**Integrating Medical Devices with Clinical Documentation Systems:**

**A Quick-Start Guide**

*Developed by the HIMSS Medical Devices Patient Safety Task Force*


**Introduction**

This guide is designed to provide points of reference and consideration for the purchase and implementation of a clinical documentation system (CDS) that integrates with networked medical device systems. Since there is no one-size-fits-all system, this guide should be treated as a reference document to assist the institution in making an investment decision. This guide is intended for healthcare professionals who are responsible for technology management within their organizations and are considering the purchase or upgrade of a CDS with the added feature of medical device integration.

**Step 1: Create the Team and Pool the Knowledge**

It is strongly recommended that the following professionals be included in the project team to provide the core knowledge necessary to produce a complete and effective analysis of system requirements:

- IT professionals who have an intimate knowledge of the institution’s clinical systems, including strategic leadership and technical expertise.
- Clinical engineering professionals\(^1\) who possess a sound knowledge of the strategic planning and technical operation of the institution’s existing medical device inventory.
- Clinical users of the technology.
- Physician leadership.
- Healthcare risk managers.

The team should already be comfortable with principles of healthcare technology management (HTM), including:

- Knowledge of standard purchase/evaluation techniques for complex technical systems:
  - Technology, business and clinical assessment, including identification of skills and/or personnel required to use and support the system. Analysis of what training will be required to use and support the system.
  - Product and market evaluation.
- Key components of a CDS before medical device integration:
- Access to patient demographic information, including problem list.
- Ability to order tests, procedures or drugs.
- Access to/input of clinical and patient notes.
- Access to test results.
- Electronic clinical decision support and clinical guidelines.
- Electronic communication.
- Patient support materials.
- Billing.

- Knowledge and experience with quality and risk management tools used to supervise healthcare technology systems, such as:
  - Change management protocols.
  - RASCI (Responsible, Accountable, Supportive, Consulted, Informed) modeling.\(^2\)
  - Healthcare Failure Modes and Effects Analysis (HFMEA)\(^3\), (reference 80001-1 section below).
  - Root-cause analysis.
  - Security.
  - Disaster management.

**Step 2: Create Goals and Objectives Together**

It is important that the team creates a common foundation from which to spring into action. Together, defining the goals and objectives for the new system will produce a more complete set of requirements. Metrics to measure development between the start and end points of the project are essential when communicating progress to oversight committees and administration.

Also, creating goals and objectives for the team will help generate synergistic working relationships that will carry on well after implementation.

To aid in these discussions, team members may want to consider sharing as much evidence-based information as possible (adverse event reports where such integration may have prevented the occurrences; management analyses showing opportunities to improve efficiency in documentation while giving front-line clinicians more time with the patient; personal experience with integrated systems, etc.). The more evidence available to demonstrate the stakeholders’ needs the better to generate dialogue among team members.

**Step 3: Review Relevant Current National and International Programs**

**ARRA and Certification of Electronic Healthcare Records**

The American Recovery and Reinvestment Act of 2009 (ARRA) was passed in February 2009, with several provisions for improving the national healthcare system. Some of those relating to clinical documentation systems and/or medical devices include\(^4\):

**Understanding “Meaningful Use” of an Electronic Healthcare Record**
ARRA authorizes the Centers for Medicare & Medicaid Services (CMS) to provide a reimbursement incentive for physician and hospital providers who have become “meaningful users” of an electronic health record (EHR). These incentive payments begin in 2011 and gradually phase out. By 2015, providers are expected to have adopted and be actively utilizing an EHR in compliance with the “meaningful use” definition or they will be subject to financial penalties under Medicare.
The Office of the National Coordinator (ONC) HIT Policy Committee recommends that the ultimate goal of meaningful use of an EHR is to enable significant and measurable improvements in population health through a transformed delivery system. The ultimate vision is one in which all patients are fully engaged in their healthcare, providers have real-time access to all medical information and tools to help ensure the quality and safety of the care provided while also affording improved access and elimination of healthcare disparities.

The recommended definition of meaningful use will depend on the healthcare setting in which it is employed. Thus, some features and capabilities will be recommended as required in an ambulatory setting before similar functions are expected to be widely used in the hospital. This reflects both the availability of the technology in these different settings, as well as the potential impact of these features on the health of the population served. Although some recommended measures used to assess meaningful use in 2011 may apply to specific chronic diseases, the recommended 2011 objectives are meant to establish a foundation for affecting a more comprehensive set of health outcomes in the future.

In identifying potential criteria for meaningful use of an EHR, it became apparent that there are considerable gaps in EHR-generated measures available to monitor desired policy outcomes, (e.g., efficiency, patient safety, care coordination). While these measures will not be required for Medicare and Medicaid incentive payments until 2013, feedback is being sought on how to best frame these measures, including measurement of key public health conditions, measuring healthcare efficiency, and measuring the avoidance of certain adverse events. These comments will be used to help revise the recommended measurement strategy to include more extensive and refined outcome measures for meaningful use in 2013 and beyond.

ONC’s working draft of “Meaningful Use” includes the following inclusions of medical devices:

1. Health Outcomes Policy Priorities
   - **2013 Objectives Goal**: “To guide and support care processes and care coordination.”
   - Upload data from home monitoring devices [OP].
   - **2013 Objectives**: Specialists report to relevant external disease (e.g., cardiology, thoracic surgery, cancer) or device registries, approved by CMS [EP, IP].
   - **2013 Measures**: Implement ability to incorporate data uploaded from home monitoring devices [EP].

2. **2015 Objectives Goal**: To achieve and improve performance and support care processes and key health system outcomes.
   - Medical device interoperability.

Be mindful of the time-frame, begin considering evaluation and purchase in 2011 and implementation in 2012-13, based on the institution’s procedure to request funding.

The ONC maintains a Web site portal where one can find updates on the current definition of meaningful use.5.

**Certification of EHRs**

Use of a certified EHR is required to meet the definition of meaningful use. The definition of meaningful use is currently in draft form, with the interim final rule expected December 2009. A provider or hospital must show use of a certified EHR as part of the process to qualify for incentive
payments. The Department of Health and Human Services is currently developing a plan to determine the process for organizations to be considered certifying bodies, such as the Certification Commission for Health Information Technology (CCHIT).

There are several reasons to implement a certified EHR as part of a clinical documentation system. We recommend that the project team review the current description found at http://www.cchit.org/certify/inpatient/index.asp as an example. Note that CCHIT certification does not include usability in the current certification criteria. There is some discussion to include usability in the future, but a scope or timeline was not made public at the time this guide was published. With or without a certifiable usability criteria, the institution is strongly advised to closely evaluate the available systems and determine the best fit to the desired workflow.

Keep in mind that a certified EHR does not need to follow any standardized structure for integrating medical devices at this time, but there are many groups working on open standards/protocols.

**IEC (International Electrotechnical Commission) 80001-1**

IEC 80001-1 is a proposed standard around risk management for medical networks on how to perform a system-level risk analysis. Due to be ratified in 2010, it proposes the following risk management activities:

- Identify the medical IT risk management function with multi-disciplinary expertise and authority to carry out the risk management functions.
- A multidisciplinary team should take responsibility for technology procurement, integration/deployment, and maintenance.
- Identify an IT integration risk manager. There is some international discussion about the new role of clinical systems engineer that could fulfill this requirement.
- Define "lifecycle process for risk management" of IT networks that incorporate medical devices.
- A project should be initiated with requirements and a project plan, followed by risk analysis, evaluation and control, ending in residual risk evaluation and approval.
- These tasks should be performed proactively, before systems/applications are brought online.
- Follow-on monitoring of these networks, ensuring the risk control measures are effective and that no new hazards have been introduced due to unmanaged changes to the network.
- A minimal set of documents must be produced and managed. These include responsibility agreements and an IT-network risk management file.
- Invoke HFMEA.

**FDA Sentinel Initiative**

A long-term effort by the Food and Drug Administration (FDA) to create a national electronic system for monitoring medical product safety. 6

**The Joint Commission Sentinel Event Alert No. 42**

On Dec. 11, 2008, The Joint Commission released a sentinel event alert concerning the safe implementation of information and converging technologies such as medical devices 7. An awareness of the unintended consequences from the use of health IT is discussed in this alert.

**IHE PCD**

The Patient Care Devices domain of Integrating the Healthcare Enterprise (IHE) is concerned with developing the technical framework for the integration and cross-communication of medical devices. 8
The goals and objectives of the IHE PCD domain are to:

- Improve patient safety and clinical efficacy.
- Reduce healthcare delivery cost by improving efficiency, reliability and operational flexibility for healthcare providers.
- Enable innovative patient care capabilities.
- Expand the international marketplace for patient care device vendors.

**Home Healthcare/Telemedicine**

Telemedicine technologies are advancing rapidly and many healthcare systems now include a home health or telehealth program as part of the services offered. The American Telemedicine Association maintains a list of clinical guidelines for use in implementing remote monitoring programs. Some relative points of interest include:

- The healthcare provider should clarify the inclusion of remotely acquired data in the CDS.
- The technology will allow both manual and computer-based analyses of collected data.

The Continua Health Alliance was created to bring clinicians and industry together to develop a common framework for personal telehealth device integration.

**Step 4: Define Typical Clinical Workflow Patterns**

Each hospital system adopts common guidelines, but they often do so in a manner unique to their institution. This is based on variables such as staffing levels, technical resources and environmental factors (design of the patient floor, for example). These variables can then influence the way in which a task is completed, whether it be fulfilling a medication request or completing a pre-op evaluation. Clinical workflows can then be very different between different hospitals in the same healthcare system and even different specialties in the same hospital. By nature, a clinical documentation system is an intimate part of a clinical workflow as are the medical devices used to monitor and sustain patients. Therefore, it is important to define the key aspects of the clinical workflow of the project team’s institution and use that to carefully evaluate CDS options and the integration methods.

The project team should consider interviewing and observing frontline clinicians to identify key aspects to the clinical workflow, looking closely at processes related to:

- Medication administration.
- Vital signs charting.
- Ordering of tests or labs.
- Activity levels on different days (weekday vs. weeknight) and different times (night shift vs. day shift).
- Activity level differences between low census/slow day and high census/busy day.

The project team can identify inefficiencies that can be streamlined with the integrated CDS and propose new clinical processes.

It will be helpful to record these processes as “typical scenarios” of everyday clinical life. Then, the project team has a viable description of the desired clinical workflow patterns, which can then be used to evaluate the CDS products and device integration methods.

These scenarios also can be useful when performing initial, pre-purchase risk analysis, such as an HFMEA or a RASCI model. Things to consider during the risk analysis:

- If the integrated medical device goes offline;
- if the integrated medical device is moved to another location;
- what mechanisms need to be in place when the CDS is brought offline for regular maintenance; and
- what procedures should be put in place to review and accept recorded data.
Other important points to consider while examining the clinical processes
- Important that the team realizes that integration is not simply a plug-and-play solution.
- Refer back to the goals and objectives of the project in an effort to manage the scope.
- Keep the measurement metrics up-to-date so that the team has a common point of reference regarding the progress of the project.

At the end, a solid list of clinical requirements can be constructed based on the information collected during workflow analysis. These clinical requirements should be reviewed by frontline physician and nursing representatives for buy-in. This buy-in will be critical when the time comes to implement the system.

**Step 5: Understand the Complexity of Medical Device Integration**

The project team should be comfortable with the basic pieces of CDS-medical device integration. A working group of the CEIT Collaboration initiative\(^\text{11}\) developed a comprehensive integration matrix that can assist with organizing the technical scope of device integration.

- The project team should consider the use of the standards-based approach and consider the benefits and the adversities (interoperability, reliability, best-of-breed, future flexibility, etc.).
- Some vendors use medical function codes (MFC) or medical data codes to link the exported data to a CDS. Therefore, it is important to know how these fields match potential CDS products.

Many vendors subscribe wholly or in part to commonly accepted technical frameworks from groups like IHE PCD and Continua. The project team should investigate the level of adoption of the framework to fully understand the level of open interoperability and how a vendor’s product is able to interface with a CDS or vice versa. In particular, it will be important to understand what additional hardware or software will be required to complete the integration.

As a CDS integration plan has an important software-hardware relationship, the project team may want to investigate the methods in which the integrated system addresses the following:

- Software/interface.
- Fault tolerance.
- Able to store and forward acquired data.
- Manage internal data in the event of power loss.
- Formats data to industry standards (MFC codes).
- Support different network connections via wireless, Ethernet, serial, etc.
- Easy software/firmware upgrade process.
- Standardized IP connectivity.

- Hardware
  - Standardized connectivity.
  - Internal battery backup/supply (power loss or patient transport).
  - Able to integrate with other devices if needed.

- Overall System
  - Manufacturing vendor agnostic.
  - Remote connection application agnostic.
  - Integration testing beyond your EHR vendor.

- Security
  - Overall system’s inclusion in the hospital’s security program including centrally-managed notification of available updates/patches, vulnerabilities and breaches, with manufacturers’ published guidelines.
- Physical location of system components—determine which can be protected by placing in a restricted-access area.
- Medical devices left unattended—determine security measures necessary to protect patient information.
- Determine security administration tasks and how those are separate from, but still coordinated with system operation, management and maintenance functions. Determine if a separate human resource is required to fulfill these tasks.
- Identify configurable audit logs/trails that can record system access.

**Step 6: Consider Support Models for Post-Implementation**

An integrated CDS is complex and requires a high level of clinical and technical support. The project team will need to consider the following when developing the system’s support model:

**Training**
- Clinical and technical.
- Level of participation/direction from vendor.
- Level of in-house participation/direction.
- Amount of desktop and hands-on training necessary before go-live.
- Method to evaluate competency after training.
- Decision if retraining/recertification of staff is necessary after a certain period of time (one year, five years, only after major upgrade, etc.)
- What percentage of staff must be trained before go-live can begin.
- Create requirements for permanent resources that are necessary to support this training program.

**Implementation Support**
- Level of ‘at-the-elbow’ support from the vendors at go-live and after.
- Need for additional consultants (clinical, project management, IT, CE, etc.)
- Decide how to define when the implementation is complete.
- Define roll-back strategies should the implementation incur irresolvable problems and the system needs to be taken offline.

**Post-Implementation/‘Operationalizing’ the System**
- Level of technical support needs to be in-house and how it is provided.
- New employees.
- Contract third-party support.
- Service level agreement with vendors—important to review these agreements to understand what is covered and what is not. With an integrated system, the vendors should clearly define the confines of their support.

**Lessons Learned**

As previously mentioned, The Joint Commission Sentinel Event Alert No. 42 is a valuable resource for understanding unintended consequences of health IT. Additional examples of lessons learned include the following:
### Human Factors Mishap Story

| **Where’s my Zero?** In a clinical simulation of a [vendor] pump, the user (nurse) expected the ‘zero’ to be under the 8, but it was off to the side instead. The user pressed 8 instead of 0 several times, mis-programming the pump. The user recognized the error when they hit a dosing limit and reprogrammed carefully, but errors crept back later in the simulation when the user wasn’t paying as close attention. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Users have a hardwired expectation for numeric keypads. Supplier swears that moving the zero has improved safety because the zero is no longer near the decimal point, reducing the potential for decimal errors. |

| **Bolus dosing.** Early versions of dose error reduction systems covered continuous infusion only, and in order to give a bolus, users had to crank the infusion rate up to a high level (999) and then turn it back down. If the clinician was distracted or pulled away before turning the rate down, a patient could be over-infused. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Several pump suppliers added the ability to program bolus doses in the drug library: hospitals select which drugs can allow bolusing and place limits on the size, duration and rate of the bolus (e.g., not too big, not too fast). |

| **Terminology.** Several earlier [vendor] PCA pumps asked for entries that were unfamiliar to nurses. For example, instead of letting the clinician set 1- or 4-hour dosing limits in terms of mg (a common practice), the pump asked the clinician to enter “# Bolus/Hour”, the total allowable number of boluses per hour. This confused users in a clinical simulation. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Newer [vendor] pumps use more standard terminology. |

| **User Interfaces, Pump Navigation.** Several earlier models of pumps with dose error reduction systems started up in rate/volume mode (i.e., with the safety software turned off) and required users to go hunting for the drug library. Older [vendor] pumps required pressing a key called “therapy.” Older [vendor] and [vendor] pumps had the library two to three menus in. Most users didn’t bother looking for the library, or couldn’t reliably find it if they looked. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Make it easy to do the right thing! Most newer pumps (and new software versions of older pumps) now either start up in the safety software (and allow the user to back out if the fluid they’re infusing isn’t in the library) or present the user with an equal choice at startup between entering the library and entering rate/volume mode. Use of drug libraries has increased due to this and other advancements. |

| **User Interfaces: Enter or Down?** Several pumps we’ve evaluated have a quirk: if the user enters data in a field and presses “enter” (or “confirm” or “yes,” depending on the model), the pump will jump to the next field and retain the entered data. But, if the user hits “down” instead, the pump will jump to the next field and erase the entered data (because it ‘wasn’t entered’). This resulted in a lot of data re-entry and confusion in a clinical simulation—several clinicians got to the end of programming only to find nothing there. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Many infusion pumps offer only two ways to leave a data field if it contains data: Infusion pumps now force users to either enter data in a field or clear that field before leaving to another field. |

| **User Interfaces: Reviewing/Confirming Settings.** Some older [vendor] and [vendor] ambulatory pumps didn’t require confirmation of settings before starting the pump: the [vendor] offered an optional review screen that could be accessed after programming, and many users didn’t bother to select this screen, starting the pump instead. The [vendor] pump scrolled through all settings after the user pressed ‘start,’ and many users didn’t stay the whole minute to view all settings as they ran by. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Most newer pumps require the user to view all entered settings on one screen (e.g., patient weight, dose, rate, time or VTBI) and confirm them before starting the pump. This confirmation screen is an important last chance to spot a programming error. |

| **Scanning Troubles.** Users reported that they couldn’t scan bar codes printed on wristbands of tiny pediatric patients—the wrists were too small and the codes were too curved. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Two solutions worked: some facilities printed codes perpendicular to the band (repeated at intervals), others bought wrist bands with little tags for the bar code. |

| **User Interfaces.** Several hospital members have complained about the navigation of their electronic ordering and documentation systems. We’ve heard all sorts of troubles, including too many or not enough choices on drop-downs or auto-text, too much or not enough free-text, can’t be read on my laptop/tablet/iPhone. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Different users and use environments may require different interfaces. Involve end-users when designing information systems that they’ll use, and have them try it out with the devices (PC, tablet, handheld, etc) they’ll be using with it. |

| **Scanning troubles-low contrast.** Some older prefilled fluid and medication bags had bar codes that identified their contents (great!) but these codes were printed in white ink on clear bags, rendering scanning impossible. |
| **Lessons or Best Practice or Mitigating Strategy** |
| Most fluid and medication suppliers have moved to higher-contrast printing, typically black or blue on clear bags. |
Conclusion

An integrated CDS will require focus and time and with proper preparation as suggested in “Integrating Medical Devices with Clinical Documentation Systems—A Quick-Start Guide”, the team will be better prepared to confront the various products that are rapidly finding their way to the market. As many new innovations are emerging at the same time the national government is revising the quality measures, the product evaluation might feel a bit like a moving target. This target will be easier to reach with a solid understanding of the institution’s needs and requirements, through the use of carefully developed clinical scenarios supported by a strong technical and clinical team.

6 FDA Sentinel Initiative http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm