

# Clinical Engineering and Information Technology Working Together to Implement Device Integration

Brian McAlpine and Derrick VanKampen

Device integration is rapidly becoming a top priority for hospitals around the world because of the many benefits it delivers, such as recovered nursing hours, reduction of charting errors, and alarm integration possibilities, overall improved patient care and safety. However, as with any technology implementation, there are many issues that need to be considered. And while the line between clinical engineering (CE) and information technology (IT) isn't always clear, it is critical that the roles and responsibilities of each be clearly defined as early as possible when it comes to device integration. This article will compare the roles of IT and CE with medical device integration, and identify some of the potential pitfalls if collaboration is not done right.

## Device Integration Planning

There are many factors for a hospital to consider when looking for an effective device integration solution. Identifying each care area's specific level of acuity, patient safety concerns, and clinical workflow is just the beginning. An issue that also needs to be addressed is the need for devices and systems that facilitate connectivity. This is significant because the sheer number and types of devices can be overwhelming. One option is to utilize a medical device connectivity solution provider that can support all these devices "out of the box" without custom development. The way in which those devices communicate and integrate with other devices and systems varies

throughout the hospital. So this, too, has to be carefully evaluated and planned to make sure that all the devices the hospital wants to connect can be connected and that the data or alarms from those devices can be sent to the receiving information system(s).

Let's review the various ways in which devices communicate and send data. The first category of device integration is often referred to as continuous high-acuity. These care areas include the intensive care unit (ICU), operating room (OR), post-anesthesia care unit (PACU), and step-down. The main characteristics of high-acuity are that the patients are in a critical state and need continuous monitoring and application of therapeutic devices such as infusion pumps, ventilators, or anesthesia machines. The data processed from this environment is sent to the electronic medical record (EMR) in unvalidated or raw form and the validation is performed by the nurse in the EMR documentation application. Refer to Table 1 for a summary.

In high-acuity areas, some biomedical devices, including patient monitors, send their data through a vendor-specific gateway computer. In these cases, the data from each patient monitor is sent to a monitoring gateway, converted to Health Level Seven (HL7) standards, and sent to the receiving informa-

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Features

Device Integration Characteristics	Continuous Data Collection	Periodic Data Collection
Care Environment	ICU, OR, PACU, step-down	General ward, medical-surgical
Device Types	Multiparameter patient monitors, ventilators, IV pumps, anesthesia machines, pulse oximeters, balloon pumps, etc.	Spot check monitors
Data Connection Type (medical device to data collector at bedside)	-Serial/RS-232 -Network via a gateway computer -Wi-Fi/wireless via a gateway computer,	- Serial/RS-232 - Some devices direct to network using HL7 protocol and bypassing a bedside data collector
Data Characteristics	Raw parameter and alarm data, can include artifact data, very high volume	Validated vital signs data, can include patient assessment data, very low data rate
Typical Data Rate to EMR	- All data, every minute - Alarms processed in real time	- When collected, typically every 4-8 hours - Alarms not a requirement because nurse is at bedside assessing patient
Data Validation	Performed by nurse in EMR documentation application, can be validated any time after data collection and receipt by EMR	Best if performed by the nurse at time of data collection and patient assessment

Table 1. Ways in Which Devices Communicate

The second category of device integration is often referred to as periodic low-acuity. These care areas include general floors and medical-surgical units.

tion systems (Figure 1). Other devices such as ventilators need to be connected serially using RS-232 cables. In these cases, there is typically a device-specific serial cable and device ID module connected from the device to another piece of hardware (such as a terminal server device or equivalent) to enable data collection from each patient's bedside. The data is then sent either wired or wirelessly from the terminal server to an aggregation server

where the resident device-integration software can filter, translate, and send that data to the receiving information system (Figure 2). Lastly, there is another class of wireless devices such as smart IV pumps that directly send their data wirelessly to a dedicated pump gateway that then forwards that data to the aggregation server (Figure 3).

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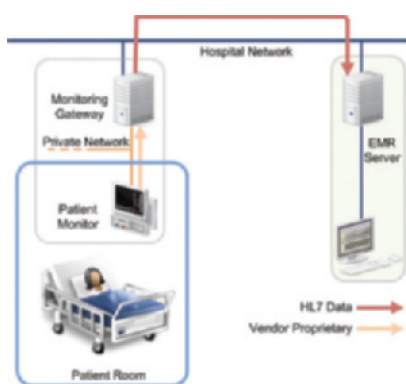


Figure 1. Patient Monitor Sending Data Through a Gateway

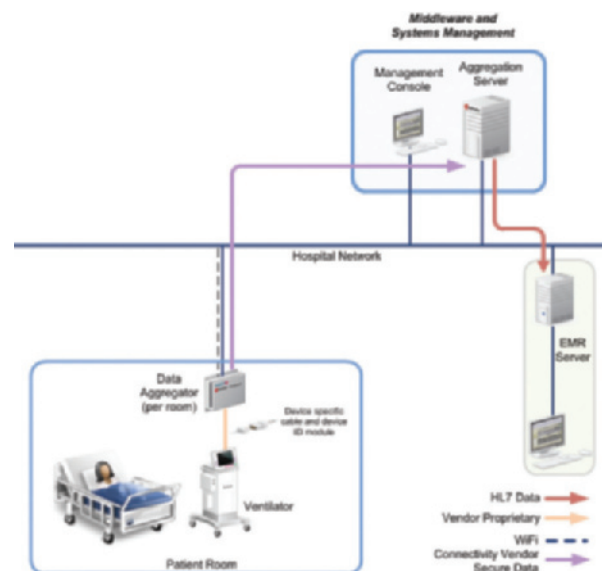


Figure 2. Ventilator, With Cable, Sending Data

low-acuity are that the patients are periodically connected to monitoring devices and there is less use of therapeutic devices. The vital signs data and patient assessment information are collected periodically, according to nursing protocol, as a key requirement for assessing the patient's condition. Ideally, this data is sent to the EMR as soon as it is validated by the nurse right from the bedside (Figure 4).

The first steps in the process are defining all the devices, determining how they will connect, and then determining which systems they need to send their data to. The management of this process is typically under the purview of CE; that department takes care of the physical connection of the devices to any bedside hardware that might be required to create the integration. The CE team has to understand the communications protocol and connection capabilities (whether they are USB, serial, gateway, or wireless); they need to know the firmware revision of the device and the parameters coming out of each device and how to map those parameters and apply correct naming conventions to ensure successful delivery to integration systems; and they need to figure out whether the device integration solution has a driver for that given device and whether the connectivity solution can handle upgrades to the device. The entire medical device arena is regulated and overseeing by a variety of organizations and governing bodies, such as the U.S. Food and Drug Administration

(FDA) and The Joint Commission. A CE department already has experience managing devices in that environment. There is no question that the involvement of CE at this stage of device integration planning is absolutely necessary.

The complexity continues to increase as these biomedical devices are integrated with other devices, to the wired and wireless networks on which they need to reside to transmit the data, and to the systems that receive that data. This is where CE and IT can collide, and why hospitals really need to proactively outline the roles and responsibilities of each department for the device integration project.

### Migrating From Devices to Systems

As we move along the spectrum from connectivity of biomedical devices to the systems they are connecting to, we start moving into the world of IT. The IT department manages the networks and the systems themselves.

Figure 5 shows an enterprise architecture diagram where the line of delineation between CE and IT responsibilities might be made—around the patient room. Hospitals we have worked with in the past have basically left the management of medical devices and systems residing in the clinical environment to the CE

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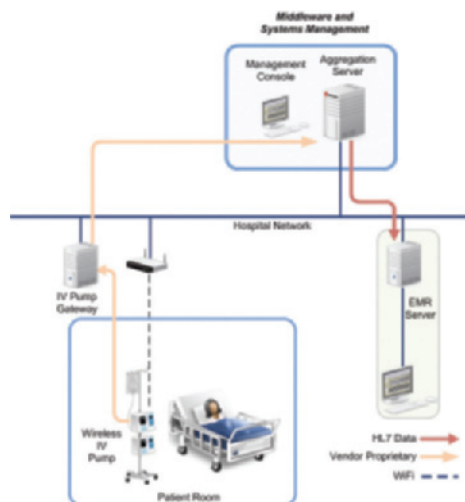


Figure 3. Smart Pump Sending Data Wirelessly

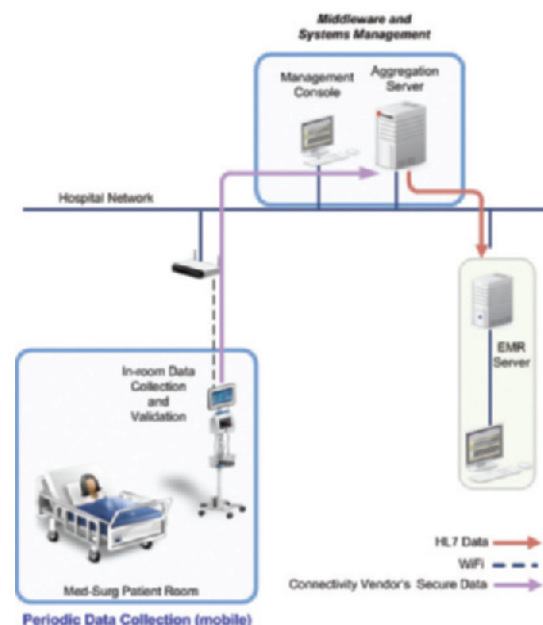


Figure 4. Data Collection in Low-Acuity Areas

department, with the IT department managing everything from the connection in the wall to the network closet and data center.

The increasingly complex world of information systems makes such a simplistic delineation impractical. For example, the whole arena of wireless devices and the wireless infrastructure, along with risk management standards such as IEC 80001, need to be considered. You also have security issues that need to be managed at both the device and system level. Then there is the mapping and filtering of parameters coming from devices that the clinical team wants to see in the electronic chart. This often involves mapping multiple data feeds from various vendor-specific device gateways to the EMR server through an interface engine. The data also needs to be filtered

and translated to ensure correct unit of measurements and labels are applied as directed by nursing.

This is just the beginning because it is only looking at the current needs and configuration of the device

integration project. When hospitals look to the future of device integration, those roles and responsibilities need to be further defined. The following are a few examples of areas that require further evaluation. It is recommended that these be addressed by a cross-functional

team that, at a minimum, includes biomed, IT, and nursing.

- **Positive Patient Identification (PPID):** The whole area of PPID and patient-to-device association needs to be sorted out. For example, wireless smart pumps and other wireless/mobile devices must be associated with the right patient. The hospital needs to determine how the clinical workflow for establishing PPID will be managed. Determine if clinicians use a manual pick-list selection in the EMR, barcoding, RFID, or perhaps a combination of these.
- **Hardware:** Who takes responsibility for the management of any required hardware and the integration? Who determines the type of hardware that should be used at the bedside? If this becomes an IT decision only, without clinical involvement, hospitals run the risk of selecting hardware that doesn't fit the way the nurse works. For example, studies have recently shown that in-room computers have some challenges to overcome such as the location, reliability, HIPAA concerns, and workflow priority issues. So these issues need to be sorted out between the entire team of IT, CE, and nursing to ensure successful adoption.
- **Clinical Workflow:** Determine who is going to manage coordination with the clinical team to ensure that whatever technology is selected for device integration and PPID, it supports effective clinician workflow.
- **Alarm Integration:** Determine how device and nurse call alarms will be sent and acknowledged. Device integration is starting to play a critical role in the delivery of alarms to the right caregiver at the right time, so this will create another set of roles and responsibilities to be defined.
- **Support:** Once a connectivity vendor is chosen, there will be the issue of who supports the system. This area includes how updates and upgrades to the solution will be managed and who performs periodic troubleshooting.

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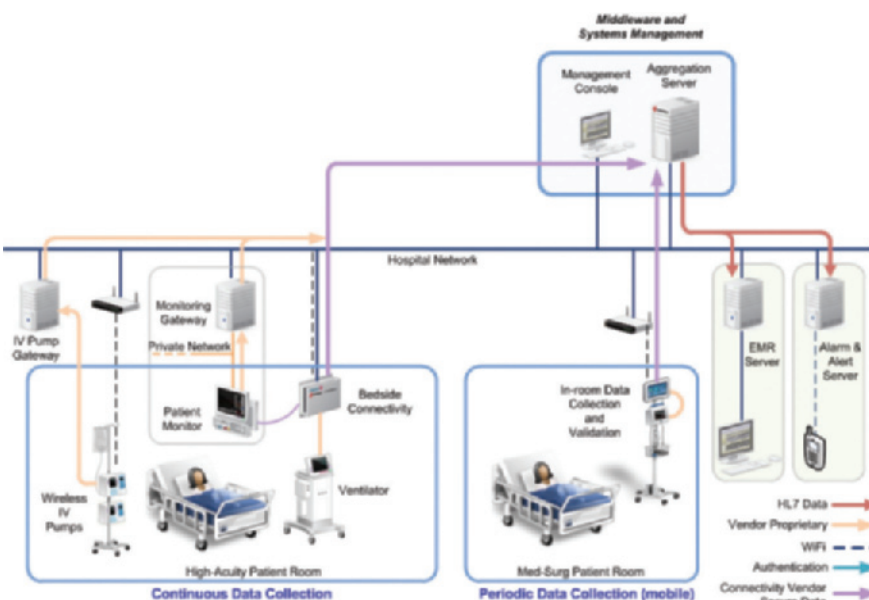


Figure 5. Enterprise Architecture Diagram

Potential vendors should be asked how they are going to help sort through all the complexities. Will the vendor provide a customized roadmap plan for the institution or take a cookie-cutter approach? Ask vendors if they have experience with all types of integration and do they have customers the hospital can talk to that have gone through a similar implementation? Hospitals that did it right recognized that collaboration and alignment across all teams—especially CE and IT—was crucial even before the connectivity vendor-selection process.

### Summary

The bottom line is that device integration delivers benefits to the entire hospital enterprise. It is critical to find a solution that meets the needs of all stakeholders in the hospital in the short and long term. The only way to do this is through due diligence in the investigational phase—to ensure that the connectivity solution not only meets the needs of the institution technically, but that it also fits within the clinical workflow.

To make an educated selection, CE and IT need to be aligned, and then work with the clinical and executive teams to map out their needs and define their roles and responsibilities. Doing so from the beginning will ensure that the right selection is made for the hospital and that implementation will be successful. More and more hospitals understand this need for cross-functional team collaboration when it comes to technology implementation. While some legacy technologies do not require close collaboration between clinical, CE, and IT, they are quickly being replaced by technologies which demand collaboration for success. ■

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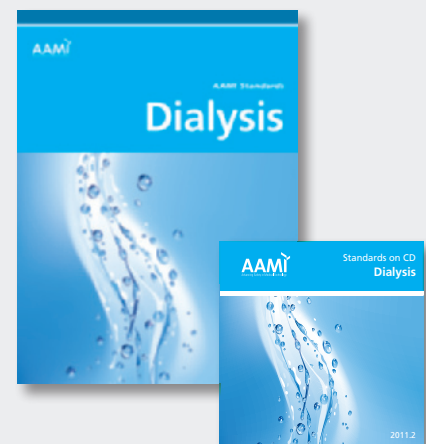
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