HIT Standards Committee
Clinical Operations Workgroup
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Identification of Barriers and Enablers for Device Interoperability - Provider Panel

Introduction:

Intermountain Healthcare has been formally collecting and storing patient information from medical devices into its electronic medical record (EHR) for over 23 years. However, initial work to collect some patient vital signs data from cathlabs started in the late 1960s. Initially, patient vitals data from bedside monitors were collected and then data from ventilators, infusion pumps, blood gas analyzers, pulmonary function machines and enteral feeding pumps were added. We are currently working on collecting data from a number of other medical devices. Numerous different programs have been developed to facilitate the display of this data to clinicians at the bedside or at their homes. We also use the data from medical devices for clinical decision support programs and to generate alerts to improve patient care. Some of these programs include computerized surveillance to identify adverse drug events, enhanced notification of ventilator disconnections and alerts for infusion pump programming errors; each of these programs have been shown to improve patient care[1][2][3].

Software/Language Interface Standards:

One of the main problems we have experienced collecting patient data from medical devices is based on the fact that we have had to create some unique middle layer software for each different device we connect to. This is due to the fact that there are currently no standard interfaces being used by the medical device manufactures. Standards for output port types, data protocols, and frequency and methods of acquiring data would be helpful. Also, there are no language standards. Devices might have textual or coded data. The textual formats may be unique or use a "standard" such as HL7 or XML. But, HL7 varies depending upon interpretation by manufacturer and the parameter names are left up to the manufacturer. XML is also usually unique to the manufacturer, but an XML output and input standard might be the best way to exchange the data since there are numerous xml parsing tools that are open source software.

Also, a common data language or data dictionary would be helpful, but this has been tried before with little success. And different devices might send out similar but different data that might use the same code, which leads to confusion later. Over 20 years ago the IEEE P1073 Medical Information Bus (MIB) was developed to provide vendor-independent interconnection and interoperability of medical devices and computer systems. The MIB utilizes an ISO/OSI-compatible layered network architecture. The primary focus was on the acute care environment at the patient's bedside, particularly in intensive-care areas. However, the MIB is suitable for use

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[1] Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized surveillance of adverse drug events in hospital patients. JAMA 1991;266:2847-2851.
[2] Evans RS, Johnson KV, Flint VB, Kinder AT, Lyon CR, Hawley WL, Vawdrey DK, Thomsen GE. Enhanced Notification of Critical Ventilator Events. J Am Med Assoc 2005;12:589-95.
[3] Evans RS, Carlson R, Johnson KV, Palmer, Lloyd JF. Enhanced Notification of Infusion Pump Programming Errors. Stud Health Technol Inform 2010;160(Pt 1):734-8.

in other areas, such as the operating room or the general ward, and for interfacing to any general medical device for simple data communication and control purposes. The proposed standard provides for a specialized local area network between one or more groupings of medical devices and EHRs. However, the IEEE P1073 standard never took hold due to the fact that the manufacturers stated that its use would result in a major increase in the cost for each medical device.

Hardware Interface Standards:
The USB, Ethernet and RS232 (25 or 9 pin) standards have been helpful in collecting the device data. These standards have greatly facilitated getting the device data to a PC or a database where it can be stored, retrieved and analyzed. In recent years, some device manufacturers have been collecting the data from their devices on a gateway. In that case we have been able to connect to a network socket as a client or server and read the data from a queue on the gateway. We can either poll for the data or sometimes it is sent at a specific frequency.

Another barrier is that some devices can only send a subset of their data and some cannot send any data. Most devices today are electronic and should all have the capability of outputting data to another system. Some of the older devices do not have RS232 ports, thus, there is no way to collect their data. For a number of years, Intermountain Healthcare has only purchased devices that we can connect to.

One change that would enable more effective and widespread use of medical device data would include the use of wireless and/or cellular interfaces. This would be a great way to receive <u>and</u> send data to medical devices. The catch there is in being able to associate a given device with a specific patient so we would know who to store the data on and then an easy way to disassociate the device from the patient.

Data Storage:
Getting the data is often the easy part, deciding where, how, what form and how much to store is always a question we've had to determine for each device. Then, determining how best to use the data can be a challenge, but also the most exciting part.

Data from any type of medical device, even implanted devices, should be stored into the EHR. Just which data and how much is debatable. In addition to the patient identification and data collected by the device, we also need to know what the device is, ventilator, monitor, infusion pump, etc, and also the brand and serial number. Not only should each device have a bar code for easy and fast manual identification but that same data should be electronically sent out from the device. It would also be nice if each device had a radio frequency ID so we could also know where it is located at any given time or where it has been. This information could then be linked to medical device specific databases that would store data such as repair histories, recalls, previous location logs that could be used to track possible infection transmission, billing data and supply chain management. The new cellular technology also offers a great way to automatically collect data from medical devices used in the home or other settings outside of a healthcare facility.

Meaningful Use:
There are a number of objectives in the Meaningful Use Stage 1 regulation where medical device data will improve the process. Patient vital signs can be either hand entered into EHRs or automatically collected from medical devices. The need to record patient blood pressure in the EHR for more than 50% of patients is an example. Also, the capability to electronically exchange key clinical information among providers and patient-authorized entities may include data collected from medical devices. Based on the definition of laboratory analyzers as medical devices, the storage of clinical laboratory test results into EHRs as structured data will also be required. A summary of care record for patients referred or transitioned to another provider or setting will probably contain patient vital signs information which may have been collected from a medical device. Likewise, providing patients with timely electronic access to their health information (including laboratory results) would fall into this category. Thus, automatic collection and storage of medical device data in EHRs will improve and facilitate the ability for many healthcare entities to meet Meaningful Use.

MDDS Definition:
The FDA's new MDDS rule defines a medical device data system (MDDS) in simple text as "only communicates medical device data" or "to act as a communication conduit through which medical device data can be transmitted". However, the formal definition is a little more inclusive, "An MDDS is a device that is intended to transfer, store, convert from one format to another according to preset specifications, or display medical device data". The FDA considers medical device data to be any electronic medical data that is available directly from a medical device that was "obtained originally" from a medical device. Thus, one of the main questions has been just what software is MDDS? Software that only collects data from the medical device or that displays that data is obvious candidates. Also, are laboratory analyzers medical devices? While the FDA states that laboratory information systems (LIS) do not meet the MDDS definition, programs that do collect data from the LIS that was "originally" from laboratory analyzers and transmits that data to the EMR probably would be since most laboratory data come from laboratory analyzers. Some systems like CPOE do not meet the FDA's definition of MDDS along with other software that are intended to be used for active patient monitoring (or decision support). The good news is that the FDA has changed MDDS from being classified in the default class III (premarket approval) to class I (general controls). However, this will still require manufacturers of MDDS to comply with new regulation. They must: 1) register and list their MDDS, 2) they must adhere to the FDA's Quality Systems Regulation (QSR) which requires manufacturers to adhere to specific minimum guidelines to assure the quality and consistency of products and 3) report any adverse events associated with their MDDS. A big question is just how much time and cost will be needed for hospitals or healthcare systems that qualify as manufacturers of MDDS to meet this regulation. Intermountain Healthcare is currently looking into how much time and money it will take to meet this regulation and also trying to identify the numerous programs that may fall into MDDS that will need to be registered. Intermountain Healthcare's CMO has taken on this task and has created a team than is already in the process to make sure that we are in compliance of the new regulation. Reporting adverse events associated from MDDS seems logical and can be used to improve patient care. The main question is how does this affect, with adherence to the FDA's QSR, the development and updating of MDDS and especially the ability to install any new or updated software in a timely manner.