Medical Device Deliberations: Data Issues to Consider When Purchasing and Implementing New Devices

By Beth Acker, RHIA

The term “medical device” covers a wide range of health or medical instruments used to treat, mitigate, diagnose, or prevent a disease or abnormal physical condition. Virtually every care setting captures data from medical devices, including vital signs, blood analysis, ventilator management, fluid management, and even x-rays.

As organizations transition to electronic health records (EHRs), they should address several key points when considering new medical devices and the processes for integrating and storing the data they produce.

Device Functionality and Storage Requirements

Often, departments within an organization have differing interests regarding medical device functionality. Therefore, a cross-functional team should evaluate medical devices prior to purchasing them. The team should include representation from clinical, technical (such as biomedical technicians), IT, HIM, privacy, security, and legal staff.

After an organization chooses a medical device, the team must consider how much of the data it generates should be saved. Data are often stored on the device itself, and most EHR systems have an interface to integrate data from separate devices. The interface allows data to be added directly into the patient record. If no interface exists, data must be transferred into the EHR system manually.

The team can consider the following technical questions when determining what data to save:

- What data are captured and stored in the device?
- What data should be brought into the EHR system?
- Is a summary of the data transferred, or is every individual piece of data transferred?
- Were the data manually captured before a device existed? If so, at what intervals were they captured?
- How long should data be retained?
- If the device does not interface with the EHR system, how will the data be handled, stored, and retrieved?

For example, vital sign monitors capture a significant amount of data, and typically not all of it is reviewed. Organizations must consider if:

- The IT system can support the additional data
- The system’s performance suffers due to the increased volume
- The volume of information is so overwhelming a clinician would never look at it

Capturing information from vital sign monitors can also bring up questions of liability. For example, if there is a drastic change in vital signs that goes unnoticed by the clinician yet is captured by the device, is the clinician or hospital liable?

Or what if an organization requires that vital sign and EKG data are integrated every 15 minutes, and somewhere in the middle of this interval the patient goes into cardiac arrest? How is that data captured in the legal health record? Do staff make a manual entry in the record that accompanies the automated upload?

These are the types of questions that organizations must consider when purchasing and implementing new medical devices.

Authentication and Attestation

The above examples are not solely about data capture; they also describe the challenge of data authentication when an important patient event occurs and how that information is used by the clinician.

The terminology used for authentication and attestation has blurred the line between the technical standard environment and HIM policy. HIM traditionally uses authentication as a synonym for an electronic signature. Technical and standards communities, both in the United States and abroad, define authentication as user identification within a system.

Therefore, it is important to consider if the medical device has an electronic signature capability. If the device does not, entities should consider the following:

- Is there a method for ensuring data cannot be changed once completed?
- Does the data captured require clinician interpretation? If so, is the interpretation electronically signed? If not, can the information be identified as complete and unchanged?
- Does the data automatically upload to the EHR once marked complete, or is there another individual responsible for uploading the data, such as a nurse, technician, physician, or transcriptionist?

HIM Policy Considerations

HIM managers must know what data are being used for clinical decision making and what is being documented. HIM managers must have a role in defining policy, detailing what data require a signature and what data do not.

It is also important to note in HIM policy, in cases where clinical data without an electronic signature exist, what measures will ensure that data integrity cannot be compromised once documentation is considered complete. Questions to consider include:

- Where is the correction made—in the device or in the EHR?
- Who is authorized to make the correction?
- If data have to be deleted from the device or the EHR, will they be archived in case they are needed for a tort claim or other purpose?
- What data source (device or EHR) will constitute the legal health record?
- How long must an organization retain the data in the device? If the data in the device is the organization's legal health record source, what is the legal retention period for health records?
- What happens if the contract with the device manufacturer ends before the legal retention period expires?

Currently, many medical devices that capture images "burn" the patient identification information into the image before it is downloaded to a healthcare system's EHR. However, problems can arise should incorrect patient information be attached to an image and it no longer resides on the device.

The only method for correcting the error is to print the image, obliterate the incorrect patient information, append the correct information, and then rescan the image. This typically reduces image quality and makes the image no longer useful for diagnostic purposes. The only other solution is to have the patient undergo the test again and ensure the patient identification is correct.

This scenario illustrates the importance of having a quality review process in place for all device capture data and the need for technical tools to edit patient information without altering image quality.

Choosing and integrating medical devices requires a group effort between clinical and biomedical staff, HIM, and other areas that use external devices to capture clinical data. Knowing what to look for and what to ask will help the team make an informed decision about what should be included in contracts for commercial devices and what must be written into local policy to help meet all requirements.

Common Clinical Procedures That Use Medical Devices

- Bronchoscopy
- Cardiac catheterization
- Colonoscopy

- Computed tomography (CT)
- Dermatology
- Echocardiogram (ECHO)
- Electrocardiogram (ECG)
- Electroencephalogram (EEG)
- Electromechanical dissociation (EMD)
- Electromyography (EMG)
- Electrophysiology (EP)
- Endoscopic retrograde cholangiopancreatography (ERCP)
- Endoscopy
- Esophagogastroduodenoscopy (EGD)
- Fetal monitoring
- Hemodialysis
- Hemodynamics
- Holter
- Magnetic resonance imaging (MRI)
- Paracentesis
- Positron emission tomography (PET)
- Pulmonary function test (PFT)
- Respiratory care
- Sigmoidoscopy
- Sleep monitoring
- Stress testing
- Ultrasound
- Vital signs monitor (VSM)

Beth Acker (beth.acker@med.va.gov) is an HIM specialist at the Department of Veterans Affairs in Cantonment, FL.

Article citation:
Acker, Beth A.. "Medical Device Deliberations: Data Issues to Consider When Purchasing and Implementing New Devices" *Journal of AHIMA* 80, no.11 (November 2009): 54-55.