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Anesthesiologists and Pharmacists Trend To Blend Teams Targets OR Drug Errors

This is the first of a two-part series addressing clinical collaboration between pharmacy and anesthesiology in the operating room.

When 1-year-old Ameer Martin died of a medication overdose in a Long Island, N.Y., hospital operating room last spring, her death cast a long shadow over a nationwide vulnerability: the risks to patient safety, institutional liability and drug budget controls when pharmacy, anesthesiology and other surgery-related specialties fail to collaborate and establish safe medication practices in the OR.

see *collaboration gap* page 34

Patient-Controlled Sedation Viable for Colonoscopy

CHICAGO—As controversy swirls around who should administer anesthesia during colonoscopy and how much, if anything, insurers will pay for it, a Philadelphia anesthesiologist has suggested ways to improve efficiency in the endoscopy suite while keeping anesthesiologists on board.

The solution: patient-controlled sedation with propofol and remifentanyl, said Jeff E. Mandel, MD, MS, of the Hospital of the University of Pennsylvania. Dr. Mandel presented his findings at the 2006 annual meeting of the American Society of Anesthesiologists (ASA). The results, he said, hold important implications for the traditional model of staffing sedation during colonoscopy.

The question of who should be permitted to administer

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Once a Tech Fantasy, Plug-and-Play OR Edges Closer to Reality

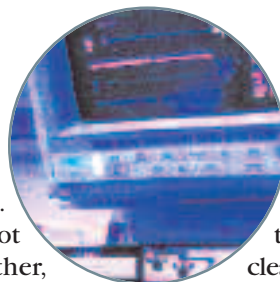
Model Standards Expected This Year

CHICAGO—For the digerati, interoperability is the technological equivalent of Esperanto, a means of universal communication regardless of brand, type of device or setting. Your thumb drive can take a Microsoft Word file from your office Mac to your home PC without missing so much as a comma. Peco de kuko! (Or, as they say in English, “Piece of cake!”)

But when it comes to health-

care technology, “plug-and-play” has proven far more difficult to achieve. And when devices cannot speak fluently to each other, patient safety can suffer. Consider, for example, the following scenarios that, while not exactly common, have resulted in serious injuries and even deaths in the operating room (OR):

- An anesthetized patient in surgery



requires an abdominal X-ray, but the ventilator may disturb the image. To obtain a clear picture, the anesthesiologist temporarily shuts off the ventilator and the picture is taken. Surgery resumes—until the anesthesiologist realizes with horror that in his distraction he has forgotten to restart the ventilator.

see *interoperability* page 15

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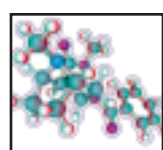
Perioperative Care and Anesthetic Considerations for the High-Risk Patient In Gynecologic Surgery (Part 2 of 4)

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EDUCATIONALREVIEW



Non-Opioid Analgesics for Acute Perioperative Pain, see insert at page 23.

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For information about the Medical Device "Plug-and-Play" Interoperability program, visit www.mdnp.org

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INTEROPERABILITY CONTINUED FROM PAGE 1

- A laser used for airway surgery ignites the oxygen-rich gas providing ventilation, burning the patient severely.

Now consider the alternatives with medical devices that "know" what other machines are doing and why. In such a network, the X-ray would fire at the moment of inspiration or expiration, but not during either process, generating a blur-free image without the need to turn off or disconnect the ventilator. In such a network, the cauterizer would not operate when sensors on the device detected sufficient oxygen to pose a combustion threat.

"Even though our consumer electronics industry has shown that interoperability is a no-brainer, it isn't available in medical equipment," said Julian Goldman, MD, director of MD PnP, an interoperability collaboration between Massachusetts General Hospital and CIMIT, a healthcare technology consortium in Boston. "In the hospital, you can build these safety interlocks yourself but you can't share them with your colleagues in other hospitals" because of regulations governing medical devices. What's more, Dr. Goldman said, custom devices, although necessary first steps, may undermine patient safety precisely because they cannot be tested and validated by other facilities.

PRIORITY SHIFT

Although the FDA does not regulate hospitals, it does have oversight of medical devices. In the past the agency earned a reputation—deservedly so, some say—for intransigence on device interoperability. Officials feared that



technologically complex systems might undermine patient safety.

That has changed in recent years. "The FDA has been very supportive" of interoperability, said Dr. Goldman, president of the Society for Technology in Anesthesia. The agency sent staff to a 2004 kickoff meeting of his group's plug-and-play initiative and hosted a two-day summit on the issue that same year. It also has several internal projects devoted to the problem.

Whether an act of profound foresight or quixotic optimism, Dr. Goldman's group plans to offer a preliminary interoperability "ecosystem" (not quite standards) this year. Dubbed—for the moment—the Integrated Clinical Environment (ICE), the guidelines are intended to help hos-

pitals arrive at plug-and-play capability by creating a digital architecture that supports the safe integration of the gamut of medical devices, enables the collection of reliable data from those devices, prevents incompatible technologies from connecting to the network and monitors the system for problems.

Dr. Goldman, who chaired a panel on interoperability at the 2006 annual meeting of the American Society of Anesthesiologists (ASA), is convinced that interoperability is essential. But he admits the era of the plug-and-play hospital is likely not near at hand. He does, however, see encouraging signs of life in the private healthcare sector.

One harbinger is the formation of the Continua Health Alliance, a group of roughly 45 members including Intel, Partners Healthcare, IBM, General Electric, Kaiser Permanente and others, whose mission is to create "a rich ecosystem of interoperable health and fitness devices." (Dr. Goldman chairs a Continua working group.)

Kaiser, the nation's largest private nonprofit healthcare system, has been particularly aggressive at promoting the notion of plug-and-play. The company now insists that its suppliers work toward interoperability with every device or piece of biomedical equipment its hospitals purchase.

"We have language in our contracts that basically states that the vendors

will be compliant with an interoperability standard that is tested at Kaiser's Garfield Center or at CIMIT," said Zachary A. Zimmerman, MS, MD, chief of anesthesia at Kaiser Vallejo and chair of the chiefs of anesthesia for the Permanente Medical Group of Northern California. "We don't specify the standard, because it's not there yet, but they have to have the capability" to meet it when it does arrive.

Small hospitals or hospital groups might have difficulty making such a policy, but Kaiser wields the carrot/stick of its 8.5-million member network. "The vendors agree to it because they want our business."

For Kaiser, the benefits of interoperability are twofold and long-term. "If you have to write new software for drivers for each device you purchase, it costs a great deal of money in acquisition, startup and maintenance costs," Dr. Zimmerman explained. "If there's a standardized format and connecting device, our operating costs will be lower. And, since there's a shortage of healthcare personnel, if you can train people to work on interfaces that are more standardized, you can and will improve patient safety."

LOW HURDLES, HIGH STAKES

Sem Lampotang, PhD, professor of anesthesiology at the University of Florida in Gainesville, and a mechanical engineer by training, said that while technical obstacles to OR interoperability exist, they are not significant.

Failing to arrive at an interoperability standard will leave patients at unnecessary risk for harm. Consider surgical fires. A panel in which Dr. Lampotang participated at the 2006 annual ASA meeting estimated that roughly 100 such fires occur each year in U.S. hospitals, causing roughly 20 serious injuries and one to two deaths. Virtually all of these incidents could be prevented, he added, if cauterizers, laser knives and other "igniters" could communicate with oxidizer sources like anesthesia machines. "Most of the technology is there and the price point's appropriate. It's a matter of knitting it together."

In addition to protecting patients, OR technologists like Drs. Goldman and Lampotang also see interoperability efforts improving the accurate monitoring of patient data. Two areas of particular interest involve respiration and heartbeat, both of which affect many physiologic processes anesthesiologists and surgeons need to follow closely during procedures.

"Timing measurements to corre- see *interoperability* page 16

Kaiser Culture Strong on Tech Benefits

While hospitals await ICE or another interoperability standard, Kaiser is moving forward with two other technology initiatives integral to seamless digital communication in its hospitals.

The first is a fully automated OR, of which the network currently has two—in Vallejo and San Francisco. "All the monitors and equipment for anesthesia in the OR is connected into our anesthesia information system," said Kaiser anesthesiologist Zachary Zimmerman, MS, MD. "If you bring in new technology, it will go into the new system."

The second measure is HealthConnect, Kaiser's program to create a nationwide electronic medical record (EMR) system for each of its 30 medical centers. Even that effort has implications for interoperability. "All the different types of monitors, etc., need to get their information out of their specific 'box' into the EMR," said Dr. Zimmerman, who is spearheading the anesthesiology component of the project. "It's a huge expense when you don't have a uniform platform."

In anesthesia, Kaiser has broken HealthConnect into two components, preoperative and intraoperative data, and is working with two software companies, Epic Systems Corporation and Philips Medical Systems, to

handle each segment.

Vallejo already has begun to see improved patient safety with the Philips CompuRecord system, Dr. Zimmerman added. "We are monitoring compliance for antibiotic administration and β -blocker therapy.

HealthConnect is up and running in South Sacramento and is scheduled to go live in Santa Rosa later this year. Kaiser hopes to have its entire network under the electronic umbrella by 2009, Dr. Zimmerman said.

The theoretical benefits to patients of the EMR are impressive. The vast majority of Kaiser's patients are "frequent fliers" who stay in the network for their hospital care, Dr. Zimmerman explained. "For any patient who has had surgery in my hospital in the last 3.5 years, I can pull up the anesthesia record. Let's say they have had a difficult airway. That information is transferred into our intraoperative record so the anesthesia provider is aware of it. Or, if intraoperatively they have a difficult airway, it becomes an anesthesia alert and that information populates the preoperative program so that if that patient ever comes back, we know they're a difficult airway. This takes literally a minute, and no chart is needed."

—AM

TECHNOLOGY |

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For information about the Medical Device "Plug-and-Play" Interoperability program, visit www.mdpnp.orgINTEROPERABILITY CONTINUED FROM PAGE 15

spond to the same phase of a breath or a heart beat is usually a good idea," said Dr. Lampotang, yet the motion of lungs and the heart can muddle results.

Dr. Lampotang and a Florida colleague, Paul Langevin, MD, designed a system to automatically synchronize portable chest X-rays with peak lung inflation—with apparent success. In a study of the technology, published

in the *American Journal of Respiratory and Critical Care Medicine* (1999;160:2067-2071), most radiologists who saw the timed images preferred them to conventional X-rays in 21 of 25 mechanically ventilated patients.

"The technical work was done in 1997 and the clinical study in 1998 with publication in 1999," Dr. Lampotang said. "This proves that the technology was there already in 1999,

but to my knowledge no commercial manufacturer has incorporated the technology in their equipment in spite of the clinical study showing it is preferred by radiologists."

Jeffrey Cooper, PhD, director of biomedical engineering for Partners Healthcare in Boston, and co-founder of the Anesthesia Patient Safety Foundation, called the creation of interoperability standards "a development that absolutely needs to happen, not

just for the sake of patient safety but for the efficient use of resources in the hospital. We've got to make it simple" for medical devices to speak to each other.

Dr. Cooper, who is also associate professor of anesthesia at Harvard Medical School in Boston, is very familiar with the challenges of knitting together a hospital's worth of medical devices. Several years ago, he was involved in efforts by Massachusetts General Hospital, a Partners facility, to integrate its machines into the Anesthesia Information Management System (AIMS). "A lot of work had to happen on the part of manufacturers and on our end to get those various patient monitoring devices to talk to AIMS," he said.

Partners, however, is still far from being a seamlessly integrated health-care network. Officials in the system are now mulling whether to go the route of Kaiser by making interoperability a first principle in its purchasing orders. "Those discussions are being had, and those of us in biomedical engineering would like to see some appropriate language to that effect in our purchasing contracts. Of course, the problem is that there isn't such a standard in existence today."

Eventually, Dr. Cooper said, interoperable technology will have a substantial impact on patient safety, although perhaps a more modest one than advances such as pulse oximetry, capnography and fiberoptic bronchoscopy. "It's a bit more like airway pressure alarms, which have been an important component in preventing injuries from disconnections. Interoperability will enable more of those advances to happen."

To be sure, he added, even technology that generally improves patient safety and hospital efficiency can undermine both if used incorrectly. Luer locks and other universal connectors are a good example of this dual-edged effect, Dr. Cooper said. "Imagine life without having standardized connectors. But the flip side is a huge safety issue because you can connect anything to anything, such as an I.V. to an epidural line, which has happened. Life is made much more complicated because we can't connect devices to networks or to each other, but developing the ways to do it will be much more complicated than it was for tubing connectors," Dr. Cooper added. "One of the biggest concerns, for instance, will be about ensuring that we know what patient is connected to what device. That's not a simple issue."

—Adam Marcus

UPCOMING
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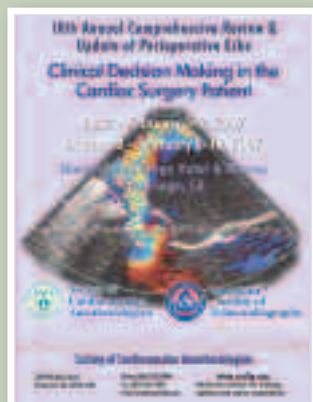
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