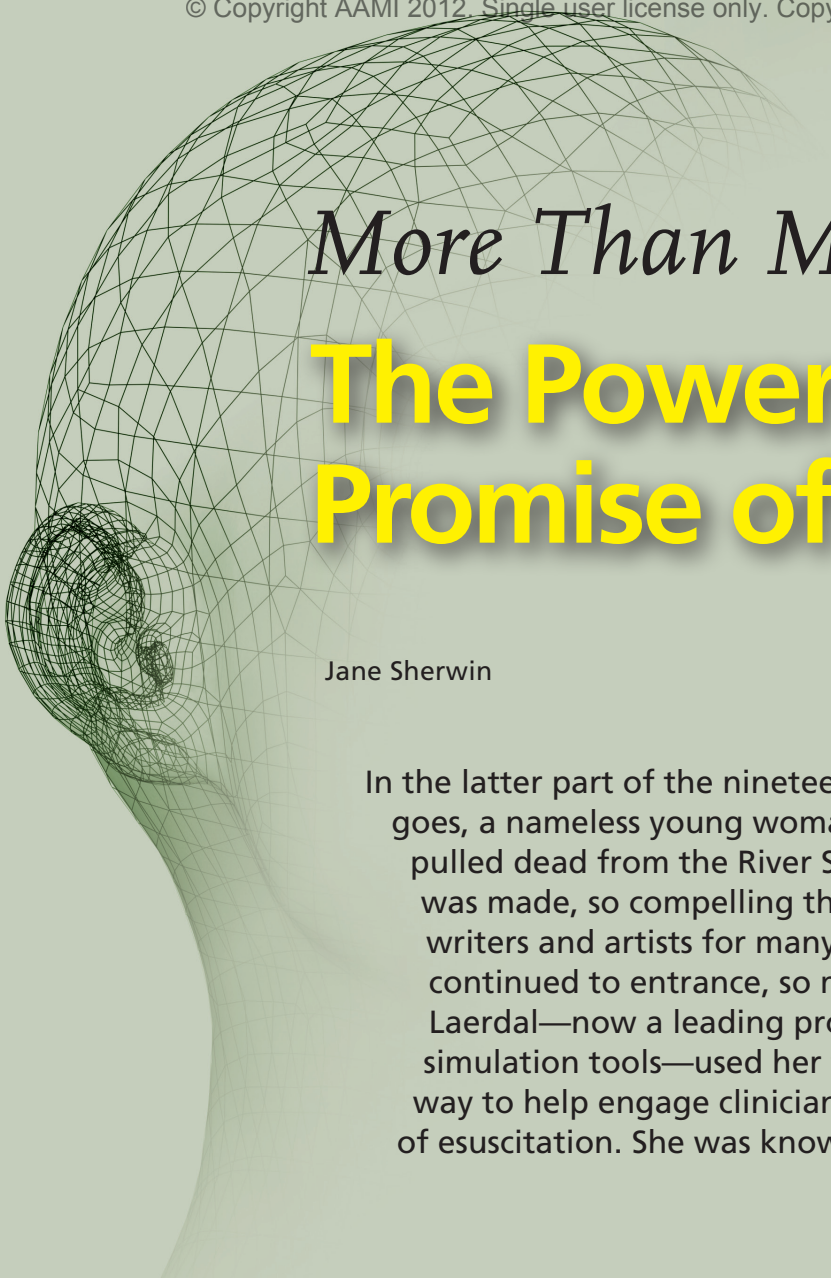

More Than Make Believe

The Power and Promise of Simulation

Jane Sherwin

In the latter part of the nineteenth century, so the story goes, a nameless young woman of great beauty was pulled dead from the River Seine in Paris. A death mask was made, so compelling that her face entranced writers and artists for many years. The image continued to entrance, so much so that in 1960 Laerdal—now a leading producer of medical simulation tools—used her face on a mannequin as a way to help engage clinicians wishing to learn the art of esuscitation. She was known as Resusci Anne.

About the Author

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If the story of simulation remained centered on mannequins for clinical learning, it would be a fairly straightforward one, telling how advancing technology enables increasingly sophisticated devices for the practice of everything from tube insertion and breech birth delivery to gallbladder and cardiothoracic surgery. But the story is much deeper and more complex. Simulation today permeates almost every aspect of modern healthcare, including product design, product evaluation and purchase, and clinical training.

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Pat Baird, a system engineer with Baxter Healthcare Corporation, said the use of simulation centers—in which events are staged and recorded—is invaluable when it comes to design testing. "This allows us to explore how users react to our designs, while collecting strong data that we can go back and replay over and over again to see exactly what happened," Baird said. "Our users are very creative, and the best scenarios are ones in which we learn something about how a user thinks, which may be different from the way an engineer thinks."

Simulation is even an important tool in testing and improving the way clinicians work in teams, evaluating how they interact to accomplish their patient-centered tasks. Human factors engineering, focused on the interaction between devices and users, frequently relies on simulation. And simulation technology has become highly sophisticated, drawing on the technology of gaming, video techniques, and much of what Hollywood has come to consider a normal part of film-making.

"Simulation-based training in healthcare has been experiencing explosive growth over the past decade," said Joseph T. Samosky, director of the Simulation and Medical Technology Research and Development Center with the University of Pittsburgh in Pittsburgh, PA. "In 2000, there were about 100 clinical simulation centers in the United States. Today, there are more than 1,000."

The U.S. Food and Drug Administration's Office of Device Evaluation has shown an interest in human factors engineering and the extent to which simulation can ensure the safe use of medical devices. In a report released last year—*Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting the Public Health*—the agency identified simulation as one way to help improve the reliability and safety of medical devices. Additionally, the FDA's new recommendations for medical device design include human factors testing or "usability."

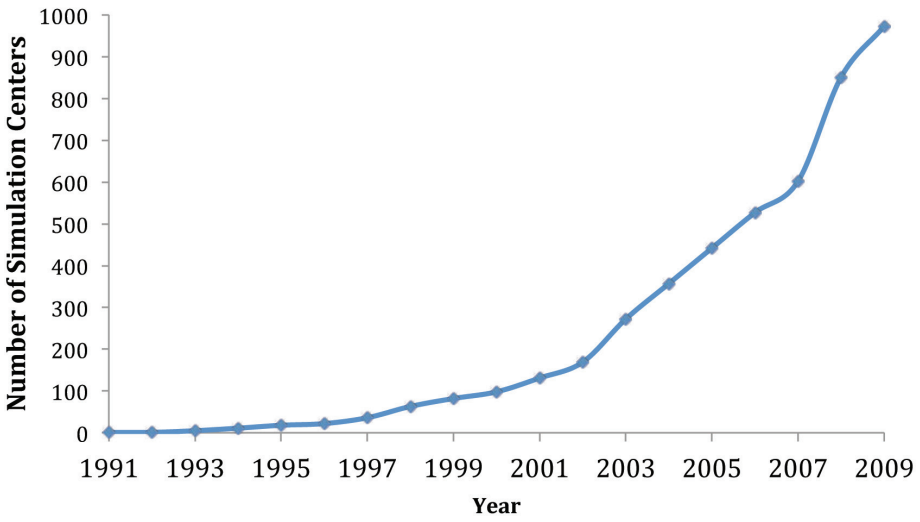


Figure 1. Growth of Medical Simulation Centers in the United States, 1991-2009. (Plot and data analysis by Emma Baillargeon and Joseph T. Samosky, Simulation and Medical Technology R & D Center, University of Pittsburgh. Data derived from Worldwide Simulation Centre Database, Bristol Medical Simulation Centre, Bristol, UK.)

'Virtual Reality'

Clinicians, first responders, fire fighters, even Girl Scout leaders are familiar with the use of simple mannequins for training in life-saving skills. Contrast these to a birth simulator tool developed by researchers at Johns Hopkins Medicine in Baltimore, MD, described in the spring/summer 2005 edition of *Hopkins Medicine*. "The maternal model consists of a mock pelvis, uterus and birth canal, and a pump that simulates birth contractions and maternal pushing. Used in conjunction with a fetal mannequin that measures tension in the infant's neck and brachial plexus, it helps determine the degree of force the obstetrician applies during delivery. Measuring that force is a separate device that contains three electrodes attached to the forearm of the physician which send data to a nearby computer."

Paul Phrampus, director of the Peter M. Winter Institute for Simulation, Education and Research, also with the University of Pittsburgh, said there have been "substantial improvements" in simulator capabilities.

"In 2000, there were about 100 clinical simulation centers in the United States. Today, there are more than 1,000."

— Joseph T. Samosky, Simulation and Medical Technology Research and Development Center, University of Pittsburgh

"There are now a dozen patient simulators, with easy-to-use software, enabling ease of teaching," said Phrampus, who will assume the presidency of the Society for Simulation in Healthcare next year. "There are virtual-reality instruments coupled with actual surgical instruments. You can watch a surgeon perform a gallbladder removal, with instruments in hand, except that there is no patient present. Rather, the screen shows the virtual reality, using software based on actual patient data."

Simulation for training can also include what is known as "haptic feedback" or the illusion of touch. Samosky described devices that can

Two registered nurses (seated) work with a vendor instructor to program PCA pumps in preparation for a simulation exercise at Huntington Memorial Hospital in Pasadena, CA.

Two nursing students practice on a patient simulator at the Smart Hospital,™ a virtual hospital on the campus of the University of Texas at Arlington.

create "the illusion of pulling on thread, and feeling the resistance of tissue. The system you are working with has been programmed to know the typology of the knot. A square knot will hold, and the system will give a green light if you have tied the right knot."

"The industry is increasingly moving to simulation rather than clinical trials. Simulation can be just as informative, or more so, about user interaction, especially when you don't need to know about patient reaction."

— Izabella Gieras, Huntington Memorial Hospital

Samosky and Mary Beth Mancini, president of the Society for Simulation in Healthcare, based in Wheaton, IL, both emphasized the use of simulation as a way to probe and test hospital systems. "Events ranging from a mock code—for example, simulating a patient suddenly collapsing in a cafeteria—to a simulated mass casualty event can be used to test systems, teamwork, communication and care coordination," said Samosky. "To learn from the experience, assessment must be included. There is the dictum 'practice makes perfect,' but that's not strictly true: if you practice something incorrectly you won't perfect it. It's *correct* practice that makes perfect. We can assess both individual and whole team performance in simulation, as well as 'best practices' themselves."

Mancini described the creation of a virtual reality situation for medical students and students in nursing and pharmacy. "When they aren't on the same campus, we can use technology to enable all of them to work on the same case study, writing prescriptions, transferring them to pharmacy, then to nurses for administration of doses," she said. "We can introduce errors intentionally and observe how they interact, and then bring them online for evaluation and assessment of the experience."

Using Simulation to Help Evaluate Equipment

For those who are charged with the purchase and maintenance of medical devices and technology in hospitals, simulation and its close partner, human factors engineering, is increasingly being used for testing and evaluation.

"When you enter a hospital as a patient, you are stepping into a system—a complex combination of data and equipment," said Michael Wiklund, co-founder and president of Wiklund Research & Design, Inc., a consulting firm specializing in human factors and based in Concord, MA. "As a patient, this is not necessarily apparent to you, but it may not be apparent to clinicians, either. Clinicians are working with

equipment and information flow; it's a challenge if these are not fine-tuned to meet the needs of the user and to ensure patient safety."

Izabella Gieras, director of clinical technology at Huntington Memorial Hospital in Pasadena, CA, said the use of simulation is clearly on the rise in healthcare facilities.

"The industry is increasingly moving to simulation rather than clinical trials," she said. "Simulation can be just as informative, or more so, about user interaction, especially when you don't need to know about patient reaction."

Gieras described her hospital's use of simulation for choosing a new PCA pump. "This was a two-day undertaking rather than a week or so. Once we had our top two vendors, we did a side-by side comparison, as in a clinical trial, to evaluate ease of use. We did the whole thing in a classroom, which we set up with stations and users. The final decision was obvious."

Frequently, simulation is possible without a simulation center and its mannequins. Emerson Hospital is a community hospital in Concord, MA, where computer-simulated arrhythmia is used for daily trouble-shooting on faulty alarms. "When the hospital needs new beds," said Ernest Stevens, biomedical engineering manager, "nurses are invited to test out a vendor's offerings, checking maneuverability down hospital hallways and testing the speed with which the bed will go prone for CPR treatment."

"Hospitals can save money in the long run by conducting these kinds of usability tests with simulation."
— Frank Painter, University of Connecticut

Frank Painter teaches clinical engineering at the University of Connecticut's Department of Computer and Electrical Engineering. Painter emphasized the value of simulation testing for hospital equipment, and made it clear that such testing need not occur in a simulation center.

"Every hospital environment is slightly different, and not every device is perfectly suited for every environment. Not enough hospitals do enough onsite testing," Painter said. "Costs, maintenance needs, and usability should all be part of the process. Clinical engineering may be short staffed, and time and

budgets may be tight, but mistakes mean long-term consequences: The new device may not even work, and the hospital may suffer for years in terms of special workarounds and extra training. Hospitals can save money in the long run by conducting these kinds of usability tests with simulation."

The Use of Formal Simulation Centers

Gieras said that simulation centers are more often called for when elaborate data is needed. "How much of the whole healthcare experience do you need?" she asked. "What human factors are involved, such as high noise levels, a wide variety of staff working together, or high-risk, multi-disciplinary equipment? Are you selecting equipment that must interconnect with devices throughout the hospital?"

Phrampus, of the Winter Institute, said medical device manufacturers often turn to simulation centers to help improve the design of their products.

"Device companies hire us to create clinical simulation, to watch how clinicians interact with devices, from mental status monitors to intravenous infusion pumps and ventilators," Phrampus said. "We help them learn how easy—or difficult—the device is to use, what contributes to patient safety, and how to adjust the design so that it's harder to make a mistake."

Jeff Cooper, executive director of the Center for Medical Simulation at Massachusetts General Hospital in Boston, offered similar comments. "We try to make the environment as real as possible," he said. "We try to create some kind of stress that would lead people to make errors. This includes people who might be around, and be distracting, just by their presence. We offer a way to test how the device is used under pressure, and reveal the different kinds of problems that people have in using it."

Wiklund's firm supports medical technology

A HISTORICAL VIEW

Biomedical engineers have long been aware of the use of simulation in other industries, including aviation, and its potential for healthcare.

Joseph Samosky, director of the Simulation and Medical Technology Research and Development Center at the University of Pittsburgh, described the development of flight simulation from the Link Trainer of the 1930s to use of simulators to develop the F35 fighter, which took its first flight in 2006. "An F35 simulator was developed not only for training but well before the plane took flight, to get pilot feedback on features and interfaces. As a design tool, simulation can offer flexible what-if perspectives that are cheaper, safer and easier to obtain than in the 'real world.'"

Given its hazards and complexities, anesthesia was an early target for simulation in the interests of patient safety. "I was a co-op student at Dupont, a place that valued safety even in the late 1960s. I got to observe what was happening in operating rooms, and by the early 1970s became interested in medical error and anesthesia," said Jeff Cooper, executive director of the Center for Medical Simulation at Massachusetts General Hospital in Boston. "I worked on the prototype of a computer-controlled anesthesia machine, one of the early medical microprocessor devices. Even then, there was a human factors emphasis: How people make mistakes and how to prevent them. The Anesthesia Patient Safety Foundation gave the first grants for simulation."

A recipient of one of those first grants was David, Gaba, MD, associate dean for immersive and simulation-based learning at Stanford University in California, who developed a mannequin-based simulator. He described several threads coming together to shape the area of medical simulation. As was the case with Cooper, it was clear to him as early as 1985 that anesthesia, with its patient safety issues, reflected the systems challenges found in areas like nuclear power and airline piloting. The question was not simply how well machines worked, or what simulators could teach clinicians, but how teams—whether in the air or the operating room—worked together. For example, "cockpit resource management training" focused on decision-making and team resources, rather than "stick and rudder skills."

The Institute of Medicine's 1999 report, *To Err Is Human,* was a driving force in the focus on medical errors and their prevention.

"People took note: The study suggested up to nearly 100,000 deaths from medical errors," said Paul Phrampus, director of the Peter M. Winter Institute for Simulation, Education and Research (WISER) in Pittsburgh, PA. "We needed to improve equipment design for safety. Complexity was on the rise in what instruments could do, and companies needed to decrease the complexity of operator input. To ensure the most accurate—and therefore safest—use of a machine, where does a critical button belong? Should it be red, or white? Simulation helps us try out the button placement and figure out what works best."

developers, from small startups to large pharmaceutical companies. He pointed to the wide range of services simulation can provide, from helping conduct research in the early stages and exploring the user interface, to evaluating device ergonomics, device compatibility with user cognitive functions, and even printed materials that would accompany the purchased product.

"We always video record when simulating," said Wiklund. "We use multichannel recording to collect top down and side views along with the facial expressions of users. If there's a use error—for example, a surgeon in simulation moving to grasp a tool upside down, the video can capture it—a tiny physical motion—as with a microscope." Wiklund described the use of eye-tracking systems to determine, as in advertising, where the user is looking, and for how long.

Tackling Challenges In Modern Healthcare

Simulation is emerging as one of the most useful tools in addressing some of modern healthcare's most pressing challenges, whether it's the effective management of clinical alarms, improving the safety of infusion systems, or reducing the risk of tubing misconnections.

"We are starting to get some traction on the alarm problem," said Phrampus. "Recognition is underway, and we've seen some good papers. In some ways, the complexity of the alarm system—or lack of system—reflects a situation where technology is driving the patient process—the reverse of what is healthy."

At Boston Medical Center's new Solomont Clinical Simulation and Nursing Education Center, there is a lot of focus on alarms, using simulation for training. "No one model fits everybody," said James Piepenbrink, director of clinical engineering at the hospital. "And there's a lot of challenge in educating staff how to respond to alarms." So Piepenbrink's team put together a self-contained telemetry system, on a cart, which can be moved from classroom to classroom for training, or even brought to staff at work if a follow-up is needed.

This self-contained and portable telemetry system is used for alarm training at Boston Medical Center's Solomont Clinical Simulation and Nursing Education Center.

"A telemetry cart like this is also critical for staff orientation," he said. "We use it to create simulated wave forms, including escalation to various arrhythmias, to replicate patient changes and to test them on recognition of arrhythmias. We throw them curve balls. Done in the classroom, annually, this simulation gives staff the ability to recognize what alarm signals mean."

Simulation is emerging as one of the most useful tools in addressing some of modern healthcare's most pressing challenges, whether it's the effective management of clinical alarms, improving the safety of infusion systems, or reducing the risk of tubing misconnections.

Similarly, simulation is proving useful in making design improvements to infusion pumps. "Soon we will begin to design infusion pump prototypes—for test bed purposes only—to evaluate possible improvements for pump safety," said Peter Doyle, a human factors engineer at Johns Hopkins Hospital. "Once developed, we will

A Matter of Teamwork

While engineers do not often think of themselves as human resource managers, the fact remains that the growing complexity of hospital systems calls for attention to human behavior and interaction. Jeff Cooper, executive director of the Center for Medical Simulation at Massachusetts General Hospital in Boston, emphasized the importance of communication between any two people or within a larger team.

"In teaching the effectiveness of team function in either aviation or healthcare, good communication is one of the highest objectives," he said. In a 2010 editorial in *Simulation in Healthcare,* Cooper cited the value of simulated handoffs in preventing the loss of critical information about the patient and all that surrounds his or her process of care.

Boston Medical Center's new Solomont Clinical Simulation and Nursing Education Center offers team training as well as clinician education and device testing and design.

James Piepenbrink, director of clinical engineering at the hospital, said "it's important to get different people together," so that they can "see how they fit into the team approach to patient care."

test those pumps in high-fidelity simulation scenarios to learn if the improvements do indeed help promote safety."

The November/December 2011 cover story of *BI&T* described the challenge of tube connectors whose confusing similarity can lead to dangerous, even deadly, misconnections. Through simulation, design engineers are recognizing that the problem is much larger than distinguishing connectors. Wiklund described using a simple, non-computerized mannequin to try out a simulated IV access with a drain line to the arm. "We need to pay attention to the peripheral devices that can get in the way, and the noises and distraction," he said. "We use a soundtrack of ambient noise, combined with the infusion pump noise—together these create the noise of the whole environment."

Tony Easty, senior scientist with the University Health Network in Toronto, agreed that redesigning connectors to signal where each belongs will address only part of the problem.

"We can use simulation, and observation with one-way mirrors, to understand what is actually happening at the bedside. To what extent are people coping effectively with the pressure and reality of medicine in the workplace? Nobody would consciously make these mistakes. Simulation allows us to understand the complexity of error."
— Tony Easty, University Health Network, Toronto

"Smart pumps, too, are a partial solution," he said. "The Holy Grail is to achieve a degree of automation where everything works together, and the nurse has only to check that the pump system is working. We can use simulation, and observation with one-way mirrors, to understand what is actually happening at the bedside. To what extent are people coping effectively with the pressure and reality of medicine in the workplace? Nobody would consciously make these mistakes. Simulation allows us to understand the complexity of error."

Cooper described creating scenarios to test how clinicians use both pumps and alarms under stress conditions. "We give them the opportunity to make mistakes safely. In a normal environment, we can't push and see how that could hurt," Cooper said. "You could say the same about dialysis machines and incubators. We want to see how they can be misused, especially devices used for treatment. We're looking at extremes of use, from an emotional sense. Studying alarm issues in a realistic simulation setting should be very effective. This can be a gap in an engineer's education—simulation gives them a larger context, and shows them how what they do fits in the larger picture."

How Much Is Enough?

There is something of a debate in professional circles about how much simulation is needed in training and testing. "You only need as much realism as your testing calls for, and there is not yet empirical evidence about how much is needed," Cooper said. "For example, if someone is learning how to suture for the first time, you want them to practice a mechanical skill in a calm, non-threatening environment, but you also want the skin to feel as real as possible. Later, you might want to add the emotional and psychological elements of suturing a patient after surgery.

"At the other end, where you may be working to get people to accept the need for effective relationships with colleagues, we generally believe that having the most realistic emotional environment is essential."

The terms "high" or "low" fidelity are often used to describe the extent to which a procedure is simulated. A simple glucose meter, blood pressure cuff, or low-activity patient monitor are not so heavily influenced by their environment—although even in these cases there may be questions of the effects of bright sunlight or a very dark theater.

Similarly, Wiklund said, testing a device for delivery of medication for an agitated patient in the emergency room may call simply for a "standardized patient," someone trained in simulating belligerence and uncontrolled movement.

In contrast, said Wiklund, testing other devices or systems calls for a far more ambitious plan.

"We would scale up massively to simulate the whole environment of an anesthesia work station in an operating room: patient, table, infusion equipment, ventilators, monitors," he said. "During a critical phase, such as intubation, we'd have a fully simulated operating room staff, including surgeons and scrub

A Closer Look at One Simulation Center

The Marcia & Eugene Applebaum Surgical Learning Center at Beaumont Health System in Royal Oak, MI, serves a variety of purposes, including research and testing, practice procedure and resident education, and team training.

"While we're called the Surgical Learning Center, it's quickly become clear that we can support many areas beyond surgery," said S. Noel Simpson, a human factors engineer with Beaumont who has conducted research at the center." Device designers and manufacturers can observe their staff testing out their equipment in a simulated environment. Medical students and other clinicians have the opportunity not only to learn techniques, but to evaluate them. We could definitely include first responders in our education programs. At this point, our clients are about 90% training and 10% R&D, but we expect to increase our R&D activity."

Diane M. Schuch-Miller, assistant director of the Surgical Learning Center, said physical space, staffing, and programs will differ with the philosophy of any given center, its primary users, and their needs.

"Staffing is going to vary widely with each center," said Schuch-Miller. "In our case, we have an executive director who is our physician champion. Our assistant director builds our curricula and our learning objectives and oversees day-to-day operations, staffing, equipment, and customer satisfaction. We have a clinical simulation educator who's in the lab most of the time, overseeing training. And our program coordinator handles paperwork, scheduling, and evaluations."

In-Depth Interview

The "View From the Top" interview in this issue of *BI&T* is with Joseph T. Samosky, director of the Simulation and Medical Technology Research and Development Center at the University of Pittsburgh.

nurses, to determine how these would affect the anesthesiologist using the new design.

"We could do it in a lower fidelity setting, such as a test lab with fewer props and actors, and still get good value, but this might prevent what could see in high-fidelity simulation." And in either case, he said, "the researchers and staff of the center have to be really good at using the simulation tools, knowing what to look for and how to get accurate results."

Wiklund pointed out that the FDA guidelines *Applying Human Factors and Usability Engineering to Optimize Medical Device Design* do not call for one standard level of simulation. "The guidelines are open to interpretation because they want to get representative users to perform representative tasks in a representative environment."

Huntington's Gieras thinks that simulation centers are naturally part of the response to the new FDA guidelines calling for infusing human factors into device design. "We do see a difference from last year," she said. "Vendors are more knowledgeable, and prepared for our questions. The fonts on their printed materials are more readable, display size is bigger and easier to see, and there are better warnings, especially with infusion pumps. These improvements definitely reflect an increase in simulation testing."

What Does the Future Hold?

There are an increasing number of simulation centers in place or in development. But "center" can mean anything from a hospital conference room or a community college classroom to full-fledged simulation headquarters with millions of dollars worth of equipment.

"SSH is actively trying to address the question of what makes a strong simulation center," Mancini said, referencing the Society for Simulation in Healthcare. "Simulation programs need not include bricks and mortar. Some hospitals have free-standing areas for training teams with simulation. The Society has an accrediting program for simulation programs, and we've worked with 20 so far. There's lots of interest: People either want our quality imprimatur, or they want to know the standards to meet as they put their center together."

Simulation, in its widest possible meaning, appears to hold something for everyone with an interest in using engineering to improve healthcare. Consider Lance Baily, who has a BA in film studies from the University of California at Santa Cruz. After working in Hollywood for four years, he began training as an EMT and fire academy graduate. Then he encountered a high-fidelity medical simulation mannequin "and all my worlds collided successfully." Until recently he was director of the Clinical Simula-

CAREER OPPORTUNITIES

As the use of simulation grows in healthcare, it stands to reason that healthcare technology professionals could see new job opportunities.

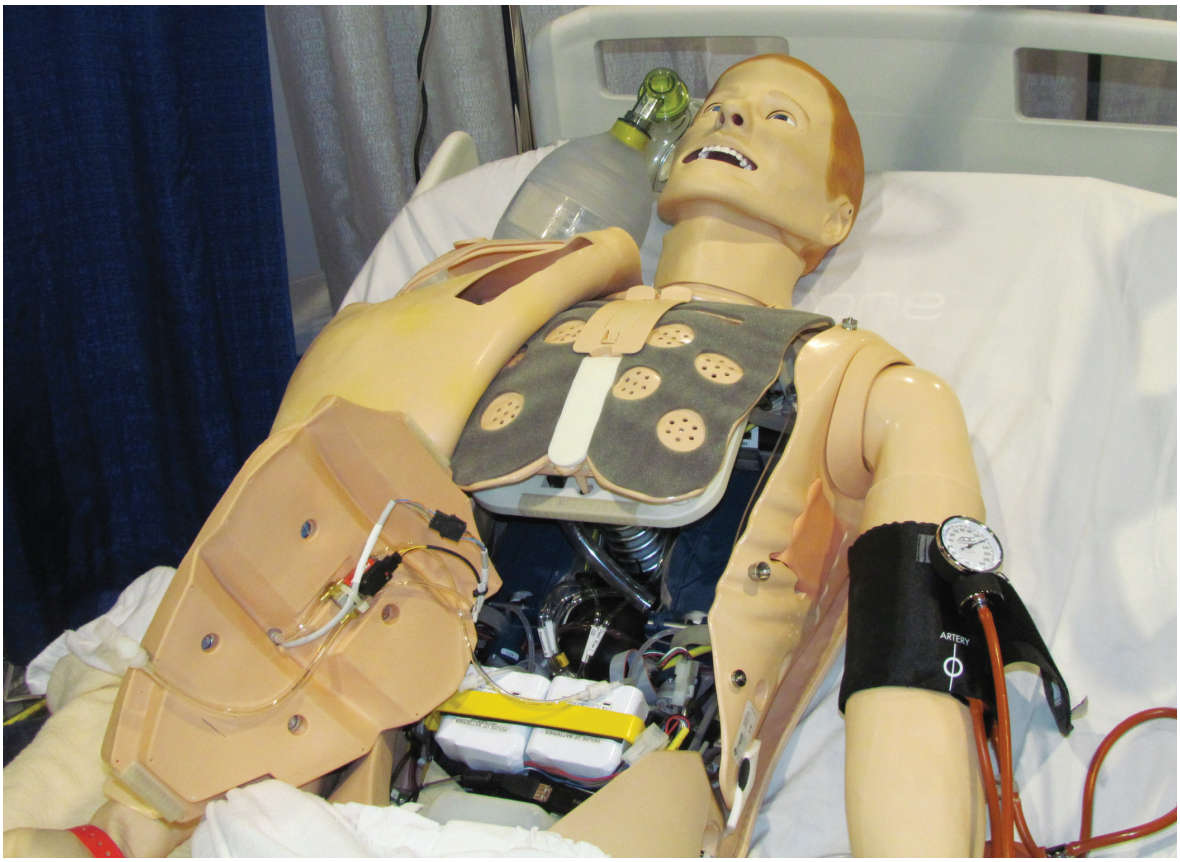
Peter Doyle, a human factors engineer at John Hopkins Hospital in Baltimore, MD, describes the role such professionals play in simulation centers.

"Clinical engineers help to populate centers with equipment, ensure the safety of those using facilities—for example, is there adequate handling of anesthetic waste gas?—and maintain the devices," Doyle said. "In some cases, they work with human factors staff to plan and conduct usability tests. Such help could be in the form of data collection methods, including video support."

Mary Beth Mancini, president of the Society for Simulation in Healthcare, said an ideal simulation center staffer would have an aptitude for patient safety and education, an ability to think on his or her feet, and some skills in patient care, but these combinations are not easily found.

"A few people have an aptitude for both engineering and healthcare," said Mancini. "We want educators and engineers to learn to think in an interdisciplinary way, but it has to happen more, and more deeply, and earlier in the educational process. We are looking for synergy and open-mindedness."

Samosky agreed that centers need multi-disciplinary, quick-thinking staff who can respond when a training setup needs to be altered, a program or A/V equipment needs debugged, or a scenario needs to be quickly altered on-the-fly in real time.



Medical mannequins, such as this one which was on display at the AAMI 2012 Conference & Expo, are a critical training and teaching tool.

tion Center of Las Vegas.

More than two years ago, Baily started the healthsimulation.com website "to provide unfiltered resources and honest advice to those developing or operating a healthcare simulation program."

"Simulation is a wide-open frontier," said Baily, "and I wanted an online-based resource that I never had when I was learning." He has also started meetings for both technicians (SimGHOSTS.Org) and administrators (HealthySimAdmin.com).

Virtual reality has its own medical simulation niche. Since 1992, when it began as the "Medicine Meets Virtual Reality" conference, MMVR/NextMed has served as "a forum for researchers harnessing IT advances for the benefit of patient diagnosis and care, medical education, and procedural training," according to its website.

David Gaba, MD, associate dean for immersive and simulation-based learning at Stanford University in California, said what's happening today with simulation is just a taste of things to come.

"Even with existing simulation tools, there is so much that we could be accomplishing," he said. "We're aiming for a future where everyone in healthcare cycles repeatedly through different types of simulation, sometimes as individuals, sometimes in teams or whole work units, and as part of ongoing performance assessment. If you are working in healthcare, you should expect to be doing simulation until you retire. This is the approach that has been so powerful in the other industries of intrinsic hazard and we should strive to match their records of safety." ■

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