Biomedical Device Interfacing to Clinical Information Systems: A Primer

Bridget Moorman

I am pleased that we get to take advantage of Bridget Moorman's background, experience, and perspective in this installment of IT World. One of the most nerve-racking tasks we run into these days is getting disparate medical devices to talk to each other over a network. This is especially so if the device you're trying to communicate with doesn't support network connectivity. Bridget shares her experience here not only with a great high-level view of network interfacing, but also with references to dig into all the grim details. She shows us a lot of facets to consider when assembling such a network. You've got to convert to hit the ramp then translate and aggregate before gaining access to the clinical information system cloud. If that doesn't make sense, read on!

—Jeff Kabachinski, IT World columnist

The scenario is familiar: A nurse manager walks into your office and says, "we could save a lot of dictation and transcription time, reduce charting errors, and possibly do decision support if only we could connect our medical devices to our clinical information system (CIS)." Or, perhaps the chief information officer has just read the latest report on device interoperability, which says now is the time to interface medical device information with electronic medical records (EMRs). Whether the bulk of the work falls to clinical engineering or information technology (IT), the challenges are the same. This article will help you identify what key things to consider if you are asked to plan and/or implement medical device interfacing to your CIS or EMR.

Figure 1 is a generic diagram for interfacing biomedical devices to a CIS. There are many interfaces to cross until the information actually resides in the CIS or EMR. The physiological information is acquired from the medical device. Then, depending on the device, that information needs to be configured for network interoperability with aggregation and reformatted into a data standard recognizable by the CIS/EMR. Along the way, a separate affiliation with either the Admit, Discharge, and Transfer (ADT) patient information system or some other patient identification function via bar-code or radio-frequency identification (RFID—not shown on the diagram) may be needed. Below are the key parts of this path.

Device Selection for Interfacing: Network Sentience and Identifying the Connection

What does a medical device provide for physical and data connections to a network, both physically and data-wise?

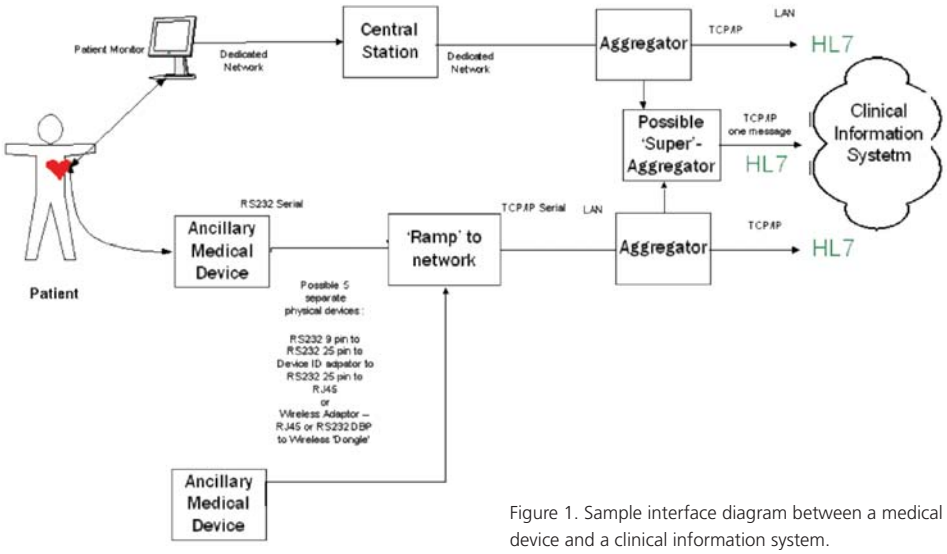

Figure 1. Sample interface diagram between a medical device and a clinical information system.

Checklist

As you begin to implement the integration process, the following checklist can help guide you through the steps needed to ensure a successful integration.

Network connectivity capability:
- Cat 5/RJ45
- DB9/DB25
- Wireless

Data type coming from device:
- Serial/proprietary
- IEEE 11073 (medical information bus)
- HL7, XML, etc.
- Manufacturer specification for data translation to IEEE 11073, HL7, etc.

Is the device part of separate network?
- Central station(s) aggregation
- Data type (HL7, XML) available from central station or aggregator and is it field modifiable to meet CIS data requests?

If the device is standalone or roaming, you need an integration broker:
- Does the broker have device identification mechanisms and translation capability (a driver) for your device and its data?
- How does this system provide the physical connector translation to the network?
  - Wireless dongle
  - Serial to RJ45
  - Other
- How does the system provide the device connection or ramp to the network?
  - Concentrator or terminal server for plug-in.
  - Access point (AP) for wireless or use of existing wireless infrastructure.
  - Is separate cabling necessary for the concentrator or AP to connect to the network?
  - What are the ramp's power requirements?
- Does this system offer an Admit, Discharge, and Transfer (ADT) interface or separate device identification interface?
  - Bar code recognition.
  - Patient ID validation mechanism; how does the validation scenario affect clinical workflow?
  - Where will the server with the integration broker reside and who will have access to monitor/modify the system?

Other tasks:
- Clinician identification of physiological parameters to be mapped to CIS/EMR.
- Service level agreement for system troubleshooting and maintenance.
- Possible test lab set up with medical devices and different types of integration brokers/aggregators to test system as well as interface to CIS/EMR.

Connection options include:
- Cat 5 or a RJ45 with general or isolated TCP/IP.
- DB9 or DB25, for RS232.
- A wireless port (bluetooth, 802.11x, etc.).

Determine if a dongle is required for the physical connection and how that is affected by the clinical environment. Once the network connection is made, how does that information get onto the network: a wireless access point (AP), terminal server, or concentrator (a ramp to the network)? What cabling is necessary? Where is the medical device located: is it part of a networked patient monitoring system, fixed, or roaming? Answers to these questions will determine which devices can be easily connected to the network and which require a separate infrastructure. Many versions and types of devices are not network sentient or plug-n-play. Most institutions can't afford to replace all devices that aren't network sentient, so a careful review of what devices will provide easy information capture and network connectivity is necessary.

Communication Standards

Unlike in the general IT industry, there currently are many healthcare-related communication standards for device interoperability that make it complex. From network standards to data standards, many conversions along the data path are necessary to provide the data that the CIS/EMR can ultimately use.

One of the more complex data and network paths is the following (see the glossary for definitions of terms): At the back of the device, an RS232 DB9 physical data port sends serial proprietary data, which then connects to a device identification (ID) adaptor/module or dongle (which provides the device type information for the aggregator) using a DB9 to DB 25 physical connector. This module or dongle then connects to network cabling using a DB25 to RJ45 physical connector and signal converter. The cable connects to a network ramp using an RJ45 connector. At the ramp, the serial data are converted to TCP/IP and then connect to the en-

terprise network. The data are then received by an aggregator, which translates the proprietary data to either XML or HL7 for resending to the interface broker for the CIS/EMR. Each interface represents a place where problems can occur.

Additionally, some standards are considered "loose" standards. For example, many devices have HL7 interface specification documents that describe which data elements in their proprietary serial data scheme map to fields in an HL7 message. How the data are formatted in the HL7 fields varies considerably among device vendors, even for the same type of device. This makes for interesting discussions between clinical engineers and CIS/EMR programmers. Moreover, each standard has different versions that need to match or be compatible with the version the receiving system uses. For example, HL7 version 2.x and HL7 version 3.x were not designed to be compatible. Standards and standards advocacy organizations are working to alleviate some of these issues. However, until there is further device development, including some of the network and data conversion functionality in the device, it will be incumbent upon you and your team to navigate the standards maze.

Aggregator or Super-Aggregator

The aggregator or super-aggregator receives all of the data from the different devices and reformats that data to send to the integration broker or CIS/EMR. This aggregator or super-aggregator is sometimes called middleware or an interface or integration broker. The aggregator has device drivers, which allow it to identify the device (the identity of which is appended to the data stream with the device ID module described above) and translate the serial data to HL7 or XML. As described above, the driver is unique to each device per the HL7 specification document. Depending on the type and version of device, you might need to develop a driver or wait for one to be developed by your interface solution vendor.

Also, the aggregator may provide archival or buffering of the device data if there is an issue with the network or CIS/EMR system. It is also at this point that any HL7 message modifications can be made for easier ingestion into the CIS/EMR. For example, bed labels or device type IDs could be standardized. Lastly, the output of the aggregator is usually the interface demarcation point for divisional and service responsibilities within an enterprise, i.e., all systems and interfaces on the device side of the HL7 message are typically biomedical engineering's responsibility, all systems and interfaces on the CIS/EMR side of the HL7 message are IT's responsibility.

Service Issues and Cost

The data path for medical device information to reside in a CIS/EMR usually crosses two different organizations' domains, making it imperative to have a clear service

Standards and Standard Advocacy Organizations

- IEEE 11073: replaced IEEE 1073, initially called the *Medical Information Bus*, is now called *Point of Care Medical Device Information* (www.ieee.org).
- IHE: Integrating the Healthcare Environment. Clinician- and healthcare-industry-driven initiative promoting vendor compliance to interface and interoperability standards. The Patient Care Devices Domain (PCD) covers interfaces between medical devices and CIS/EMRs (www.ihe.net).
- Continua Alliance: An alliance within the healthcare industry to market a mechanism to signify interoperability between certified products. Initial efforts are in the home healthcare and sport device arenas. (www.continuaalliance.org).
- MD PnP Program—Medical Device Plug N Play Interoperability Program, affiliated with the Center for Integration of Medicine and Innovative Technology (CIMIT), has sponsored a functional standard for the medical device to CIS/EMR interface called *Integrating the Clinical Environment* (ICE). This functional framework incorporates possible future feedback control loops and a more clinician-driven perspective to the interface (www.mdpnp.org).

Interface Product Vendors

- Philips: www.philips.com
- GE: www.gehealthcare.com

Non-Medical Device Vendors

- Sensitron: www.sensitron.net
- HCSTI: www.isirona.com
- Cerner: www.cerner.com
- CapsuleTech: www.capsuletech.com

Software Vendors

- WebReach Inc: www.mirthproject.org
- NeoTool: www.neotool.com

Hardware Vendor

- Digi International: www.digi.com

level agreement regarding service hand-offs. Generally the first indication of an interface issue is detected by the clinician—they don't see the device data in the CIS. Because the path is complex, the ability to isolate a problem to a specific location within the data path becomes important. Many devices do not indicate if any data are actually transmitting on their RS232 port. Having some sort of virtual centralized tool that can "walk" the data path to where the problem might be versus having someone physically do the "walking" will allow you to more easily service your side of the interface. It will also greatly simplify troubleshooting when interoperability becomes a requirement and ubiquitous across all clinical environments.

A general retail cost estimate to provide interfacing—if currently there is no device network sentience and you use a cabled approach—is $10,000 per bed for a roaming or fixed device. This amount includes hardware, software, and personnel costs to implement. These costs can be reduced if central monitoring or aggregated central monitoring HL7 functionality from the medical device vendor is used. However, the medical device vendors tend to have minimal flexibility for HL7 message editing. This does *not* include the costs associated with the CIS/EMR side of the interface, which will involve software configuration and physiological parameter mapping to a database field or charting module.

Summary and Advice

Unless there is a compelling strategic imperative within your organization, wait until devices are more network sentient and the standards in this interface area stabilize to begin implementation. The communication standards are still in a state of flux and dominant ones have yet to be established. This may be the time to set up a multidisciplinary team to identify what devices should be connected and what is expected in terms of data transfer, testing, service, and reliability. If your organization wishes to have this functionality, start interfacing with the networked medical devices systems, then graduate to the fixed non-networked and finally to the roaming devices. Additionally, set up a test lab in your facility to ensure that the connectivity path can be vetted and a system can be developed that will work in your institution. ■

Glossary

- **AP:** Access point—A device that connects wireless components to form a wireless network.
- **CIS:** Clinical information system—Information technology that is applied at the point of clinical care.
- **DB9; DB25:** A standardized physical interface for connecting equipment. DB9 has 9 pins, DB25 has 25 pins, and each pin has a specific functionality: power, ground, data, etc. These connectors are usually used for serial communication.
- **Dongle:** A piece of hardware that attaches to a computer to make a piece of secured software run.
- **EMR:** Electronic medical record.
- **HL7:** Health Level 7—A standard for information exchange between medical applications.
- **OSI Model:** Open System Interconnection—A model that defines network communication in terms of a framework consisting of seven layers.
- **Ramp:** An analogy to a highway ramp—The device is isolated until it connects to the ramp, which gives it connectivity to the network.
- **RFID:** Radio frequency identification—An automatic identification method that stores and remotely retrieves data.
- **RJ45:** Registered jack—A standardized physical interface for connecting telecommunications equipment. This interface is generally used for computers to connect to a network; the network protocol is usually TCP/IP.
- **RS232:** Recommended Standard 232—A standard for serial binary data signals commonly used in computer serial ports.
- **Sentience:** Awareness—In the context of this article, it means the device has an ability to connect to and communicate with a network. This would include physical, network, and other OSI layer recognition.
- **TCP/IP:** Transport Control Protocol/Internet Protocol.
- **XML:** Extensible markup language.

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