“Big whirls have little whirls,
That feed on their velocity;
And little whirls have lesser whirls,
And so on to viscosity.”
— Lewis Fry Richardson, English mathematician, physicist, meteorologist, psychologist, and pacifist

By education and training, clinical engineers and other healthcare technology management (HTM) professionals are problem solvers. But today’s problems are markedly different than they were in the past—a trend that is accelerating as information technology (IT) becomes increasingly complex, connected, and crucial in healthcare. Tried and true tools and protocols for managing stand-alone equipment are proving insufficient for dealing with systems issues.

Right now, most healthcare technology managers inhabit an in-between world—one that straddles the “break–fix” mentality of the past and the systems thinking that experts believe is the future for improving patient safety and clinical practices.

“Over the past 10 years, my job as a clinical engineering director has changed from managing the majority of medical systems as stand-alone devices or isolated systems to, today, these same systems are either integrated or in the process of integration with other systems,” says Gregory Herr, director of clinical engineering at the Christ Hospital Health Network in Cincinnati, OH.

Donald Armstrong, a certified biomedical equipment technician with GE Healthcare, sees “a huge difference” in his responsibilities because of the growing systems dynamic. “We spend a lot more time these days tracking where the failure lies, instead of just fixing the immediate problem,” he says.

Pat Baird, an engineering director with Baxter Healthcare Corporation, sees real value in embracing systems thinking in healthcare. “The motivation that I have for bringing more systems theory to the health-
care environment is that I see the people constantly reinventing the wheel in healthcare. Many of the challenges in healthcare are the same challenges other industries have faced decades ago. Healthcare needs to catch up and I think that ‘systems thinking’ could help speed the process.”

**Understanding the Abstract**

Getting to the practical side of systems thinking in healthcare first requires a journey through abstraction, because a system is “a whole bunch of levels of abstraction,” in the words of Lane Desborough, a product strategist with Medtronic.

Participants at the 2012 AAMI-FDA Interoperability Summit emphasized that people are an integral part of any system, because people interact with technology. Summit participants urged the use of the term “sociotechnical” to describe—and guide the design and life cycle of—systems in healthcare.

Recently, the phrase “system of systems” has been in vogue, and yes, there’s an acronym for that: SoS. Purists say that term is meaningless, however, and that “system” suffices and says it all.

Regardless of the terminology, the interaction of individual components is the key differentiator for true systems, or systems of systems, in healthcare technology, according to Ken Maddock, vice president of facility support services at Baylor Health Care System. “We have had networked medical devices tied to a back-end database for years,” he says. As an example, he cited electrocardiogram (ECG or EKG) systems. “You’d send an EKG cart out, and you’d run a 12-lead EKG on a patient. And you were able to hook those up to a network and download the studies. The devices connected, but they didn’t really interact.

“Most people are considering the device and the backend database to be a system of systems now,” Maddock adds. “A lot of people are confusing just connecting devices to a network and feeding data into an electronic health record [EHR] to be a system of systems. Even with the EHR, that is still basically one-way communications. To me the real system of systems is when you have live or close-to-live communication back and forth that impacts the setup of the device and the way the device interacts in some way with

**Recently, the phrase “system of systems” has been in vogue, and yes, there’s an acronym for that: SoS. Purists say that term is meaningless, however, and that “system” suffices and says it all.**

**What’s a System?**

- “A system is built from a group of parts, whose combined interactions produce a behavior that no one part alone can produce.”
  — John Thomas, president, International Council of Systems Engineering

- “A system does something different than its constituent parts taken individually. It exhibits some property that the individual subcomponents don’t. So, for instance, flight is a system property of an aircraft. It’s only when you assemble the constituent parts—an engine, the wings, and the pilot together into a system—that this emergent property, or system property, of flight takes place.”
  — Lane Desborough, product strategist, Medtronic

- “A system is variously defined as ‘a group of interacting, interrelated, or interdependent elements forming a complex whole.’”
  — Raymond Zambuto, president, Clinical Engineering Concepts, LLC

Rick Schrenker, systems engineering manager with the Department of Biomedical Engineering at Massachusetts General Hospital, says systems share these concepts:

- **Synergy:** The whole is greater than the sum of the parts.

- **Emergence:** Value-added properties and capabilities of a system emerge only when the components are intentionally integrated (unless you want to rely on natural selection and evolutionary time scales).

- **Boundary:** Systems are bounded. The properties and capabilities that add value are delivered across the boundary to a recipient. Similarly, a system is a recipient of information, goods, energy, and so on from outside its boundary that it uses to create that which it delivers.

A “system of systems” can be described as a group of interacting, interrelated, or interdependent systems forming a system. A hospital is obviously a system of systems—operating room, emergency room, nursing units, materials management, and so on. Ditto a regional healthcare delivery organization. At some point you extend the boundaries to include payers, including insurers and government agencies.
Systems Concerns Dominate AAMI List of Top 10 Challenges

Four of the top 10 healthcare challenges identified in a 2012 AAMI survey of healthcare technology management professionals in 1,900 U.S. hospitals have an explicit systems focus. These challenges, and the percentage of respondents who cited them, are as follows:

- Managing devices on the IT network (72 percent)
- Integrating device data into electronic health records (65 percent)
- Maintenance of infusion pump systems (48 percent)
- Cybersecurity of medical devices and systems (47 percent)

All of the other top challenges—including broken connectors, battery management, alarm management, setting preventive maintenance strategies, medical device incident reporting and investigations, and medical devices brought in by patients—involve multiple systems.

The challenge of any system is that desired behaviors, emergent properties, and interactions can go awry. In short, there are often unintended consequences.

The role of medical device incident reporting and medical technology management pro-

Desired behaviors such as patient safety and clinical decision support could emerge from medical technology and health IT systems. But experts say these kinds of behaviors are unlikely to emerge unless systems engineering principles and tools are applied, beginning in the design stage, to produce them. Worse, failure to attend to potential unintended consequences could compromise patient safety—a prospect that is increasing as more components and systems are connected.

That’s where systems engineering will be valuable. “In my mind, systems engineering is as simple as balancing what you’re trying to achieve versus what are the potential unintended consequences of connecting all of these things together,” Desborough says. “How do we understand what the positive and negative effects are before we put them into the overall system, so that we aren’t surprised when something bad happens?”

For the U.S. Department of Defense, systems engineering means “planning, analyzing, organizing, and integrating the capabilities of a mix of existing and new systems into an SoS capability greater than the sum of the capabilities of the constituent parts.” Note that according to the Defense Department’s definition, a system doesn’t really manifest itself in its true sense—in terms of producing desired behaviors—without systems engineering.

“Systems engineering has been practiced...
with intent in industries like defense and power generation for decades," says Rick Schrenker, a systems engineering manager with the Department of Biomedical Engineering at Massachusetts General Hospital in Boston. “The drivers for their earlier adoptions in those domains included rapidly increasing complexity in deployed systems, rapidly increasing rates of change in these complex systems, and costs that spiral out of control in the absence of intentional and formal control. It is so obvious to me that healthcare can learn from these domains. Frankly, anyone in a systems development role in healthcare who doesn’t at least see the need to familiarize themselves with work in other domains needs to get out of healthcare management. Now.”

What could be the practical value of a system, or system of systems, approach in healthcare? Fewer risks to patients, a reduction in costs for healthcare facilities, and greater efficiencies would top the list, according to experts.

“In my mind, systems engineering is as simple as balancing what you’re trying to achieve versus what are the potential unintended consequences of connecting all of these things together,” Desborough says. “How do we understand what the positive and negative effects are before we put them into the overall system, so that we aren’t surprised when something bad happens?”

— Lane Desborough, Medtronic

### 10 SYSTEMS ENGINEERING PRINCIPLES

Experts suggest 10 systems engineering principles that are relevant to a system, or “system of systems,” environment in healthcare. For all of these principles, there are robust, practical tools, such as matrices, charts, and diagrams, that support systems thinking and management:

1. **Use case**—a series of comprehensive steps to identify, clarify, and organize system requirements
2. **Requirements management**—a process of documenting, analyzing, tracing, and agreeing on system requirements and then controlling and communicating system changes to stakeholders
3. **Pugh matrix**—a quantitative technique, also known as a decision-matrix method, used to establish and rank many criteria, and options for satisfying the criteria, to make system design decisions or choices
4. **Quality functional deployment (QFD)**—a method to help system designers and planners focus on the needs of users and build these qualities into systems and components
5. **Traceability**—a method of documenting system and component requirements, including their origins; how requirements are met, tested, and changed; and how changes could affect requirements
6. **Architecture (functional and structural) models**—methods of modeling how a system functions (its decisions, actions, and activities) and how it is structured. IDEF0 diagrams (an acronym for integration definition), among other architecture modeling tools, can be used to analyze, develop, re-engineer, and integrate systems.
7. **Interface design**—the application of user-centered design, which focuses on human factors, clinical workflow, user needs, experiences, and interactions with technology. Use cases and sequence diagrams of clinical workflow, for example, are key to informing interface design.
8. **Risk management**—a process for identifying, prioritizing, and managing risk. In healthcare, ISO 14971 for individual devices and IEC 80001 for connected devices are standardized references for managing risk, but some experts say they are underused by healthcare delivery organizations.
9. **Validation**—processes for ensuring that devices conform to defined user needs and intended uses, including testing of production units under actual or simulated use conditions. Simulation is a validation tool.
10. **Verification**—processes for evaluating whether or not the system actually meets the design requirements, specifications, and regulations
“Medical professionals can receive data from the system of systems and perform a more extensive trending analysis of a patient or hospital—predicting issues that could arise for a hospital floor during a particular season or when cases have similar data,” says Kathleen Whanger, quality assurance manager with the vascular division at Teleflex Arrow International. Prediction, she explains, is key to reducing risk and cost. More accurate forecasts could help determine, for example, “how many gauzes to order or how many times a catheter will have to be changed.”

And what does this move toward systems thinking mean for HTM professionals in the field? At the very least, it underscores the changing nature of their jobs and highlights the need for new skills and knowledge.

“At the clinical engineer director level, advanced project management skills become necessary,” says Dan DeMaria, director of Bio-Medical Services & Communications with Olathe Medical Center in Olathe, KS. “The ability to manage an interdisciplinary project is critical to success.”

The move toward a systems dynamic also opens the door to HTM professionals playing even greater roles in their facilities.

“Healthcare technology managers will be using the information from practical applications of systems engineering to improve their infrastructures within a particular hospital unit and throughout the entire hospital,” Whanger says. “With this information they can engage in discussions about improving data trending and communication between devices so as to improve overall healthcare to a patient or patients as well as ease the burden on nurses writing information into charts. This will also allow for improved communication between nurses during shift changes as well as better communication between other healthcare professionals at the hospital.”

Raymond Zambuto, president of Clinical Engineering Concepts, LLC, says that what he calls “clinical systems engineers” will need to take on new, specialized roles, in collaboration with other stakeholders, such as IT professionals, clinicians, and manufacturers, in these areas:
- Process engineering
- Data mining and analyses
- Systems modeling and simulation
- Human factors engineering
- Reliability analysis, root cause analysis, and failure modes and effects analysis
- Risk management
- IT service quality management guidelines
- IT and networking technical skills

Systems thinking advocates believe there is an emerging, but largely unfilled, need for systems integrators in hospitals and other healthcare delivery organizations. That role entails bringing big-picture thinking to sociotechnical systems. Moreover, if clinical engineers and other HTM professionals do not step into these new roles, they risk being marginalized by others who can evolve to meet technology needs, Zambuto says.

New skills are required at the technician level as well, DeMaria says. In addition to working closely with or as a part of IT, “we must understand basic networking and have a ‘big picture’ understanding of the entire data flow from medical device to the network to the electronic medical record.”

Plus, he says, biomedical professionals are often in a position of “triaging” reported problems and engaging appropriate subject-matter experts, including network engineers, systems analysts, or communications engineering staff. While HTM staff may not actually resolve problems, they do take ownership of them and ensure resolution.

“It is my expectation that HTM technicians will be more involved in initial trouble analysis of complex interdisciplinary systems,” DeMaria says. “I can envision a day in which HTM will become a tier 2 help desk function. I expect we will be providing
A complicating factor to the systems evolution is the fact that more healthcare is moving outside the hospital setting and involves issues as complex as EHR implementation and alarm management. The systems dynamic will go with that migration.

resources to a unified help desk, which will further blur the lines between HTM, IT, and even communications.

Some HTM professionals are beginning to use systems engineering principles and tools more deliberately. “I have seen more and more collaboration in working with IT and risk management as we further develop our EMR, medical device integration, and new electronic adverse event reporting systems,” Stiles says. “As we introduced these new systems, we have followed new and unknown implementation and validation processes developed by our informatics groups based on new and different established standards. We are developing workflow strategies now that include our other major support groups—IT, nursing practice councils, pharmacy—during medical equipment management and support activities.

“An acute example,” Stiles adds, “is that we can no longer just take a system down without advance notice to clinicians and IT support. Our actions performed on medical devices now can make a real-time effect on data reaching the EMR interface.”

A complicating factor to the systems evolution is the fact that more healthcare is moving outside the hospital setting and involves issues as complex as EHR implementation and alarm management. The systems dynamic will go with that migration.

LEARNING FROM OTHER INDUSTRIES

The nuclear power, aviation, petrochemical, and defense industries are farther along in their application of systems engineering principles and tools, experts say. Many acknowledge that healthcare is different from those industries. Patients, clinicians, and healthcare environments have considerable variability, for example, making it difficult to come up with one-size-fits-all approaches.

Still, the experts also believe there are lessons to be studied and adapted from industries that have applied systems thinking for many years, such as:

Standardization—“The aphorism is that if you’ve seen one hospital, you’ve seen one hospital,” Desborough says. “In other industries, Joe doesn’t decide he’s going to land his airplane a little differently than Bob did, or Sally doesn’t say, ‘I’m going to put the fuel rods in my nuclear reactor slightly differently than Billy did.’ Every hospital is its own system, every doctor is his or her own system. I think that’s changing in pockets, and that’s usually the way it is with the diffusion of any new idea.”

Managing requirements, risks, and connections—“The healthcare industry can learn the importance of defining ‘strong and testable’ requirements, defining the architecture of products or family of products, understanding the importance of assessing the risk of a system of systems, understanding the importance of interface requirements between systems, and the importance of testing and tracing those interfaces,” Whanger says.

“What other industries have worked out different ways of making sure that pieces connected together actually work together as intended, while minimizing unintended consequences,” Baird says. “Other industries know how to specify, install, and test connected systems. They also know how to continue working safely when components they are connected to stop working.”

Learning capability and sharing—The ability to learn from a system, and use that learning for continuous improvement, is lacking. Learning capability can be a system behavior—if it is engineered into the system. Likewise, routine sharing of learnings throughout the healthcare community is lacking.

“We can get a sort of ‘peace dividend’ from the set of tools and techniques from other domains,” Desborough says. “We don’t have to go and build a differential algebraic equation solver—we can just go and get one off the shelf that somebody else from another industry has built. The availability of these tools has never been better.”

What About Risk Management?

Fewer than 60% of healthcare organizations surveyed employ a proactive, technology-related risk management process, according to a 2012 survey of representatives of community hospitals, academic medical centers, and enterprise healthcare systems by HIMSS, with support from AAMI, the American College of Clinical Engineering (ACCE), and the American Society for Healthcare Risk Management (ASHRM) (HIMSS 2012).

Survey respondents indicated that their organizations attend most often to risk management processes for systems that are clearly identified as either biomedical systems or IT systems.

“Some questions of ownership of hybrid systems may result in their ‘falling through the cracks’ of risk management,” according to the survey report.
Who’s Regulating Systems?
Currently, it’s up to manufacturers and healthcare delivery organizations to attend to the potential complications when multiple devices or systems are connected.

“It’s not that regulators are avoiding the issues posed by complex systems,” Schrenker says. “Regulatory professionals were among the parties who advocated for the creation of 80001, and MDDS [Medical Device Data Systems rule by the U.S. Food and Drug Administration (FDA)] is a regulation. Rather, it’s that the laws they are required to enforce were created in a very different technological context. Until consequences emerge that make the risks of the current context evident, regulatory paradigms will not change.”

He believes it will take a serious adverse event that implicates the lack of regulatory oversight for the implementation of a complex system, in which serious risks were not systematically assessed and managed, to change regulations.

“We are assuming support of physician offices, outpatient clinics, and other nonhospital care areas as the hospital builds its healthcare network,” Herr says.

Systems Applications In Manufacturing
Systems engineering, architecting, and integration are increasingly relevant to manufacturers in designing and developing health IT equipment.

“There are a number of companies today that have developed or are building competencies in these areas, whereas before there might’ve been functional engineering departments like electrical or mechanical or software engineering,” Desborough says. “It’s a recognition that these things are all part of a broader system and we need to be thinking about these different aspects proactively.”

In Desborough’s own work developing an artificial pancreas, model-based design and simulation are powerful tools. Models and simulations allow designers and developers to accurately predict desired behaviors and unintended consequences of a system—and tweak the system to weed out negative effects—in early stages of design and development.

With such tools, manufacturers can get more “proactively engaged” in designing products to fit into a broader system, Desborough says. Models and simulations are applicable as well to healthcare delivery organizations that are engineering or re-engineering systems. Some healthcare systems, in fact, have created simulation centers for this purpose.

“I also think that many companies are going to have to think defensively about their designs,” Baird says. “Think about when you learned to drive a car. There is a style of teaching that is called ‘defensive driving techniques’ where you anticipate that things will go wrong, and your behavior is to minimize the impact of things going wrong—things like maintaining a safe distance between you and the car in front of you.”

“Similarly,” Baird says, “in other industries that have successfully connected systems together, there are defensive design techniques that minimize the effects of a network that is down, or of a connected component that has failed,” so that no single point of failure takes down a whole system.

Whanger says manufacturers need to broaden their perspective and communicate even more with stakeholders outside their own facilities. “Manufacturers should think about how their device can improve the health of the patient and work with other companies developing other supporting medical devices to develop and define integration points,” Whanger says. Companies also should improve communication between the hospital environments and the company for postmarket surveillance, she says. “They should also realize there could be a market for simpler devices but with the same communication capabilities for hospitals without the technology infrastructure—and also for in-home devices. There are lots of great possibilities by thinking beyond one device.”

In a sign that industry is beginning to recognize these possibilities, the CEOs of nine device makers (Cercacor, Cerner, Dräger, GE Healthcare Systems, Masimo, Smiths Medical, Sonosite, Surgicount, and Zoll) announced in January 2013 that they would work together to make their devices interoperable. Specifically, they will work toward sharing information across different devices to improve patient care—a systems-thinking approach.

The Impact on Life Cycles
Managing the life cycle of equipment will require a systems perspective as well. This begins even before purchasing decisions are made. “Obviously there will be more requirements in the request for proposal (RFP) that need to be thought through,” Baird says.

“Healthcare technology managers are going to need to demand more information from
“Medical devices are part of a larger electronic data management system,” Zambuto says. “BMETs need to take account of this in their approach to repair and maintenance protocols.”
— Raymond Zambuto, Clinical Engineering Concepts, LLC

their vendors, and will need to work closely with the vendors to ensure that everything works together as intended, without unexpected consequences.”

At the purchasing level, there’s a growing list of variables to consider. “The purchasing process needs to take account of the environment, work flows, human factors, and other equipment systems it will be interacting with,” Zambuto says. “The design of medical equipment is a much more complex business if it is to be done right. My concern is that not all manufacturers will recognize these factors, making it all the more important for the hospital and its clinical engineers and BMETs [biomedical equipment technicians], whether in-house or contracted, to be aware of the reality of system of systems interaction.”

In practice, this means that the clinical engineering job of managing medical systems is not only changing, but expanding. “Our clinical engineering program still follows our basic goals of equipment management, preventive maintenance, repairs, and reporting,” Stiles says. “We still report to facilities, as most other hospitals do, but we have created many shared processes with other system owners such as IT, pharmacy, and risk management.”

To work more effectively in this systems environment, Long Beach Memorial Medical Center has adopted different processes to support the acquisition of new equipment, design of medical device integration workflows, and collaboration with new groups and committees, he says:

- A universal workflow and efficiency process based on Toyota LEAN that provides standardized goals and effects for all disciplinary groups and services. This LEAN-based approach has been useful in studying and developing many system-based approaches, such as bar code medication administration, or the introduction of an additional EMR module such as anesthesia workflow. The medical center is now using the LEAN process in all areas of focus. This has helped the institution adopt standardization of system validation, downtime processes, and evaluation of even newer system implementations coming on line in the future.
- The medical system has introduced into its culture the use of its strategic plan in every aspect of employees’ jobs to achieve our goal of matching these systems to work as one.
- A new capital and construction request process now requires review by facilities, IT, and biomedical to ensure that requests meet the new systems approach in infrastructure, technology, and informatics.

Likewise, with a systems approach, medical and health IT upgrades, repair, and maintenance will increase in scope, at least over the short term.

“If there is a software upgrade for one device, this might cause a communication error to other medical devices or cause a communication error to the nurses’ station,” Whanger points out.

The fact that just about everything is connected in multiple ways in the modern hospital is the main point that healthcare systems considerations for purchasing decisions

Kathleen Whanger, quality assurance manager with the vascular division at Teleflex Arrow International, provided these system-oriented factors for healthcare facilities to consider when buying medical equipment with communication features.

- How often is the medical device used?
- How does the medical device integrate with the current hospital communication center?
- How does the information from one medical device integrate with information from another medical device?
- How is the information from multiple medical devices relayed to the nurses’ station or to a doctor’s mobile device?
- How is the information from multiple medical devices relayed to the companies building the devices?
- How do the alarms and alerts from the devices impact quality of work for healthcare professionals and quality of stay for patients?
- How transportable are these devices?
- What is the cost to install the equipment, train healthcare professionals, and maintain these interfaces?
- Will the interactions between the devices reduce costs and risks to the patient eventually?
- With software upgrades, does the company understand how the device will interact with other devices?
Taking a Broader View

To add value in a systems environment, “I would suggest that clinical engineering professionals need to consider emerging issues less from a perspective of ‘what does this mean for me in the here and now?’” Rick Schrenker of Massachusetts General Hospital advises.

Instead, he suggests a more strategic, longer-term perspective: “What does this imply regarding organizational strategy? For example, what are the strategic implications of 80001 and the MDDS regulation?”

IEC 80001 is a risk management standard, with standardized tools. The FDA’s MDDS rule reclassifies these systems from Class III (subject to premarket approval) to Class I (subject to general controls).

“What opportunities and threats do they expose? What gaps exist between an organization’s capabilities to address them and what will be needed? What tactical and strategic options exist to address those gaps, assuming doing so is deemed worthwhile? What are the risks of doing nothing?”

technology experts keep coming back to. Virtually no piece of equipment operates in isolation anymore.

“Medical devices are part of a larger electronic data management system,” Zambuto says. “BMETs need to take account of this in their approach to repair and maintenance protocols. For example, the loss of data transfer on a monitoring system could be a hardware problem, a software problem, or a network problem. Coordination needs to be maintained with the IT department. Similarly, when working on a system that supports more than one patient, care must be taken to not disturb the flow of information from other beds while troubleshooting or maintaining a problem area.”

Collaborative efforts like these might not be easy—at least at first. “I like to compare this to cleaning out my garage,” Baird says. “I have so much clutter in my garage right now; when I finally decide to reorganize it, during the actual reorganization itself, the garage looks much worse—everything is moved out of place, piled on top of each other, as things are moved around to make room. Eventually, I get one corner organized, then another, and eventually all of the clutter and chaos in the middle of the garage is gone and I have a much more efficient setup.”

Ironically, it could well be that more systems will help solve some systems issues. At the Christ Hospital Health Network, Herr says the computerized maintenance management systems (CMMS) incorporates more than traditional clinical engineering devices management. It includes IT information and regulations related to the Health Insurance Portability and Accountability Act (HIPAA). “Systems management is part of this CMMS,” he says.

Creating these systems and making them work smoothly won’t happen all at once, and it will be challenging. But there are ways to start. “Let’s just say that without recognizing that we are dealing with a system of systems, and breaking the delivery of care in today’s and tomorrow’s hospitals into smaller ‘chunks’ or subsystems, we will never get a handle on how it all really works or how to improve operations and safety,” Zambuto says. “If we try to treat it as a whole, we will drown in a tsunami of unintended consequences.”

References

