Integrating devices for patient safety

The anesthesiologist switches the patient from the ventilator to the cardiopulmonary bypass machine but forgets to resume ventilation after the patient is removed from bypass. The possible results? Longer surgery time, permanent brain damage, or even death.

This isn’t an uncommon error. A simple “smart system” would give a warning if the patient is off the ventilator and not receiving flow from the bypass pump. But that system doesn’t exist.

A 32-year-old woman died when the anesthesiologist failed to restart the ventilator after stopping it for an x-ray. He had been distracted by the need to help remove a stuck film from under the OR table. Why not simply synchronize the x-ray machine to the ventilator to get an accurate image and protect the patient by avoiding the need to turn off the ventilator for the x-ray?

Episodes like these have been reported in the literature and predicted from workflow analyses. Why haven’t solutions followed that address interconnectivity and interoperability?

Vendors’ viewpoints

One challenge has been manufacturers’ concern about legal liability and regulatory issues.

When multiple devices are integrated by a hospital’s engineering department, vendors worry one of their devices might be implicated in an adverse event even if it wasn’t the cause.

“They ask themselves, ‘Do I need this headache?’” says Julian Goldman, MD, of Massachusetts General Hospital (MGH), Boston.

“The answer is: We need the patient to be safe. We need to connect devices together into a safer system,” says Dr Goldman, who is an anesthesiologist at MGH and founding director of the medical device plug-and-play (MD PnP) interoperability program in the Center for Integration of Medicine & Innovative Technology (CIMIT).

He adds that being clear about who is responsible for what during product development helps address liability concerns. For example, a manufacturer might be responsible for making a product that interfaces with a pulse oximeter but not responsible for how the oximeter functions.

Dr Goldman and others have also been collaborating with the Food and Drug Administration (FDA) to understand safety and regulatory questions. In June 2007, the agency issued a letter outlining its support of interoperability and acknowledging potential issues. The FDA is currently working on a unique device identification system to address some of those concerns.

In January 2010, the FDA cosponsored a workshop on medical device interoperability. Program materials, including videos of the presentations, are available at www.mdphp.org/FDAInteropWorkshop.php
Too accepting?

Another reason for lack of interoperability is that clinicians are too accepting of the status quo, says Dr Goldman. “Most of us don’t realize that we are customers, and if we can effectively convey our requests in an organized way, we can change the market.”

He calls on clinicians to get involved in efforts to develop interoperability. To make their voices heard, clinicians need to work together and with manufacturers through initiatives such as MD PnP.

Several national and international associations have now endorsed device interoperability, including the American Medical Association.

Plug and play

MGH and CIMIT, a nonprofit consortium of Boston teaching hospitals and engineering schools that facilitates the development of technology to improve patient care, started MD PnP in 2004. Manufacturers, hospitals, clinicians, and engineers participate in the program.
“You need both intercommunication and interoperability for medical devices to be integrated,” says Dr Goldman. Intercommunication, or “bidirectional data communication capability,” refers to electronic health records (EHRs) being able to acquire data from a variety of sources such as infusion pumps, monitors, and ventilators.

“We need to integrate all the information into some type of communication dashboard,” says Janice Crosby, RN, MBA, director of business development at CIMIT.

Comprehensive data acquisition supports development of better alarms, innovative ways of supporting clinical decision-making, and more robust databases for clinical quality improvement.

Interoperability enables devices to be integrated into smart networks that can make systems “error-resistant.” For example, a device with a preset ventilatory pause timed to an x-ray machine would produce an accurate image and protect the patient.

Interoperability also improves efficiency through automated equipment inventory, automated patient records, and clinical decision support.

The future is now

MGH and CIMIT collaborated to build the OR of the Future. A lesson learned was that more comprehensive data integration was needed.

Surgeons and staff at MGH are already seeing benefits from connectivity, says Lisa Morrissey, RN, MBA, CNOR, the OR nursing director. In several ORs, large screens display information from multiple sources. For example, patient allergy data is pulled from the patient’s record, names of OR team members from the OR nursing documentation, and real-time hemodynamic information from anesthesia equipment.

In a pilot project, a subset of the information in 3 ORs was transmitted to the postanesthesia care unit (PACU).

“This allowed the PACU staff to know what was happening in the OR, when the patient was coming, and what they needed to do,” Morrissey says.

Expanding connectivity

“We’re looking at how we can expand connectivity,” adds Morrissey. Future goals include displays of radiology imaging and information from equipment such as the cardiopulmonary bypass machine. MGH’s perioperative executive team has also met with a vendor about how connectivity can be used to facilitate the timeout before incision.

“The goal is to have the perioperative team view a screen containing patient information defined in the (Joint Commission’s) Universal Protocol and allow the team to confirm the elements of the timeout,” Morrissey says, “and the surgeon to have a mechanism to electronically document the timeout.”

Recently, MGH selected Black Diamond Video, Inc, Alameda, California, as the communication system for its 28 new ORs opening in 2011. Leaders are reviewing how to incorporate this technology into existing ORs as well. MGH is developing what will be displayed (including how to display timeout information) through the communication system.

Sample contract language

Speaking a common language and having standards can go a long way toward accelerating change.
One challenge of interoperability is how clinicians and purchasing agents can communicate what they need to vendors.

To provide sample language that hospitals could include in contracts and requests for proposal, Dr Goldman led a task force that developed a white paper, Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE) (http://mdpnp.org/MD_FIRE.php)

The document will evolve as standards develop.

**Companies positive**

Dr Goldman reports positive feedback from companies. “Now engineering has something to show their companies about why devices need to be interoperable—because it’s what clients want.” As companies provide more options for interoperability, he says, they will gain a marketing edge.

In addition, a draft international standard specifies requirements for integrating equipment to create an Integrated Clinical Environment (ICE)—the safe and effective integration of devices in high-acuity environments. ICE Part I: General Requirements and Conceptual Model (F2761) was published by ASTM International in December 2009.

“When it’s approved, it will make it easy for federal agencies and the Joint Commission to have a standard they can use as part of their own standards,” says Dr Goldman.

The Joint Commission issued a Sentinel Event Alert in December 2008 titled “Safely implementing health information and converging technologies” (www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_42.htm), indicating support for integration and giving strategies for achieving it.

**Black box for devices?**

Dr Goldman acknowledges that ICE is a first step. “You need more than just a standard. It’s like Bluetooth wireless. It took a while to get it working and adopted by consumers.”

He says ultimately systems will likely include a device similar to an airplane flight recorder that records all communications and activities.

“If someone increases the tourniquet pressure, you’ll have that recorded,” says Dr Goldman. Such a system will help manufacturers. “If they don’t think their device caused the problem, they can go back and get that information.”

Crosby suggests raising vendors’ awareness by asking them how they are involved in efforts to develop standards to improve interoperability.

“Start sowing the seed for industry to respond,” she says. “Help them understand that’s where we are going, and that’s how we are going to be making decisions.”

**Implementing interoperability**

Like other changes in the OR, it’s important to involve key players in decisions on interoperability.

“As a perioperative team, decide what you want to display and then work with vendors and your team,” says Morrissey. “Make sure you are hearing from all the stakeholders when you’re making decisions.”

“Work closely with your purchasing agent,” adds Dr Goldman. He suggests sharing MD FIRE with departments such as purchasing, engineering, information systems, and risk management.
“We’re all under increasing pressure to ensure patient safety, while managing increased productivity,” notes Morrissey. “Connectivity and interoperability can help with that by improving the accuracy of patient information, flow of patient events, and help staff adhere to regulatory requirements.”

**Expect the best for patients**

Dr Goldman sums up MD PnP and the power of interoperability as “change expectations, change technology, and change health care.” He points to the evolution in printer technology as a sign of hope. Ten years ago, hooking up a printer to a computer was challenging.

“Now you can easily switch from one type of printer to another, printers can be in another room, and you get error messages, like you are out of ink, based on real-time status information,” Dr Goldman says. “Shouldn’t we have similar expectations—ease of use, real-time information, standardization—for equipment used to keep our patients safe?”

—Cynthia Saver, RN, MS

*Cynthia Saver is a freelance writer in Columbia, Maryland.*

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**What’s needed to improve integration?**

Functions needed to achieve integration are:

- safety logic (the need to encode safety rules and procedural knowledge)
- device access (safety logic needs to know medical device status and patient physiological parameters)
- device control (safety logic needs to be able to control devices to successfully intervene)
- interoperability (every device needs to be able to communicate/interoperate)
- clinical information systems/records access (safety logic must access patient data in clinical information systems and add device clinical and technical data as relevant).


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**OR scenarios invited**

Here are 3 questions OR managers can ask about the interoperability of medical devices, suggested by Julian Goldman, MD, of Massachusetts General Hospital:

- What are we doing today that we are having difficulty getting done that could be done better with connectivity?
- What do we wish we could do today but can’t because we lack interoperability?
- What technology is the consumer-electronics world using that we could benefit from?
Real-life examples

Real-life examples are needed of how OR services and safety could be improved by device interoperability.

“We need more tangible, specific examples of how efficiency can be improved through interoperability,” says Dr Goldman, director of the medical device plug-and-play (MD PnP) interoperability program in the Center for Integration of Medicine & Innovative Technology (CIMIT).

He invites OR personnel to send examples of situations where they are having problems because they can’t get data or think patient safety is compromised because of the lack of device interoperability.

E-mail scenarios to clinical@MDPnP.org