

INSIDE EDGE

IT & Biomedical Device Integration: Cultural, Technical, Analytical

EXECUTIVE SUMMARY

Like two subatomic particles aimed at each other in an accelerator, the worlds of IT and biomedical (or clinical) engineering have been on a collision path ever since the first patient monitor was implanted with a computer chip. However, the merger of the two worlds is being hastened by the demand for integrated data to support coordinated care.

Medical devices are no longer stand-alone, connected only to a patient and provider. Today's clinical communication requires not only integrating disparate information systems but also data and images from patient-care devices—and sharing them with the EMR. It's not surprising that the trend is to bring biomed under IT management. As technology becomes "brighter" healthcare delivery organizations want to extend that intelligence to EMR data in the clinician's workflow. For many organizations, placing biomed under IT makes the job easier.

In this issue of Inside Edge we talk to biomed and IT experts at major academic medical centers and an HIT sup-

plier to determine the challenges, lessons learned and best practices for successful convergence. Simultaneous to the wave of smart clinical devices crying for network connectivity is the proliferation of consumer-driven devices like iPads and iPhones—creating a secondary headache for CIOs. Convergence is necessary and promises great benefits from integrated information and coordinated care. There just may be a few minor explosions.

U of Chicago

A biomedical engineer by background, Clara Guixà in her previous job worked with the CIO at an academic medical center to build the relationship between clinical engineering and IT and move the team to reporting from the COO to the CIO. Today she's continuing that mission at the University of Chicago Medical Center as director of clinical engineering where she reports to the CTO. The U of Chicago is a three-hospital integrated delivery system with \$1-billion in annual revenue, 700 attending physicians, 9,500 employees and includes University of Chicago Pritzker School of Medicine.

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“Here the department has already been moved to IT. I was brought in to strengthen the collaboration,” says Guixà.



**Clara Guixà, director,
Clinical Engineering,
University of Chicago
Medical Center**

Bolstering the bond between clinical engineering and IT is critical to improving the U of Chicago’s enterprise infrastructure, including integrating the patient-monitoring system and bedside medical technology with the EHR.

“What IT shops typically discover is that a lot of medical device manufacturers do not meet IT standards,” she says, including designs for disaster recovery and high system availability. “How do we apply those same standards to our patient monitoring systems? And not just technology standards, but also metrics and service-level agreements?”

Executives charged with integrating IT and biomed also find that education is integral to filling gaps in expertise respective to each area. Clinical engineers have traditionally been strong in customer service, human factors and technology’s impact on workflow. IT staff, on the other hand, are great at network and server design and building information architecture.

Increasing dependencies

While IT teams are generally much larger than their clinical-engineering counterparts, they’re usually less exposed to actual daily hospital operations and workflows. Clinical-engineering teams, on the other hand, tend to be more directly focused on supporting patient care, the user and maintaining high availability of bedside technology for and addressing such questions as, “How does engineering design better service solutions and deliver them to our clinical team?” There’s more focus on the user and high availability.

“As we integrate more and more systems, the number of dependencies increases. It’s important our clinical and IT teams work together,” Guixà says. However, facilitating the convergence must be incremental. “You have to be very cautious as to how much your team can absorb and how you plan for the change. Training is expensive. The change must be achieved progressively to ensure the team is on board and that there’s executive support to allocate the funding.”

At the U of Chicago, training for both IT and clinical engineering staff addresses a wide array of regulatory components and preventive maintenance practices. “We also want to be highly specialized; we review our support models and align the in-house team to support the strategic goals of the organization,” she says.

When integration is done well, clinical engineers are trained to become more

familiar with IT standards and speak the same language as IT; the IT group is trained to become familiar with devices and how they fit into clinical workflow, to take a more hands-on approach.

Develop a hierarchy

The U of Chicago created a device hierarchy to help guide its integration of IT/biomed. With patient monitoring at the top of the list, the first initiative was to consolidate all patient monitoring data into the organization's Epic EHR. "We're trying to do this per type of device and try to measure value. You need a hierarchy on how and why this should be connected," says Guixà.

The hierarchy considers such factors as:

- Volume and frequency of data to be documented in the EHR
 - every nurse has to validate a patient's vital signs (Patient monitors)
- Regulatory Standards/Compliance
- Patient Alarm Management
 - bedside devices are critical (Ventilators, dialysis, infusion devices)

The challenge for academic medical centers, she notes, is the sheer amount of infrastructure required at the bedside in the context of such a highly diverse and complex environment. "We have multiple buildings with their own unique distinct systems—and we're building a new hospital, making infrastructure standardization challenging and costly, says Guixà.

To date the U of Chicago has connected to its EHR 500 patient monitors. Next on the list: anesthesia machines, ventilators, dialysis machines and infusion pumps. Alarm management—which involves transmission of alarms from the bedside to all patient-care providers with VoIP-enabled nurse telephones—has become a major emphasis. "We're redesigning our entire alarm-management for patients," she says.

Single vendor

Guixà notes that the need to share medical-device data with the EMR or any other system is driving the medical center to really standardize medical equipment across the hospital. "It's forcing us to stay with one vendor." Previously the hospital used monitors from multiple vendors such as GE and Philips; the pediatric hospital would have one platform and the adult hospital another.

"As integration complexity increases it requires our technology teams to evaluate equipment and their interdependencies much more than we did in the past. It then becomes strategic to find a single partner for a particular type medical device," Guixà says.

That's even more important considering industry workgroups are studying the problem but have not yet developed interoperability standards for medical devices. "It's still feels like a bit of vaporware. The liability is on the hospital. If you don't make the right patient association with the right device it's the

Even the temperature monitoring of refrigerators is now transmitting data across the network.

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organization's fault unless you can prove a faulty design by the vendor," she says.

And, while product development is a lot more rigorous for medical devices than other products, the technology is moving faster than the FDA can keep up. Medical device vendors are continuously playing catch-up and software applications that run devices always seem 10 years behind.

"When I talk to groups of clinicians, I can't stress enough the risk involved," says Guixà. We work very closely with them to develop a solid workflow that will support their operations." Validation sessions involve presentations to multi-disciplinary groups of physicians in which the technology teams walk through the process and help them validate the "5 Rights" for medical device connectivity: the right patient, right time in the workflow, right data source or device, right provider and the right regimen.

VCU

"Traditionally, IT and biomed didn't converge," says Rich Pollack, VP and CIO at Virginia Commonwealth University Health System, an 845-bed academic medical center in Richmond, Va., with 600 physicians and more than a half-million outpatient visits a year. Two changes have occurred, he says, to bring those two worlds together.

First, it's almost impossible to buy any kind of biomedical device that doesn't rely on some sort of IT capability, includ-

ing network connectivity, servers or application software. "That doesn't even mention integration with the EHR," notes Pollack.



**Rich Pollack, VP/
CIO, Virginia
Commonwealth
University Health
System**



That arrival of IT centric biomedical devices—their evolution into so-called

"smart" devices—has pushed the biomed world toward IT. "Pretty soon they're knocking at my door," he says. Even the temperature monitoring of refrigerators is now transmitting data across the network.

Second, the proliferation of connected bedside monitors, pulse oximeters, ventilators, infusion pumps and even smart beds all raise the complexity of coordination, management—and integration with the EHR. Organizations have to address a wide range of intertwined factors: data interfacing, available IT and biomed resources, wired versus wireless technology, licensing costs and the man-hours required to make it to work.

Responsible partners apply

"This all requires an unprecedented level of collaboration and teamwork between IT and biomed," says Pollack. "It's one thing to achieve BMDI [biomedical device integration] with 250 Philips

Bedside Monitors but that's just the tip of the iceberg. We still struggle with issues like who's responsible for which aspect of that connected system. Is it IT? The biomedical service company? Or is it the vendor Philips? When something goes wrong with the software is it in the Philips gateway or Cerner EMR? To the degree you can have really good vendor and biomed partners you're better off."

Lacking a true clinical engineering department, VCU outsources biomedical maintenance to Aramark. Besides bedside monitors and telemetry, it includes ventilators and smart pumps. There's more to come: VCU just ordered 500 new smart beds from Hill-Rom.

"This is only going to grow," says Pollack. Not having biomed within IT at VCU is something Pollack views as a drawback. "I've been to places that have biomed under IT and they have a better chance of getting it right. I'd be all for it." Today VCU's biomed team consists of a small six-person crew; biomed capital expense is between \$10 million and \$20 million.

Although the medical center has not experienced any serious adverse events as a result, subsequent to its BMDI efforts, it has incurred a few interruptions of bedside monitors. In those cases, however, nurses can manually document vital signs and hemodynamics in Cerner's interactive flow-sheet for critical care. Because it's been less than two years that the process has been automated, it wasn't difficult to fall back on hand documentation. What's more of a

concern, says Pollack, is that as patient monitoring necessarily increases, so does the FDA's regulatory presence. "Especially in those biomedical networks where there's a diagnostic interpretation being made," he says.

Analytics

Expanding along with the data integration work and regulation is the demand for business intelligence. "We're all starting to finally ramp up our efforts around analytics," says Pollack. "But absent the data you couldn't really do much." Despite the attention paid to analytics recently, most of the data, in the past, has come from billing systems, he notes. Clinical data is now becoming accessible because VCU has spent the past five years building out its core EMR.

"We have rich nursing and physician documentation, CPOE, meds, labs. We're awash in clinical and billing data but not yet able to optimally manage chronic disease for a particular DRG population," he says. To reach that level will require being able to aggregate data from all disparate sources including biomedical devices. VCU is now recruiting a senior director to lead its analytics initiative to achieve such capability, which Pollack predicts will take another few years.

Analytics is on an ever-ascending arc. While Pollack's 200-person IT team is largely devoted to implementation and optimization today, that will change. "Those activities will stabilize and many of those folks will transition over to the analytics side. Today I have only about

continued

FORTUNE magazine placed The Methodist Hospital System on its annual list of "100 Best Companies to Work For" since 2006.

As a private, adult teaching hospital affiliated with Weill Cornell Medical College and New York Presbyterian Hospital, it offers the latest innovations in medical, surgical and diagnostic techniques.

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Welcome to Marc Boom, MD, CEO, Robert Eardley, CIO and the Methodist leadership team.

SI TELECONFERENCES

January 26

Ten Things to Help Ensure Success in Negotiating IT Agreements

- Ray R. Bonnabeau, attorney at law, Hellmuth & Johnson, PLLC

February 7

Putting the Meaningful in Meaningful Use

- Eric Finocchiaro, specialist leader, Deloitte Consulting LLP

February 14

Ambulatory Patient Safety

- Erica Drazen, managing director, Global Institute for Emerging Practices, CSC
- Caitlin Lorincz, research analyst, Global Institute for Emerging Practices, CSC

February 27

SI-Cerner Users Collaborative No. 40: Meaningful Use Update

- Roy Foster, director, Regulatory Affairs, Cerner Corporation

February 28

Clinical Decision Support

- Coray Tate, research director, KLAS

March 1

Centura and Colorado HIE

- Dana Moore, SVP/CIO, Centura Health

March 6

Meaningful Use —Stage 2, 3

- Eric Finocchiaro, specialist leader, Deloitte Consulting LLP

March 8

Improving Care Coordination at NMPG

- Lyle Berkowitz, MD, FACP, medical director, IT & Innovation, Northwestern Memorial Physicians Group

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a dozen in analytics, but five years from now we'll have more than 100. Health reform, bundled payments and ACOs are driving the need for those knowledge workers. Everything coming out of health reform assumes we'll have the intelligence to determine and deliver the lowest cost and best outcome to our patients," he says.

Taming the wild BlackBerry

Nibbling at the edges of such a transformation—or maybe helping drive it—is the explosion of consumer-driven devices like iPhones, BlackBerry smartphones and iPads, all of which vie for integration into the network too. Besides its 10,000 PCs, VCU has 1,500 laptops and 1,000 BlackBerry phones.

Security is a top concern, as these consumer devices are often unsecure out of the box.

A second concern is how a hospital or health system actually supports such consumer-controlled devices. Under a traditional policy, VCU would supply the iPad and the iPhone to the employee and then lock down the device—essentially making it “boring”—by preventing users from downloading favorite songs, apps, video or other personal data.

Another scenario would be to allow users to buy the devices themselves and setup their own iTunes accounts, download media or apps if they so desire, but also provide separate, secure access to the health system's email and EHR. In that case, a user legally cedes data ownership

to the health system, which can delete that data when the employee leaves. “We have those policies in place now,” says Pollack. “You can download as much media and apps as you want. We provide a virtual desktop to access the Cerner EHR and a mobile device management tool to delete all data on the device, if we need to.”

VCU is also considering the thought to subsidize personal portable devices. “We'll give you x dollars toward an iPhone or iPad so you can get what you want. Then we'll set it up with security and access to systems at various levels based on the user's role. It's a very big change, but recognizes the convergence of personal and business use.

“Eventually we may really reduce our number of PCs, because the tablet form factor is so popular,” he says.

That raises even more device issues, of course, given the tablet's limitations in screen size and lack of a keyboard. To facilitate effective EMR interaction, Pollack notes, often requires at least a 24-inch flat-screen monitor. “You really need the real estate if you're doing flow sheets and other complex documents. You also need a conventional keyboard. We're now visioning installing 42-inch flat-screens in each inpatient and outpatient room, with a full-sized keyboard, Bluetooth, mouse and docking station for a tablet,” says Pollack, adding that that may be piloted within three years at VCU's future children's pavilion.

“Once we figure out how to best use and support iPads and iPhones it will be a done deal. Biomed, however—that’s a continual, ever-expanding issue.”

BYOD

“Most hospitals have no idea what they have in terms of biomedical devices,” says Dean Sittig, PhD, professor of biomedical informatics at the University of Texas in Houston. That situation is being exacerbated by people bringing in their consumer devices like laptops and smartphones and trying to do work on the health system network. “That’s a really hot topic, right now,” he says.



Dean Sittig, PhD,
professor, Biomedical
Informatics,
University of Texas in
Houston

Instead of the party-goer admonition, BYOB, CIOs are referring to the trend as BYOD: bring your own device. “Usually we don’t allow a device in a hospital unless it’s been organizationally approved. You can be allowed as a guest. That’s the mantra of any IT department because it allows you to enforce passwords, system logouts and encrypt hard drives,” says Sittig.

As devices such as iPads proliferate and healthcare organizations try to accommodate users by synching them into the network, the risk is that patient

data may be stored inadvertently on the portable device and, if security and confidentiality is compromised, the organization could be hit with a huge fine or worse.

John Halamka, MD, CIO at Beth Israel Deaconess Medical Center in Boston, discussed the BYOD trend in his blog “Life as a Healthcare CIO,” (<http://geekdoctor.blogspot.com/2011/10/bring-your-own-device.html>). Halamka oversees 10,600 desktops and 2,000 laptops that are “locked down,” but also has more than 1,000 iPads and 1,600 iPhones accessing BIDMC’s network for email and web applications. “I absolutely see the value of the Bring Your Own Device movement. However, the compliance and regulatory requirements that grow more complex every day make the BYOD movement very problematic,” he notes.

In his follow-up blog (<http://geekdoctor.blogspot.com/2011/11/more-byod-worries.html>), Halamka says, “It’s very clear that in 2012 and beyond we will have to move beyond policy-based controls and we’ll have to implement technology-based controls that may cost up to \$10 per device per month. Given our 1,000+ mobile devices, that could be a \$150,000/year increased operating expense to protect consumer devices brought from home...CIOs—it’s time to tell your CFO to expect an unplanned 6 figure expense to protect your institutional data while at the same time embracing the mobile devices

continued

March 13
Meaningful Use and Accountable Care Series

- Erica Drazen, managing director, Global Institute for Emerging Practices, CSC

March 14
Spending Trends Relevant for Successful ACOs

- William D. Marder, SVP, Analytic Consulting and Research Services, Thomson Reuters

March 19
SI-Cerner Users Collaborative No. 41: Topic TBD

- Joel Shoolin, DO, VP, Clinical Information, Advocate Healthcare, moderator

March 22
Downtime Procedure Survey Results

- Dean F. Sittig, PhD, University of Texas - Memorial Hermann Center for Healthcare Quality & Safety
- Daniel A. Gonzalez Carrero, University of Texas - Memorial Hermann Center for Healthcare Quality & Safety

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that will enhance productivity and user satisfaction.”

However, there may be a silver lining in the BYOD movement, according to U of Texas’ Sittig. Some hospitals are beginning to see an opportunity to save money. “Hospitals are thinking, ‘Maybe I can reduce costs’ if physicians and others buy their own devices.’ There’s a lot of risk but there’s also some opportunity. Docs see a huge benefit if they can access the EHR through an iPad,” he says.

An HIT firm’s perspective

Here’s some news: not every biomedical device is smart. Absent the luxury of being able to replace their entire biomedical device inventory at one stroke, hospitals do so incrementally. That means a lot of older devices on hospital floors aren’t state of the art. It’s also why Kansas City-based Cerner has developed its CareAware iBus architecture to provide network connectivity to devices that aren’t so smart. The software/hardware solution allows plug-and-play to more than 800 bedside, laboratory, imaging and communication devices and also safe and accurate patient-to-device association.

“Replacement of medical devices is usually done in stages,” says Don Bisbee, Cerner VP for IT and medical devices. “Hospitals don’t usually replace devices like that until they reach the end of their lives.”

The bigger opportunity is to be able to take smart devices and, using the



Don Bisbee, VP, IT
and Medical Devices,
Cerner

vendor’s iBus technology, allow the medical device data to be combined contextually with the clinical data in the EMR and allow smart alerts over

the data network to improve patient safety and workflow efficiency. “We know from a clinical perspective, connecting these sources of data can tell us if certain patients are at high risk for things like sepsis and thus avoid unnecessary complications and costs. First we have to make the connection between the data sources (medical devices & the EMR), then create intelligent use of that information real time to improve healthcare outcomes,” he says.

Connecting biomedical devices to the health system’s network can generate returns. The following are some examples of the problem and the solution enabled by IT/device integration:

- Medical Device Alarm Management
 - *Boston Globe* reported at least 15 deaths during a six-year span in Massachusetts related to missed alarms or physiologic monitor problems.
 - Olathe Medical Center improved alert response time by an average of 45 seconds due to automatic escalations.

IN THE IE PIPELINE

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- Medication Administration
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 - WellSpan Health avoided 30 potential ADEs during a two-month stretch by integrating Auto Programming and Infusion Management to smart pumps.
- Data Transcription Errors
 - *CIN: Computer, Informatics, Nursing* reported that error rates of vital signs originally captured on paper and later entered into the EMR are between 4.4% to 10%, while vitals automatically uploaded into the EMR reduced the error rate to less than 1%.

Bisbee believes the proliferation of consumer devices is only going to accelerate and that it can play an important role in physician adoption of EMRs. “Physicians like the iPad. We absolutely want to utilize that interest,” says Bisbee, adding that some organizations have used iPads as rewards to physicians for successfully completing CPOE training.

Obviously, hospitals have to institute security controls for those devices coincident with the credentialing of doctors, and that would include storage of data

on the EMR and not on the device. Also, the growth of smart biomedical devices and consumer-driven devices will drive more demand for asset management technology like wireless and RFD-based location tracking, he says. The devices will get smarter and smarter. “We’re working on intelligence that can tell us whether a device has been cleansed or not,” he says. “With the high concern about infection control, if we know we need a certain ventilator, but I know that ventilator has not been sterilized yet, maybe I remotely prevent that device from being turned on. Those are things you can bring together using intelligent devices linked on the network.”

Conclusion

Integrating IT and biomed is an inevitable result of the need for integrated information and coordinated care and the convergence of the two worlds is another form of healthcare breaking down silos and becoming more patient-centered. As healthcare technology continues to get smarter than we can even imagine, we must do so too. It’s a cultural, technical and analytical challenge that puts the term “knowledge worker” in a whole new perspective.

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