wellness of Veterans is the timeliness and error resistance that seems to be lagging in implementing systems of networked medical devices. As more and more devices are networked to each other and with a centralized database, the complexity of these systems has increased. The complexity comes when multiple vendors and systems are implemented. This complexity has driven personnel within the VA to quickly learn how to successfully implement and support these systems as a whole.

From a standard-based interoperability stand-point a significant issue revolves around common standards that are implemented consistently. Medical devices use either proprietary protocols or standard-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 vendors devices into their enterprise.

Consistent adoption of standards including terminology would remove some of the barriers. Unlike information system, medical devices often undergo a longer product lifecycle, as 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.

VA medical centers are currently in the process of installing off-the-shelf clinical information systems from multiple different vendors. For certain telemedicine applications it has raised a rather complex and potentially costly issue of VA medical centers now being less able to share information and share resources between VISNs. In the current marketplace vendors have no incentive to make their information systems interoperable with other systems. There is actually a disincentive to do so because non-interoperable systems force an enterprise to continue to expand with one vendor versus being able to seriously consider other vendor's solutions. This has been an ongoing problem for many years in the

private sector, but it is now a challenge that the VA will also need to address as the multiple clinical implementation systems are installed in VA medical centers.

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?

I would have all devices use the same standards for output of data so that the interface with EHRs would be no more difficult than consumer product syncing is today. For example, I bought a new Bluetooth wireless keyboard for my laptop and syncing it took a matter of minutes. A contract did not have to be negotiated with the vendor of the device or the laptop vendor to have code written. It was quick, intuitive and accurate. It might be easiest for nurses if a barcode scanner could identify which device should sync with which patient record in the EHR. Ideally there would be device and vendor certification requirements so that the medical consumer would be assured that any device being marketed would pass interoperability standards. Currently the consumer has to have intuition to ask all the hidden tricks of the vendors about how their devices work, if you fail to ask the right question in just the right way you may get stuck with a device interface that doesn't work with your EHR. Less convoluted process of interfacing the available health care devices is necessary along with an increase in the financial and staffing resources. There are many clever employees that if given the resources could make a huge impact in the implementation and use of health care devices.

A magic wand would upgrade all the old, stand-alone devices to become networked and to be able to communicate with information system 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 as needed. Nurses would be notified by medical alarms only on those conditions that are truly dangerous for that patient.

A magic wand would also affect products under development to be built from the ground up on standard terminology.

The implementation of a test environment, separate from the healthcare setting but controlled by the VA, would ensure the system that is being implemented within the VA healthcare setting will in fact work. This environment will allow for authentication and verification of these systems ability to communicate to other systems. In turn, this will allow for a wider adoption of networked medical systems and more effective use by clinical staff within the VA.

Also, consistent use of human factors principles and usability testing in the design of user oriented displays and operating controls by the device manufacturers is necessary.

Finally, manufacturers should include standards based Real Time Location System (RTLS) technology internal to their devices so that users would not have to apply external tags and deal with the operational problems and costs associated with regular battery replacements and tag replacements when they come off.

<u>Provider Panel:</u>

8. What data about devices is needed in EHRs?

a. **Devices that are prescribed, implanted, or become part of the care record** – device type, model, manufacturer, Unique Device Identifier, alarm events, prescribed settings, Model #, HL7 links, network name, local name (IP Address), manufacturer, serial #.

b. **Devices that transmit or record data used in the EHR** – device type, model, manufacturer, time, device settings for the patient, alarms, Vendor, HL7 codes, alarms, parameters, verification/ time stamp of transmit, manufacturer.

9. Questions related to Meaningful Use.

a. How would device data in EHRs affect Stage 1 measures?
All data related to ventilators (Ventilator Acquire Pneumonia Bundle), IV lines (Blood Stream Infection Bundle), falls, hemodynamic status, rapid response advisories, alarms, education, restraints, IV medications, predictive trends, labs and mental status.

Medical device data is not explicitly referenced in Stage 1. Medical Device data would be indistinguishable from user-entered data in the EHRs. The National Institute of Standards and Technology (NIST) approved Test Methods for Stage 1 (http://healthcare.nist.gov/use_testing/effective_requirements.html) do not require medical device data export or import in the same way that it requires laboratory results and ePrescriptions, but medical devices will contribute to the discharge summaries, clinical decision support, patient summaries, and other requirements explicit in Stage 1.

b. What device-related patient safety and/or quality issues should be measured or reported?
Key issues to report include any data associated with the wrong patient, data corruption, delays in data transmission, mislabeled data, and data expected but missing from the EHR.

From a technical stand-point, it would be beneficial if medical devices were capable of sophisticated self-diagnostic to alert the operator when specific hardware or software is unstable or on the verge of failing. Interoperable medical devices may be able to alert the operator if the firmware version is too old and an upgrade is needed, for instance, to address specific defects or enhanced capabilities.

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

There is no real impact right now but it may be a precursor. The rule simply recognizes that the Medical Device Data System (MDDS) is a device or [device+device manager] system capable of exchanging information with other system. It identifies some basic requirements for medical device integration.
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.

Medical device data consist of numerical or other information available from a medical device in a form suitable for processing by computer. This data can represent many types of information (e.g., clinical values, alarm conditions, error messages). MDDS are not intended or designed to provide any real time, active, or online patient monitoring functions. Medical device data systems can deliver and store alarm data but do not have the capability to display, create, or detect alarm conditions, or to actually sound an

alarm. In particular, a MDDS can record the fact that an alarm sounded, but cannot by itself sound an alarm in response to patient information. Medical device data systems cannot create alarms that are not already present from the connected medical devices. By themselves, MDDS do not provide any diagnostic or clinical decision making functions. Medical device data systems can transmit, exchange, store, or retrieve data in its original format or can be used to convert the medical device data from one format to another so that the arrangement or organization of the medical device data is in accordance with preset specifications

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

VA currently provides care to 48,000 Veteran patients using home telehealth technologies. Home telehealth technologies receive vital sign and disease management data from the home. These data are used by VA care coordinators to help patients self-manage chronic conditions. No comprehensive set of standards is in place to systematize the way in which these data items are acquired and communicated from the home to electronic health record systems. This situation provides an impediment to the growth of home telehealth networks and has both cost and quality implications for this emerging field of health care, both within and outside VA.

VHA has been addressing this issue. Multiple vendor products are available to receive this type of data. The Telehealth Program is in the process of HL7 integration of the data collected by the various telehealth vendor applications. - this is 90% complete. This data populates Veterans Health Information Systems and Technology Architecture VA Information System Technology Architecture (VistA), and then is written into Computerized Patient Record System (CPRS). According to a local telehealth supervisor, the automatic download had to be turned off currently as all sites integrate their data. After all sites in the VHA have integration capabilities, the automatic downloads will be retested and turned back on.

All vendors for telehealth are held accountable to adhere to disease management protocols.

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

Devices are interrogated as recommended by regulatory agencies. The facility is responsible to collaborate with the vendor/manufacturer to ensure proper function and use. This should be addressed through national policy, standards and procedure for implementation.

The device classification (class I, II, or III) does not make a great deal of difference in terms of integration. The same level of rigor of precision should be allowed for any type of device. The precision of the measurement and any other information should be captured as well.

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

Databases to maintain and track devices must be in place in order to trace if warnings or recalls occur.

Right now devices have many, ad-hoc identifiers issued by multiple authorities. The key to a unique identifier is to have a well-defined scheme and a consistent policy. There are many standards ready for adoption but only the FDA has the authority to promote the adoption of these standards in a consistent way such that adverse events could be traced to a specific medical device. UDI holds a lot of promise to bring order to a very chaotic environment.

The medical device is used to associate a patient with their devices and eventually with the data those devices send to the information systems including the EHRS. Behind the scenes the medical device id sent by the device interface enable the association between device data and the patient's record.

> ***a. In supply chain management and other management processes.***
> Acquisitions and Materials Management is responsible for these processes. Serial numbers or other identifiers are linked to an identified service that is contacted when a question arises.

A significant problem is that each assigning authority (e.g. vendors, wholesalers, providers) assigns new identifiers. The only relationship to Unrestricted Device Interface (UDI) is that they will be replaced by it. Since only the device identifier provided by the vendor is available through the device interface (rather than a provider's or wholesaler's inventory number) the manufacturer id is the most relevant for interoperability. UDI is intended to be implemented by vendors using an identifier root assigned by Food and Drug Administration (FDA) and will have a positive impact on device interoperability. The identifier will be available through the interface, bar code for inventory control, and even (Radio Frequency Identification Device (RFID) and be consistent and traceable to a manufacturer's lot number.

b. In safety processes including identification of recalled implanted devices.
A recall is immediately reported to and coordinated by Patient Safety and Acquisition and Materials Management. The devices are immediately taken out of use if external to the patient. Implant devices such as pacemakers or intracardiac defibrillators (ICD) are replaced. Each facility has a recall process in place.

Standards for identification have not been adopted by the industry. The main issue with improper identification of devices is that adverse reports cannot be traced to a specific device. The device id is not related to how patients identifiers are assigned but the device id and patient id are used in establishing which devices are monitoring or supporting a patient and thus associating their data output with the patient's record.

All implanted and in-inventory devices need to be registered in the VHA Implant Database system that is being developed so that information can be accessed by the Product Recall Office and other offices and disseminated to the appropriate clinicians and patients.