

AD \_\_\_\_\_

Award Number: W81XWH-07-1-0391

TITLE: 4<sup>th</sup> Annual Conference Enhancing Awareness of Medical Simulation

PRINCIPAL INVESTIGATOR: Jackie Eder-Van Hook  
Robert J. Waters, JD

CONTRACTING ORGANIZATION: Center for Telehealth & E-Health Law  
Washington, DC 2005

REPORT DATE: September 2007

TYPE OF REPORT: Final Proceedings

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

|                                                                                                                                                          |                         |                                            |                                             |                                                    |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------|---------------------------------------------|----------------------------------------------------|---------------------------------------------------|
| <b>1. REPORT DATE</b><br>01-09-2007                                                                                                                      |                         | <b>2. REPORT TYPE</b><br>Final Proceedings |                                             | <b>3. DATES COVERED</b><br>8 May 2007 – 8 Aug 2007 |                                                   |
| <b>4. TITLE AND SUBTITLE</b><br><br>4 <sup>th</sup> Annual Conference Enhancing Awareness of Medical Simulation                                          |                         |                                            |                                             | <b>5a. CONTRACT NUMBER</b>                         |                                                   |
|                                                                                                                                                          |                         |                                            |                                             | <b>5b. GRANT NUMBER</b><br>W81XWH-07-1-0391        |                                                   |
|                                                                                                                                                          |                         |                                            |                                             | <b>5c. PROGRAM ELEMENT NUMBER</b>                  |                                                   |
| <b>6. AUTHOR(S)</b><br><br>Jackie Eder-Van Hook<br>Robert J. Waters, JD<br><br>Email: <a href="mailto:jackie@ctel.org">jackie@ctel.org</a>               |                         |                                            |                                             | <b>5d. PROJECT NUMBER</b>                          |                                                   |
|                                                                                                                                                          |                         |                                            |                                             | <b>5e. TASK NUMBER</b>                             |                                                   |
|                                                                                                                                                          |                         |                                            |                                             | <b>5f. WORK UNIT NUMBER</b>                        |                                                   |
| <b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b><br><br>Center for Telehealth & E-Health Law<br>Washington, DC 2005                             |                         |                                            |                                             | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>    |                                                   |
| <b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b><br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012 |                         |                                            |                                             | <b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>            |                                                   |
|                                                                                                                                                          |                         |                                            |                                             | <b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>      |                                                   |
| <b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b><br>Approved for Public Release; Distribution Unlimited                                                  |                         |                                            |                                             |                                                    |                                                   |
| <b>13. SUPPLEMENTARY NOTES</b><br>Original contains colored plates: ALL DTIC reproductions will be in black and white.                                   |                         |                                            |                                             |                                                    |                                                   |
| <b>14. ABSTRACT</b><br><br>Meeting summary of the Fourth Annual Advanced Initiatives in Medical Simulation held May 2007.                                |                         |                                            |                                             |                                                    |                                                   |
| <b>15. SUBJECT TERMS</b><br>medical stimulation, simulation-based medical training, TATRC, AIMS                                                          |                         |                                            |                                             |                                                    |                                                   |
| <b>16. SECURITY CLASSIFICATION OF:</b>                                                                                                                   |                         |                                            | <b>17. LIMITATION OF ABSTRACT</b><br><br>UU | <b>18. NUMBER OF PAGES</b><br><br>28               | <b>19a. NAME OF RESPONSIBLE PERSON</b><br>USAMRMC |
| <b>a. REPORT</b><br>U                                                                                                                                    | <b>b. ABSTRACT</b><br>U | <b>c. THIS PAGE</b><br>U                   |                                             |                                                    | <b>19b. TELEPHONE NUMBER</b> (include area code)  |

## Table of Contents

|                      |      |
|----------------------|------|
| Meeting Summary..... | 1-27 |
|----------------------|------|

### Appendices

|                          |    |
|--------------------------|----|
| A - Meeting Agenda.....  | 28 |
| B - Accomplishments..... | 29 |



*Educating America about the Value of Medical Simulation*

*A d v a n c e d   I n i t i a t i v e s   i n   M e d i c a l   S i m u l a t i o n*

# **MEDICAL SIMULATION'S ROLE AS AN AGENT OF CHANGE: Activating Change in Patient Safety, Education, and Preparedness**

***Building a National Agenda***

***For Simulation-Based Medical Education***

***4<sup>th</sup> Annual Advanced Initiatives in Medical Simulation Conference***

Center for Telehealth & E-Health Law, formerly the Center for Telemedicine Law  
Advanced Initiatives in Medical Simulation

June 2007

**Advanced Initiatives in Medical Simulation  
Medical Simulation's Role in Promoting Patient Safety**

**Forest Glen Annex of the Walter Reed Army Medical Center, Silver Spring, MD 20910  
May 8, 2007**

**Welcome and Acknowledgement**

---

*Steven Dawson, MD, Center for the Integration of Medicine & Innovative Technology (CIMIT),  
Massachusetts General Hospital*

*CAPT Joe Lopreiato, MD, MPH, FAAP, National Capital Area Medical Simulation Center,  
Uniformed Services University of the Health Sciences (USUHS)*

*LTC Chris Macedonia, MD, Telemedicine and Advanced Technology Research Center (TATRC)*

*Lisa Sinz, MD, Society for Simulation in HealthCare (SSH); Simulation Development and  
Cognitive Science Laboratory, Pennsylvania State University*

Steven Dawson, MD, welcomed participants to the fourth annual Advanced Initiatives in Medical Simulation (AIMS) meeting. He explained that the agenda would be revised because Congressman J. Randy Forbes was unable to attend the meeting and deliver the keynote address. Dr. Dawson also announced that Ms. Melissa Atkinson is the new Executive Director of AIMS.

CAPT Joe Lopreiato, MD, MPH, FAAP, also welcomed participants to the meeting on behalf of Charles L. Rice, MD, President of USUHS. This meeting provides an opportunity for representatives of industry, government, and academia to come together to discuss medical simulation.

CAPT Lopreiato described his goals for medical simulation from the educator's perspective. As an educator, CAPT Lopreiato wishes for:

- Curricula—Plans are needed for integrating medical simulation technology into medical education. These plans should begin with a needs assessment to identify the learners and the training deficits to be addressed. Based on this information, goals and objectives should be created and definitions of success need to be identified so that it will be possible to measure the impact of medical simulation. All of these steps need to be completed before purchasing any medical simulation equipment.
- Hybrids—Different simulation methods should be combined when devising an education plan. This would be effective and efficient.
- Faculty development—A great deal of skill is required to use medical simulation in education. Faculty members need training in how to teach with simulators.

CAPT Lopreiato invited participants to tour the National Capital Area Medical Simulation Center after the meeting.

LTC Chris Macedonia, MD, explained that TATRC is based at the Department of Defense (DoD) Medical Research and Materiel Command headquarters. The center supports innovative

research, especially in the proof-of-concept stage. When TATRC receives good proposals that it cannot fund, it tries to identify other government agencies that might support the research.

Many of the people served by TATRC are deployed combat medics and soldiers. For this reason, TATRC takes its mission very seriously. LTC Macedonia invited participants to contact him for advice on ensuring that their research is relevant to soldiers and their families.

Lisa Sinz, MD, distributed information on the Society for Simulation in HealthCare (SSH). She invited all current members to ask their colleagues to join the society. SSH provides an opportunity for those interested in simulation to learn from one another, advance the field, and avoid reinventing the wheel. The society's journal, *Simulation in Healthcare*, is expected to be indexed shortly.

### **AIMS Accomplishments to Date**

---

*Bob Waters, JD, Drinker Biddle & Reath LLP*

Bob Waters, JD, thanked Dr. Dawson and the U.S. government for their support of medical simulation. He explained that during the first annual AIMS conference, participants focused on identifying gaps and exploring appropriate roles for the public and private sectors. A great deal has been accomplished in the 3 years since that first meeting.

Medical simulation offers a way to address today's concerns about medical errors and the future of medicine. For example, simulation can be used to help train people, test their proficiencies, and move them through the pipeline.

Mr. Waters began his involvement in medical simulation after meeting Dr. Steve Dawson and Dr. Gerry Moses. He toured TATRC and recognized the importance of this emerging field, which will transform the education of medical personnel. He believes that medical simulation will change the way that students learn about anatomy.

Mr. Waters reminded the audience that the idea of putting a man on the moon seemed very audacious when Jules Verne first proposed it 120 years ago, but it has happened. No one would have believed that it would be possible to clone animals 20 years ago but cloning is a reality today. Like putting a man on the moon and cloning a mammal, medical simulation is an audacious idea.

Medical simulation technology has several assets that can help the field interest the public and policy makers. The technology is "cool" and people like to play with it. It is intuitively logical; the public can easily understand the value of allowing people to practice procedures before performing them in patients. Medical simulation could help prevent a large percentage of medical errors by making it possible to test providers' proficiency before allowing them to do certain procedures. Many interim success measures are available for medical simulation—the technology can be beneficial even if it does not achieve all of its goals.

The field also has some challenges. First, the market for these products is limited. In addition, the technology is expensive, making it difficult for some companies to invest in it. The high cost of

the technology is also a barrier for schools that want to acquire it. Many potential users are concerned about validation for the use of the tools.

Mr. Waters listed some of the major visions that our society has pursued, such as putting a man on the moon and mapping the human genome. Achieving the vision for medical simulation will require a “big tent” approach and several champions. It is important to create “magic moments” to persuade potential supporters of the value of medical simulation. It is also necessary to identify key decision makers in professional societies and give them a transformative experience so that their world changes forever and they understand the importance of the technology.

One of the most recent accomplishments of AIMS is the development of legislation that was to be introduced into Congress to support medical simulation. The Enhancing Safety in Medicine Utilizing Leading Advanced Simulation Technologies to Improve Outcomes Now (SIMULATION) Act of 2007 will be sponsored by Representatives Randy Forbes (R-VA) and Patrick Kennedy (D-RI). If passed, this legislation will:

- Provide support for medical and nursing schools, as well as other health professional schools, for the purchase of medical simulation technologies and tools.
- Offer resources to support centers of excellence for very complicated simulation tools that could not be supported in a single medical or nursing school.
- Encourage professional associations to address the use of simulation to improve the quality of care in their profession.
- Support the identification of challenging areas in the medical simulation field that are difficult for commercial entities to address.
- Establish a coordinating council to bring together the federal agencies that work with medical simulation.
- Expand medical simulation research.

The FY 07 House appropriations bill directs the Agency for Healthcare Research and Quality (AHRQ) to work with TATRC, DoD, the Department of Veterans Affairs (VA), and the National Institutes of Health (NIH) to support medical simulation.

Other AIMS accomplishments include outreach to federal agencies and professional associations.

## **The VISION Thing**

---

*Steven Dawson, MD, Center for the Integration of Medicine & Innovative Technology (CIMIT),  
Massachusetts General Hospital*

Dr. Dawson hopes that some day, we will no longer ask the least experienced people in medicine to complete their training by treating the sickest people in society. Everyone involved in medical simulation is a visionary because their goal is to transform the current system.

Americans spend more than \$2 billion a year to whiten their teeth, \$1.2 billion a year to purchase cell phone ring tones, and \$3 billion a year to visit tanning salons. The Navy recently spent \$1.2 billion to develop a single fighter simulator. In contrast, this country has spent \$61 million on medical simulation over the last 8 years, or about \$8 million a year. A 2005 worldwide survey

found that 86% of simulation center directors were dissatisfied with the equipment and technology they were using. Dr. Dawson argued that something is wrong with these facts.

Medical simulation is at a very early stage in its history. In comparison, animal models are more than 1,000 years old and residency models are more than 100 years old. Medical simulation is, at most, 40 years old. This is therefore a good time to influence the direction of this field.

It is important to influence government agencies as they make decisions about medical simulation. The Food and Drug Administration (FDA) recently hosted a conference on the future of medical care. Virtual reality/immersive training simulators were one of 27 important topics in the future of medicine and the FDA concluded that the requirements for simulation training will increase. It is critical to influence the FDA as it moves forward in this area.

Dr. Dawson suggested proving the effectiveness of simulation by starting with a small number of successes and building on these. The community then needs to bring these successes to the attention of those who can use the evidence to advance the field.

However, questionable science will not help the cause. Dr. Dawson discussed an article published in the *Journal of Vascular Surgery* (January 2007, volume 45, pages 149-154). In this study, nine residents completed a pretest before training for 8 hours with a simulator and then completing a post-test. Their performance on three measures (time to complete a vascular surgical catheter-based procedure, contrast volume used, x-ray time used) improved after simulation. But the residents' performance on these measures would probably have improved after 8 hours of training without simulation. The fact that a machine can measure an outcome does not mean that the outcome is a critical clinical indicator.

Dr. Dawson characterized the current status of standards in medical simulation as a "can of worms." It is not clear what the term "standards" means in this context, who will develop them, or what their effect will be on creativity. The cost of developing standards is not known, but someone will have to pay to create them and someone will need to enforce them. It might be too early to establish rigid standards but this issue needs to be jointly considered by industry and the medical field.

Another challenge is informing the public. People readily understand the need for medical simulation once it is brought to their attention. Dr. Rick Satava has suggested that simulators be loaded onto trucks and taken to Wal-Mart parking lots to give members of the public a chance to see and learn about simulators. Another way to spread the word might be through gaming technology. Much of the technology used in medical simulation comes from the gaming field, which has a large budget. But it is not clear how to link gaming with serious content.

More innovation is needed in the medical simulation field. Although simulators have come a long way, they still cannot replicate some important basic procedures. For example, mannequins can make breath sounds but these sounds cannot be heard because the mechanical sounds are so loud. Mannequins are also needed that can speak to trainees and guide them.

Simulation is a small industry. A survey found that the national U.S. market is approximately \$105 million a year; about two-thirds of this is for mannequins and the remaining third is for everything else. Small businesses can ill afford to fund risky research. Simulation will not

achieve its goals by relying on small businesses funding risky research. A national pool is needed to support research in partnership with industry.

Simulation is in the proof-of-concept stage but business investors want to know the return on investment. Federal partnerships could help move from proof of concept to return on investment so that the risks of the research are shared.

Dr. Dawson offered several “provocative” statements:

1. Evidence-based medicine is not a useful concept in medical simulation. It is not possible to control all of the variables involved in treatment because diseases and training programs vary and medicine is not quantifiable at this level. The Accreditation Council for Graduate Medical Education (ACGME) has agreed to accept consensus-based evidence rather than evidence-based standards as proof of simulation’s effectiveness. Evidence-based proof of the efficacy of current training methods has never been available.
2. The wrong simulation methods have been used to prove the technology’s efficacy. Simulation was first used in anesthesia, where proof is difficult to obtain. Perhaps stronger results will be produced by using simulation to offer skills training because this can produce individual, quantifiable results that could yield generalizable metrics.
3. All simulation is local. The American Academy of Orthopaedic Surgeons tried to establish a national simulation center in Chicago to train orthopedic surgeons but the center did not do well because people did not want to take the time to travel to Chicago.
4. Haptics has been oversold. It is more useful to learn higher level performance skills.

Dr. Dawson also offered a less provocative statement: Simulation will enable a powerful evolution in attaining expertise in demonstrating mastery. Ericsson’s model of deliberate practice, feedback on that practice, and more practice is being used as a model in the American College of Surgeons approach to the use of simulation to ensure that experts maintain their skills.

Training standards need to be nationalized and performance assessment must be centralized. If every program were held to the same standards, it would be possible to identify the programs with the best skills in certain areas. These programs could then serve as models for others.

Dr. Dawson proposed a taxonomy of simulation. Class 1 simulators would be designed for novices and focus on the basics. Class 2-4 simulators would be used by those with intermediate levels of skill to address concepts and evaluation. Class 5 simulators would provide advanced experiences for experts.

Cultural changes will be required. Training *is* work and should be considered part of what providers do at work. The reduced work week for residents in the United States will have an impact on physicians’ levels of experience and simulation is one way to address this impact. This problem is more difficult to address than electronic medical records.

A robust, encompassing implementation of simulation will allow deliberate practice, feedback, and more practice. This will result in better healthcare providers throughout their careers. But to accomplish this goal, simulation must become important, relevant, and rewarding.

### **Disruptive Aspects of Simulation: Tearing us from our Moorings: Personal Perspectives on the Changing World**

---

*Randy Haluck, MD, Penn State Milton S. Hershey Medical Center*

*Howard Champion, MD, SimQuest International LLC*

*David Gaba, MD, Stanford University*

Randy Haluck, MD, presented the surgeon's perspective on simulation as a disruptive technology.

Simulation is a discipline or field of study, not a technology. In this respect, simulation is similar to computing. Simulation involves many technologies at varying degrees of maturity and utility. Unlike cell phones, PDAs, and other technologies, implementing simulation requires extraordinary knowledge and skill. The market is tremendously fragmented and under-informed.

The concept of disruptive technologies was originated by Clayton M. Christensen in *The Innovator's Dilemma*. According to Christensen, the characteristics of disruptive technologies include:

- Worse product performance in the near term—This is true of some simulation technologies.
- Not embraced by mainstream markets—This applies to medical simulation.
- Success based on trial and error.
- Eventually evolve to mainstream technologies.
- Emerge where technology “overshoot” exists.
- Offer a different value proposition (cheaper, simpler, smaller)—In simulation today, the trend is to pursue higher levels of complexity rather than simpler and cheaper modalities. However, that tide may be turning.

Christensen offers suggestions on how to harness the characteristics of disruptive innovation.

- Markets that do not exist cannot be analyzed. Any market analysis of medical simulation will invariably be wrong. Trial and error is part of the process and many failures are likely. The technologies that will drive the field forward cannot be predicted.
- An organization's abilities define its disabilities. The first step is to determine what NIH, the American Board of Surgery, FDA, and ACGME are good at. For example, ACGME is good at setting standards and documentation requirements. But this organization has not provided the community with good tools to meet these requirements; industry can help fulfill this tremendous unmet need. It is also important to consider what the simulation community is good at to help identify unmet needs and potential areas of synergy.

- Companies depend on customers for resources. The first challenge is to identify the customer, which could be the doctor in a simulation lab, a resident or student, or the dean who writes the checks. Industry does not know what end users need.

Dr. Haluck believes that simulation is not a disruptive technology. Those in the field are working to develop the mainstream market but disruptive technologies will be developed shortly.

Training for complex medical surgical care requires judgment, decision making, and complex three-dimensional thinking. Some parallels can be drawn between aviation and medicine but these fields involve different levels of complexity. For example, an altimeter can tell the pilot the altitude, but a provider must build a construct to find the patient's blood pressure. Training for medical and surgical patient care requires complex collaboration and coordination and the execution of complex tasks.

After companies develop simulators, users need to test these simulators and provide useful feedback to the companies so that they can refine their simulators. Dr. Haluck believes that educational objectives should be the basis for all simulator design, training, and assessment.

To help move the field forward, surgeons should use and understand simulators and simulation. They should define their educational objectives, develop metrics, and set criteria. Their curricula should be based on these criteria.

Dr. Haluck concluded that it is important to continue to educate and listen to end users. To understand simulation, it is necessary to understand education. Better simulators are needed but little progress will be made without substantial input from users.

Howard Champion, MD, reported that in addition to the advances in simulation in the United States, a great deal is happening in the field in Europe, Asia, and Australia. Many countries in these regions have shorter training weeks and this is opening the way for simulation and defining a role for simulation in medical education and assessment.

Simulation will happen; the only question is when and how. It is being used more and more to provide transparency of proficiency evaluation. However, it has not been well integrated into curricula.

Dr. Champion listed several shortcomings in current simulation products. A wide range of products have been developed that are not linked to each other or to curricula. Many companies are claiming that their products have been validated but the validation studies conducted to date are weak. A great deal needs to be done to show that simulators bring added value to medical education. No company has developed true physics-based simulators that could be used for different sets of pathologies. The training goals and expectations of simulators are narrow and often leave students ill prepared to treat real patients. The industry is providing a very frail foundation for improving quality, practice, and training. Dr. Champion compared the current situation to the "pre-Model T" era because the industry is far from a major breakthrough.

Industry shortcomings include the frail link between prototypes and actual products. Some market makers have begun to create a market but some of the hype associated with their efforts is not necessarily doing a service to the field. The business models for simulation are very frail.

People are making some money in the field but large companies are not interested because the potential is very limited. The field has limited capability and very little capacity to respond to any demand.

Shakedown time is looming and Dr. Champion believes that the sooner it comes, the better. The small enterprises need to consolidate. Companies need to work with end users to develop standards so that everyone is working with the same construct.

Many simulation centers are being created but their work will quickly become obsolete unless it is done in conjunction with a plan. Simulators need to be acquired in a more thoughtful way.

Dr. Champion believes that the field will grow in the next 3-5 years. Constructs will be developed through collaboration with end users and simulation will be better integrated into the curriculum. Once a business model is developed, larger companies and their resources will move into the field. Simulation will ultimately have a significant effect on training, transparency, proficiency, and the ability to ensure patient safety in a more structured way.

David Gaba, MD, pointed out that the quality of medical practice in the western world varies tremendously and none of the major providers is as good as it could be. Too many people are being hurt or even killed by medical errors.

Unlike healthcare, aviation is a high-reliability industry. In recent years, the industry has experienced 0-3 fatal accidents a year with more than 10 million departures each year. But healthcare differs from aviation and other high-reliability industries in important ways. Providers do not design and build human beings and do not always have the option of avoiding or delaying a dangerous intervention regardless of the risk. Healthcare also involves many more social, societal, and ethical issues than other industries. For example, consumers do not care who their pilot is but they are very concerned about who their surgeon is.

Healthcare is extremely decentralized. The approximately 6,000 hospitals in this country are owned by more than 1,000 firms. In aviation, about a dozen firms own 95% of the business. If a good idea is developed, implementing the idea will require convincing 6,000 CEOs that it is worth doing. Although healthcare funding is regulated, the daily work of clinicians is not. The workforce is very diverse and under very loose organizational control. This is very different from the flight deck of commercial airlines, where the workforce is relatively homogeneous and under tight control.

All high-reliability organizations provide intensive and continuing training of individuals and teams. Simulation is therefore a key tool in making healthcare a high-reliability organization. In healthcare, learning only by doing the real procedure is not optimal. Simulation can be scheduled, targeted, safe, and intense and offer experience in unusual or dangerous events and interventions.

Simulation is a technique, not a technology, for interactive and often immersive activities that recreate the experiences of a real-world environment. Simulation can be used for education, training, assessment, and research. Units of participation can be the individual, team, work unit, or hospital. Simulation can address different levels of knowledge, skill, or behavior. Simulation

covers all patient ages from neonates and infants to the elderly. The technologies and techniques include role play, computer screen, virtual reality, and computerized mannequins.

A great deal of qualitative data exists on the impact of simulation on safety. These relatively small studies should be continued and, in some cases, can be highly persuasive. But none of these studies is likely to convince a true skeptic. A true test of simulation requires long-term adoption of a comprehensive, integrated model of career-long (simulation-based) training, with evaluation over a long time horizon. But such definitive experiments are impossible to do due to logistical barriers and cost

Dr. Gaba hoped that simulation would achieve the five “Fs”:

1. Frequent—training every year or more often.
2. For everyone—regardless of discipline or domain.
3. Forever—no matter how senior.
4. Focused—on real challenges of individual and team performance.
5. Fit into work routines—not an add-on.

These are the characteristics of training in high-reliability organizations. Pilots are not asked to obtain continuing flying education on their own time and to pay for this training with their own money. Their continuing education is part of their work.

Dr. Gaba identified some potential drivers for further adoption of simulation in healthcare that could help achieve this vision. These drivers include the simulation community, professionals, insurers/risk managers, payers for medical care, government (local, state, and federal), and the public. The public is the biggest driver to achieve this vision of integrated adoption of intensive training and assessment.

Potential implementers of simulation activities or requirements are professional societies, specialty boards, hospitals/networks, professional schools, accreditors, government (regulators and legislators), simulation organizations, and industry.

To help drive the field forward, AIMS needs more organizational members with more money. Several industry members are part of the AIMS industry council, but more are needed. The number of academic institutions that have joined AIMS has been low. More professional societies are needed as organizational members. In addition, more effort is needed from people and organizations to make this vision a reality.

## **The Marketplace Perspective: Simulation’s Early Impact on the Medical Device Industry**

---

*Mike Madden, Cordis Endovascular*

Mike Madden discussed the experience of Cordis Endovascular with cardiovascular medical device simulation-based education. The Cordis Cardiac & Vascular Institute (CCVI) has 12 training facilities around the world that are dedicated to customer training.

About 700,000 strokes occur each year in the United States. Carotid artery disease and stroke is the third leading cause of death; 168,000 people die each year from stroke. Stroke is also the top cause of adult disability and accounts for \$53.6 billion each year in healthcare costs. About 19

million patients around the world have some level of carotid artery disease but only about 2.2 million of these cases are diagnosed, 1.5 receive medical therapy, 600,000 receive surgery, and 85,000 patients in the United States undergo carotid stenting procedures.

According to the FDA, the medical device industry is responsible for providing customer education programs to qualified physicians that support the safe and effective use of medical devices. Use of the products must be consistent with their use in the clinical trials that led to their approval.

In developing the carotid artery stenting (CAS) training program, many factors had to be taken into consideration. These included the fact that carotid stenting is a high-risk procedure to prevent stroke that can actually cause stroke if the procedure is done without sufficient training. The procedure is of interest to many specialties, including cardiologists, vascular surgeons, interventional radiologists, neuro-radiologists, and neurosurgeons. Government agencies, including the FDA, Center for Medicare and Medicaid Services (CMS), and AHRQ, are interested in the procedure, which is a perfect challenge for simulation.

Cordis began developing its training program in 2002 with the creation of a cross-specialty educational advisory panel. The content was piloted at medical meetings. The FDA approved carotid stenting in 2005 and post-market surveillance studies were published in 2006 to validate the training program's effectiveness.

The training program has five components: online didactic, observation, simulation, staff training, and proctor network. This is the first time that industry has developed a training program for using a device with built-in proficiency requirements—trainees need to achieve a specified level of competency before they can move to the next step.

Cordis wanted to use simulation to show how competency, efficiency, and patient safety can be combined to achieve optimal patient outcomes. The training also allows practitioners to practice the procedure before performing it, replaces the animate model of device training, trains practitioners in device deployment and sequencing, provides proficiency metrics, and ensures proper use of the product.

Cordis offers three levels of simulation training:

- Level 1: Experienced in CAS and Cordis devices—exempt from simulation training

- Level 2: Experienced in CAS but not experienced with the device—intermediate training with level I-II simulation

- Level 3: Trained in endovascular techniques but no experience in CAS—full simulation training with levels I-III

Cordis has 110 simulation systems for training in CAS in the Johnson & Johnson global network of educational institutes and hospitals. These simulators can provide training in 50 procedures.

The program's goal is to train physicians so that they achieve outcomes similar to those achieved in the pivotal trial that led to FDA approval for CAS. The post-market surveillance study included centers with differing volumes, locations, and experience with CAS. The primary endpoint was 30-day major adverse events in patients. The trial found that Level 3 physicians did as well as experts after completing the simulation-based training.

Simulation developers should partner with companies that focus on digital entertainment and video gaming to create professional-quality, high-fidelity, three-dimensional models more efficiently. This could also lead to massive multi-player online role-playing games applications.

Ultimately, the field needs to become sustainable and simulation centers need to stop depending on grant funding.

Mr. Waters reported that the impact of the new Congress on simulation is not clear. Although power has shifted from the Republican to the Democratic Party, the margin is very narrow and the current atmosphere in Congress is much more partisan than in the past. Because of the war on terrorism, generating support for a cause requires demonstrating how that cause fits the military mission.

The budget deficit is a major issue. Mandatory spending has grown significantly in recent years. In 1995, mandatory spending for such programs as Medicare and Social Security accounted for approximately half the budget. If current patterns do not change, mandatory spending will account for 62% of the budget in 2015. Non-homeland security domestic spending represents just 16.3% of the federal budget.

The new Congress is focused on terrorism and the war in Iraq. Democrats support pay-go budgeting, which means that any expenditure must be offset by a spending decrease to balance the budget. A major push has focused on removing earmarks. Most of the funds for simulation come from congressionally designated projects.

Several issues of interest to many legislators could be addressed by simulation. For example, simulation could play a role in reducing medical malpractice premiums. Simulation might also help reduce errors in the healthcare system and help with the nursing shortage.

Mr. Waters emphasized the need to avoid letting the perfect be the enemy of the good. He advocated generic support rather than small pools of money from different institutions because the result will be disjointed. The simulation field also needs to identify non-federal sources of support, such as the risk-management industry and individual institutions. A strategy must be identified that ensures long-term sustainability.

Mr. Waters listed several key elements of the proposed simulation legislation:

1. Grants to academic medical centers and schools of medicine, nursing, osteopathy, podiatry, dentistry, and allied health to incorporate medical and interdisciplinary simulation technologies into curricula and training protocols
2. Simulation centers of excellence to provide leadership and conduct research on enhancing and expanding the use of simulation technologies and simulation-based skills training for physicians, nurses, and allied health professionals
3. Grants to academic medical centers, professional organizations that provide accreditation or quality assurance to healthcare professionals, and health profession licensing boards to deploy simulation technologies to train healthcare providers
4. Clearinghouse of simulation technologies that are currently available or under development

5. Federal medical simulation coordinating council in the Department of Health and Human Services to coordinate the federal government's activities in the research, development, deployment, and use of medical simulation technologies

Melissa Atkinson, JD, reviewed the legislation, which was to be introduced by Congressman Randy Forbes, with Congressman Patrick Kennedy as cosponsor. The legislation would serve as a starting point for the AIMS agenda because it would provide core funds to increase the use of medical simulation technology.

### **Town Meeting**

---

*Dale Alverson, MD, Center for Telehealth, University of New Mexico*

*COL Mark Bowyer, MD, USAF, National Capital Area Medical Simulation Center*

*Robert Waters, JD, Drinker Biddle & Reath, LLP*

*David Gaba, MD, Stanford University*

*Randy Haluck, MD, Penn State Milton S. Hershey Medical Center*

Dr. Alverson opened the town meeting session, an open discussion period. He asked the industry representatives to explain why, although several companies have expressed an interest in working on simulation, many are not following up on that interest. Mr. Waters speculated that companies need to understand how simulation fits into their business plan before making a commitment.

Bruce Nappi of the University of Florida has had a different experience. Many commercial companies are interested in working with his center but he is unable to establish relationships with them because of the university's structure. He also noted that the major companies are unlikely to join the field at this time, although much smaller companies are ready to become involved.

Dr. Alverson agreed that industry is not the only source of the problem because many barriers to collaboration stem from the academic side. It can be very difficult, for example, to establish a nondiscrimination agreement between a university and a company.

A participant who works for a small company said that his company understands what the simulation field is trying to accomplish. However, larger companies did not participate in the meeting because the field does not have enough money to bring them in.

Dr. Alverson pointed out that academics share information and publish jointly. He wondered how to balance the issue of standards and interoperability with proprietary interests and making a business case.

Mr. Nappi said that before the National Institute of Standards and Technology (NIST) was established, many recommended standards were in place and this system did not always work well. For example, both VCR and Beta systems were released at around the same time and it took a few years before VCR became the standard. It is possible to work with a provisional standards promulgated by organizations like SSH that bring people together. At that time, a consensus standard can be developed.

William Dunn, MD, of the Mayo Clinic stressed the need to reach the point where simulation is used for high-stakes assessment in healthcare in a credible way. Until that point is reached, it will be difficult to convince people of the need to add simulation to residency programs. Unless educational programs have a mandate to change their curricula, they will not start using simulation. He asked about the potential impact of the proposed legislation on efforts to create enforceable standards for academic institutions.

Mr. Waters explained that the proposed legislation does not establish mandates. Instead, it provides incentives to universities, medical centers, healthcare education institutions, and professional societies. Dr. Dunn asked whether accrediting agencies, such as ACGME, could apply for funding through this legislation. Mr. Waters replied that AHRQ can provide funding to accreditation agencies.

COL Mark Bowyer, MD, said that the American Board of Surgery and Society of University Surgery have jointly developed a national curriculum for residents that will include simulation where appropriate. Simulation should also be part of the certification process to prove that physicians have the skills needed to practice their trade.

Dr. Haluck asked if programs use simulation in high-stakes assessment. Dr. Dunn said that credentialing at the Mayo Clinic is relatively recent. But other countries, such as Israel, are using simulation in credentialing. Whenever a learning curve is steep, simulation can play an important role. But the impact of simulation on skill development is difficult to prove, especially without standards. Expert opinion is currently the best source of support for the use of simulation.

Elizabeth Poster, PhD, RN, from the University of Texas at Arlington said that the large number of nursing students that enter her institution each semester is challenging because of the faculty shortage. Simulation is one way to train these nursing students in the current situation. Universities need to stop assessing a student's accomplishments in terms of the number of semesters. Instead, students should show that they have learned the first lessons before moving on to the next phase. Boards of nursing are supporting the use of simulation because students might not otherwise have the experience they need with certain kinds of patients.

### **Tales from the Frontlines: What's the Role for Simulation in Warfare, Homeland Defense Preparedness Training, and Disaster Response**

---

*Rich Satava, MD, Chair AIMS*

*COL Mark Bowyer, MD, USAF, National Capital Area Medical Simulation Center*

*Jay Schnitzer, MD, PhD, Harvard Medical School, Massachusetts General Hospital, Shriners Burn Hospital*

Rick Satava, MD, pointed out that no one in the federal government is responsible for medical education. States certify people to provide medical care and are thus responsible for educating them. For this reason, the federal government is not likely to provide funding for medical education. The law needs to be changed so that the federal government is responsible for continually funding medical education and training. Otherwise only short-term funding will be available.

We are in the middle of a fundamental revolution and the existing scientific method is inadequate for today's rapid discoveries. Evidence-based medicine cannot provide assurance for all medical needs. A new methodology is needed that will help us understand and improve new science and technologies.

A paradigm change is occurring in scientific method. The steps in the scientific method are hypothesis, study design, experiment, results, and reporting. But modeling and simulation has now been inserted between study design and experiment. Modeling and simulation can do much more than just train someone—they represent a fundamental change in the way we should live our daily lives. Society is already using simulation through such mechanisms as MySpace, YouTube, multi-user video games, and Second Life. Simulation is also being used in science in the form of flight simulators, building information modeling, and computer-aided design (CAD) and modeling.

Every soldier killed in Iraq has a total body scan on which a virtual autopsy is done to supplement the real autopsy. This yields data that can be used to make decisions on DoD and national policy. Virtual autopsy is a form of simulation. Currently, autopsies are performed on less than 9% of patients who die in the hospital and national policies are built on cause-of-death data that do not come primarily from autopsies.

Simulation gives people permission to fail in a safe environment. It also provides a global experience, which is particularly valuable in the context of a shortened work week for residents, as this reduces their exposure to patients. Simulation can ensure that each student is trained in everything he or she needs to know and it lets students explore beyond the existing world; for example, simulation makes it possible to explore nanotechnology. If whole-body scans were conducted on everyone, clinical trials could quickly be done on large numbers of people. Medicine is the only field that does not do this.

The Naval Air Warfare Center awarded contracts worth \$1.25 billion to support simulation-based training systems. But nothing like this is happening in medicine.

The traditional “see one, do one, teach one” paradigm is criterion-based training. The focus is shifting to proficiency and the requirement that students continue to train no matter how long it takes until they achieve proficiency. Simulation can provide immediate feedback and objective assessment of performance.

The American College of Surgeons has a certification process for simulation training centers. The college surveys and rates centers and awards certificates indicating the quality of the education, training, and follow-up provided.

COL Bowyer discussed lessons from the current military conflict that can be used to enhance training for future warfare and civilian disasters. Military medicine exists to deal with multiple-casualty events and it can teach the civilian community a great deal. Multiple-casualty events strain civilian hospital or facility resources, while mass-casualty events or disasters yield a casualty burden that exceeds the capabilities of on-site medical resources. The Battle of the Somme in 1916 is an example of a mass-casualty event, with more than 25,000 casualties in a single day. A significant bombing incident in the United States could yield a similar number of casualties.

COL Bowyer argued that if you fail to prepare, you must prepare to fail. No matter how prepared you think you are, you are not prepared. The ideal time to learn the skills needed to deal with an event is not during the event. Furthermore, the training should be as realistic as possible.

The wounds experienced in the war on terror are beyond the comprehension of most people. Therefore, training of medical personnel needs to focus on desensitization. The more realistic the training, the shorter the time needed to be able to care for these injuries. COL Bowyer showed images of some of the types of wounds seen in the battlefield. A small team might see many different types of wounds within a short period of time and need to care for these soldiers with a small team.

The goal of disaster response is to establish order out of chaos. Medical response must maximize salvage of life. The goal of treatment changes from the greatest good for each person to the greatest good for the greatest number. The focus of treatment is on the population rather than the individual.

Teams are a critical part of disaster management medical care. Small teams are needed around each patient bed. They must make a rapid (30-60 second) evaluation, develop a prescription, and move on. No imaging or lab tests are ordered but the team has a system for reassessing casualties. Surgery is done to control damage.

Preparing to care for injuries in the battlefield and after civilian terrorism events will require planning and rehearsal, post-event debriefing and critique, standardized analysis, and dissemination of experience. This is an ideal setting for simulation.

Simulation can be used to help train medical personnel and teams to respond to terror and disaster incidents. Part-task trainers can be used to train for low-frequency, high-stakes procedures, including emergency airway cricothyroidotomy, chest tube insertion, and decompressive craniectomy for non-neurosurgeons. However, it is not clear that these trainers can teach team skills or whether training in a sterile environment provides the ability to perform in a stressful environment.

Team training is key to effective disaster management. Ideally, teams should train in the same way that they are expected to perform. Unfortunately, this is difficult in practice. Teams consist of at least two people and the members are assigned specific roles, perform specific tasks, and interact or coordinate to achieve a common goal or outcome. Teams make decisions. They have specialized knowledge and skills and often work under high-workload conditions. Teamwork requires team members to adjust to one another, either sequentially or simultaneously.

An emergency room team, for example, includes not only the doctor, nurse, and technician, but also the admitting clerk, x-ray technician, respiratory therapist, and many other people. Teams vary greatly in size depending on their purpose. Medical teams are usually multidisciplinary and all team members rarely train together. They work in high-stress environments with several distracters.

A high level of training environment fidelity is particularly useful in training teams that will perform under stressful conditions. Simulation training is especially appropriate in such settings.

Research suggests that training should be conducted under the same stressful conditions that the team will encounter operationally.

Simulation offers a good way to train teams to function in austere environments, such as military deployment, combat, or mass casualties, while subjected to multiple stressors such as noise, extreme temperatures, and fear of personal harm. Some of the simulation tools available to train teams include standardized patients, part-task trainers, high-fidelity human patient simulators, serious games, and immersive environments. The best system is an integrated combination of all of these simulation techniques.

Simulated immersive environments cannot recreate exactly the type of environment that medical personnel will face but these environments can include distractions, such as noise and threats of attack. Maximizing the usefulness of simulation in healthcare team training requires carefully tailoring the training needs, goals, content, and evaluation measures to reinforce each other. Case studies and role playing should be used to train team members in teamwork-related knowledge and attitudes. Part-task trainers can be used to train in teamwork-related skills to the point of overlearning so that the skills become automatic. Full-mission simulators should be used to hone teamwork-related skills under conditions of ambiguity, time pressure, and stress.

Jay Schnitzer, MD, PhD, said that a mass casualty incident will occur in the continental United States at some time in the future. The country's medical system was ill prepared for the events that have occurred in the past, such as the September 11, 2001, attacks and Hurricane Katrina. And the system is not much better prepared now than it was then.

The biggest challenge in any disaster is communications. Command and control is another major challenge. A federalized medical response is needed to provide accountability, reliability, and quality control. Such a system could ensure integration with other rescue efforts, secure the scene, and ensure that a full spectrum of medical personnel with personal protective gear, credentials, and renewable supplies are available.

Rapid response teams need to be able to respond quickly (wheels up in 4-6 hours), operate independently; be flexible and task organized; have direct links to higher echelons; and have multiple capabilities in assessment, triage, and treatment. This is not what most people do in their normal daily practice and team members do not typically train together.

Dr. Schnitzer was a supervising medical officer at Ground Zero after 9/11. Downtown Manhattan had become a third-world zone with no electricity, water, or communications. He was unable to coordinate care with the other agencies. Every time he came on shift, he had to find out who was in charge of the emergency medical response team and establish communications with that person.

The United States also had difficulty responding to the earthquake in Bam, Iran on December 26, 2003. The United States team was the last of 66 teams from other countries to arrive on site. After Hurricane Katrina, water was stockpiled only a mile or two from thousands of thirsty people but the logistics were not in place to transport the water to those who needed it. This problem has not been solved.

Dr. Schnitzer described a hypothetical scenario in which a small craft loaded with explosives collides with a tanker with 33 million gallons of liquified natural gas in Boston Harbor. Models have shown that the fire would burn for 8.1 minutes with a span of 500 meters. The fire would burn at 3,000 degrees Fahrenheit and would create burn zones of up to 2 kilometers from the site.

The number of casualties would depend on the tanker's location, weather, wind, time of day, and other factors. But several thousand people could be killed, with tens of thousands wounded. Although local first responders would quickly activate their disaster plans, chaos and panic would ensue. The city does not have the surge capacity to deal with a disaster of this magnitude.

When a Rhode Island nightclub caught fire in February 2003, five badly burned patients were taken to the Massachusetts General Hospital surgical intensive care unit (SICU); caring for them brought the unit to a standstill for 2 weeks. The entire country has just 1,200 burn intensive care unit beds and 800 are occupied at any time. The country is nowhere near prepared to deal with a major disaster.

Most providers are trained to do the most good for a single patient, not to deal with a mass-casualty event. Dr. Schnitzer is also concerned about the rapidity with which leadership and hospital services degrade during a disaster. Communications in disasters is another challenge that needs to be resolved.

Simulation could address these challenges. To train people for mass-casualty events, simulation would need to model complex scenarios with an emphasis on command and control, incident command, and communication.

### **Simulation as an Agent of Change for Education**

---

*Steve Dawson, MD, Chair, AIMS, Massachusetts General Hospital-CIMIT*

*Neal Seymour, MD, Baystate Medical Center*

*Elizabeth C. Poster, PhD, RN, FAAN, University of Texas at Arlington School of Nursing*

*Gerry Moses, PhD, University of Maryland Medical Center and School of Medicine*

Neal Seymour, MD, commented that there is a clear relationship between poor surgical skills and poor outcomes in minimally invasive surgery. Medical education in the clinical environment is expensive and given the limitation on resident work hours, these hours need to be maximally beneficial.

A validation system is needed that demonstrates that performance gained in simulation transfers to the clinical environment. The difficulties associated with laparoscopic cholecystectomy prompted Dr. Seymour's study with Tony Gallagher at Yale University. This study showed that residents trained with virtual reality incurred fewer errors during the procedure than the standard training group. Dr. Seymour has repeated the study in other settings and found similar results. Of about 15 studies in the literature, all but one have shown that simulation training produced better results than no training, which is the standard.

Using controlled trials to demonstrate skill transfer is ponderous and raises ethical questions if one of the groups has no training. The study design is ponderous and these studies are difficult to do. Controlled trials are not the way to validate simulation training. Dr. Seymour believes that

face and construct validity, where an expert agrees that the surgeon can do what he or she is supposed to do, are more important for implementation.

Other methods are available to show a cause-effect relationship between simulation and clinical performance. For example, comparisons could be made between the surgeon's skills before and after training. Subject-controlled trials show that trainees achieve educational objectives without control groups. Clinical skills can be assessed to see if performance improves in predictable ways. Careful clinical assessment is another technique that requires validated models for assessing performance in the actual setting.

Dr. Seymour uses an online assessment tool to rate a resident's performance at the end of an operation. The data in this system can be linked to resource use, length of procedure, and patient length of stay. The database covers the resident's performance for every operation during 5 years of training. A multi-institutional study could look for performance outliers to identify residents who need more training and those who are so good that the training needs to be modified to meet their needs. This system allows the comparison of contemporaneous performance in the clinical operating room and in the lab.

In June 2006, ACGME said that new graduates must document competence in laparoscopy, without specifying how training programs are to accomplish this. American College of Surgeons (ACS) education institutes focus on enhancing patient safety through simulation. The Association of Program Directors in Surgery (APDS) Simulation/Skills Curriculum Committee is charged with constructing a national curriculum for teaching the mastery of surgical skills. It is supposed to lead the way in developing a simulation curriculum on a national basis in collaboration with the American Board of Surgery and American College of Surgeons.

A long list of skills is included in the APDS/ACS curriculum. These efforts have resulted in a roadmap rather than a mandated curriculum. Developers should regard the completed product as an opportunity because the educational leadership has identified these areas as vital for lab-based training.

We are in a new training environment. One of the most difficult steps is to implement simulation training. Educational interventions must be chosen that achieve lasting effects in competency areas. Resources need to be placed in all training programs, even small ones, because simulation is local.

One of the challenges is to educate people who do not understand how simulation can be used to increase the power of training programs. The current training system needs to be rethought in terms of competencies.

Elizabeth Poster, PhD, RN, explained that the University of Texas at Arlington has more than 1,000 students and 100 faculty members. It is affiliated with more than 100 hospitals and health care facilities. The school operates in the context of a nursing and faculty shortage. The 75 nursing schools in Texas graduate 6,000 nurses a year, but Texas needs an additional 28,000-40,000 registered nurses. The average age of the nursing faculty is 56 years.

If nursing training could be individualized for adult learners, students could graduate more quickly with the same level of competence and confidence as in the current system. If the use of

simulation were increased, the shortage of clinical sites would be less of an issue. Nursing students still need to work with patients but some of that time could be spent with simulation.

The University of Texas at Arlington has espoused simulation as an educational modality, not an episodic event. Each clinical course uses simulation and a simulation coordinator works with faculty to increase their proficiency in this area. The school has 12 high-fidelity simulators and another 15-17 simulators, as well as 30 standardized patients.

The university has developed the Smart Hospital™, which serves as a regional education and training site. It is also a regional workforce enhancement site that local hospitals can use to cross-train their staff and retool nurses who are returning to work. The facility offers regional disaster training and response as well as surge capacity.

The faculty has partnered with Hill-Rom and will serve as the company's national demonstration showcase. The company has agreed to replace equipment as newer technologies become available so that the facility remains state of the science. The university will cover the overhead costs.

To be successful, a simulation center's building and simulation have to be an asset not only to the school but also to the community. University representatives have talked to community leaders, service clubs, chambers of commerce, and others so that they understand how the facility benefits them. The facility conducts tours on a regular basis and communicates its accomplishments through press releases. The facility will continue to develop additional partnerships to obtain more funds and supporters.

Gerry Moses, PhD, reported on a survey of professional agency responses to medical simulation. The survey was designed in response to the development by agencies of policies related to medical simulation. In addition, the conversation about the use of simulation for certification is increasing and the growth in medical simulation centers demonstrates the need for a current understanding of agency views. Also, public policy makers need to understand agency support and demand for medical simulation.

The survey was designed to determine professional agency interest in simulation, assess the growth of policies and programs, identify formal positions taken on the use of simulation, and collect views on important research needs. The agencies were surveyed in writing or by telephone interview.

The agencies surveyed were:

- American Board of Podiatric Surgery
- American Board of Surgery
- American College of Cardiology
- American College of Surgeons
- American Nurses Association
- American Society of Anesthesiologists
- National Board of Medical Examiners
- Radiological Society of North America
- U.S. Food and Drug Administration

The survey found that 44% of these agencies have a written policy pertaining to medical simulation for training and 78% have formed a committee to study simulation for continuing medical education (CME) approval. All of the agencies say that medical simulation is important to their agency's current and future functioning and all now have a formal position on medical simulation.

The American College of Surgeons has a formal policy for the accreditation of educational institutions to enhance patient safety through medical simulation. Other agencies are considering residency-focused accreditation programs based on medical simulation. The most important research needs identified were psychometric analyses of preliminary test results compared to standard oral exams, a wider variety of cases and better metrics, and opportunities and appropriate insertion points for simulation in the training curriculum.

This abbreviated survey provided assurance that professional agencies are continuing to expand their appreciation of medical simulation, and policy makers need to know this. These responses need to be communicated to the growing community of medical simulation users. Agency response to medical simulation needs to be measured through formal studies on an ongoing basis.

### **The Business of Medical Simulation: The AIMS Industry Council Update**

---

*Elizabeth Sanchez, SimMedical*

Elizabeth Sanchez explained that the AIMS industry council has 20 members and is growing. The council's goal is to harness its collective experience, technologies, and ambition to improve patient safety through simulation.

The AIMS industry council wants to partner with government, suppliers, and healthcare professionals to implement pilot programs that integrate simulation technologies. The council also helps professional societies understand how simulation can support their training objectives. Other council activities are to support the establishment of government funding for the acquisition of simulation technologies by healthcare and academic institutions, support the establishment of standards, play an increasingly integral role in AIMS, and conduct an annual market survey.

Ms. Sanchez discussed interoperability. A short-term solution could be to standardize some of the output data from different products and technologies. This is an opportunity for industry and end users to work together.

Every year, AIMS conducts a survey and the results are shared with the industry council. This year, the survey had 40 responses from university teaching hospitals, education or training institutions, and healthcare professionals. Of these respondents, 48% are influencers and 43% make decisions about simulation.

Two-thirds of respondents use simulation in nurse training and emergency training, one-quarter in operating room team training and general surgery resident programs, and 20% in cardiovascular and advanced laparoscopic skills training. Only 7% spent more than \$250,000 on simulation training last year; most spent less than \$100,000 and almost half spent nothing. Most

(82%) would spend more on simulators if they had more money and 50% would spend more if a cost-benefit analysis were favorable and better simulators were available.

Drivers that would lead the respondents to buy more simulators include studies validating the effectiveness of simulators, credentialing and mandated training and certification, accepted and available standard curricula, assistance in retaining and training new physicians, simulation requirements for residency programs, evidence that simulation training reduces insurance risk and helps attract residents, and evidence that simulation can be used to overcome the challenges associated with the 80-hour work week requirement for residents.

Respondents would like improved pediatric simulators, hybrid trainers for surgery, improved current human patient simulators (infant, child, and adult), geriatric mannequins, and combined advanced full-body mannequins with the option of combining surgical procedures.

Survey respondents regard industry as interdisciplinary, enthusiastic, eager to hear from the end user, and honest about the technology's current limitations. Competition in the market is increasing and research and development (funding) is growing. Weaknesses identified include the cost of equipment and laboratory setup, the need for more validation of effectiveness, the lack of support and training, and limited competition.

### Discussion

A participant asked whether the industry council members are examining current requirements for residency training. Lucas Huang of B-Line Medical replied that the company's clients are identifying the content they want and the company is encouraging them to match this content to competencies. The company guides its clients through the process.

CAPT Lopreiato encouraged the industry representatives to check the websites of the ACGME and its Canadian equivalent each month, as their requirements change frequently. All of the specialty societies are developing lists of procedure-based tasks that all residents should be able to do before they graduate. These requirements will drive residency directors to demand simulation and provide the standards needed to develop simulation.

Mr. Nappi asked how often the council meets. Ms. Sanchez explained that the council has monthly teleconference calls and a face-to-face meeting before the annual AIMS conference. In the future, the council hopes to meet in person more often. Mr. Huang added that the council also wants to work more closely with AIMS on lobbying and other activities.

Dr. Alverson asked the council members to address the potential conflict between intellectual property and interoperability. A council member explained that interoperability and opening up source codes limits industry ability to make a profit and provide users with what they need. One shorter term solution is creating standardized information output. Professional societies need to then tell companies whether this output meets their guidelines. Another council member commented that protecting intellectual property is very important to small companies. But it is possible to have the benefits of interoperability without giving up intellectual property. Many companies are using open architecture into which other systems can be plugged without interoperability. Mr. Huang said that companies can establish working relationships with other companies to benefit end users.

COL Bowyer said that the challenge in the military is that many simulators are purchased with no plan for using them. Industry can help by ensuring that their products match the curriculum. A council member said that end users need to share their curricula and operational problems with companies so that companies can develop solutions, which might not be simulators.

A council member stressed the need for companies to work with customers to validate the use of simulation.

A participant pointed out that academic institutions do not have facilities and companies do not have research and development funding. Academic institutions and companies should therefore be an ideal match but such partnerships are difficult to develop. A council member has been trying to establish a partnership with a university for a year but has had difficulties with the institution's legal department over intellectual property. Companies need help moving through academic institutions in a reasonable timeframe. Ms. Sanchez said that her company collaborates with the Widener Institute in Pittsburgh, so collaborations between companies and academic institutions are possible.

Mr. Huang said that his company prefers to work with customers who have innovative ideas and do not need to own the intellectual property. If the client wants to keep the intellectual property, the company will not make money from the relationship.

Dr. Gaba has a list of companies that his institution likes to work with. In the last few years, regulators have established new requirements for industry relations. Many of these come from the drug industry, and Dr. Gaba wondered about their impact on simulation company relationships with clients.

Ms. Sanchez encouraged participants to continue to interact with the industry council. The annual survey should not be the only opportunity for dialog.

### **Closure and Adjourn**

Dr. Dawson invited participants to the fourth annual AIMS exhibition the following day at the Rayburn House Office Building. He thanked the representatives from AIMS, TATRC, and the National Capital Area Simulation Center who organized the meeting.

Mr. Waters thanked all participants in the conference. He planned to keep in touch with all audience members about AIMS activities and hoped to find ways to use their talents in advancing the simulation field.

## Appendix A – Agenda

### **MEDICAL SIMULATION'S ROLE AS AN AGENT OF CHANGE Activating Change in Patient Safety, Education, Preparedness**

**Tuesday, May 8, 2007**

**Daniel K. Inouye Auditorium**

**Walter Reed Army Medical Center, Forest Glen Annex**

**7:15 – 8:00 a.m. – Continental Breakfast and Registration**

**8:00 – 8:20 a.m. – Welcome and Acknowledgement**

- CAPT Joe Lopreato, MD, MPH, FAAP, National Capital Area Medical Simulation Center, Uniformed Services University of the Health Sciences (USUHS)
- LTC Chris Macedonia, MD, Telemedicine & Advanced Technology Research Center (TATRC)
- Lisa Sinz, MD, Society for Simulation in HealthCare, Simulation Development and Cognitive Science Laboratory, PSU

**8:20 – 8:40 a.m. – AIMS Accomplishments to Date**

- Robert Waters, JD, Drinker Biddle & Reath LLP

**8:40 – 9:00 a.m. – The VISION Thing**

- Steve Dawson, MD, Chair, AIMS, Massachusetts General Hospital-CIMIT

**9:00 – 10:00 a.m. – KEYNOTE**

- Introduction: David Gaba, MD, Stanford University
- The Honorable J. Randy Forbes (VA-4), Chair, Modeling and Simulation Caucus, Honorary Co-Chair, AIMS Exhibition
- Q&A: Robert Waters, JD, Drinker Biddle & Reath LLP

**10:00 – 10:15 a.m. – Break**

**10:15 – 11:15 a.m. – Disruptive Aspects of Simulation: Tearing us from our moorings: Personal perspectives on the changing world**

- Introduction: Melissa Atkinson, JD, Drinker Biddle & Reath LLP
- Tony Gallagher, PhD, National Surgical Training Centre Royal College of Surgeons in Ireland
- Randy Haluck, MD, Penn State Milton S. Hershey Medical Center
- Howard Champion, MD, SimQuest International LLC

**11:15 – 11:35 a.m. – The Marketplace Perspective: Simulation's Early Impact on the Medical Device Industry**

- Mike Madden, Cordis Endovascular

**11:35 a.m. – 12:00 p.m. – The Changing Landscapes: National, Regional, and State**

- Introduction – Dale Alverson, MD, University of New Mexico, Center for Telehealth
- Robert Waters, JD, Drinker Biddle & Reath, LLP
- Melissa Atkinson, JD, Drinker Biddle & Reath, LLP

**12:00 – 1:00 p.m. – Lunch**

**1:00 – 1:45 p.m. – Town Meeting**

- Dale Alverson, MD, COL Mark Bowyer, MD, Randy Haluck, MD, Jim Azukas, Elizabeth Sanchez, and Robert Waters, JD

**1:45 – 2:30 p.m. – Tales From The Frontlines: What's the Role for Simulation In Warfare, Homeland Defense Preparedness Training, and Disaster Response**

- Overview by Rick Satava, MD, University of Washington
- COL Mark Bowyer, MD, USAF, National Capital Area Medical Simulation Center
- Jay Schnitzer, MD, PhD, Harvard Medical School, Massachusetts General Hospital, Shriners Burn Hospital

**2:30 – 2:45 p.m. – Break**

**2:45 – 3:30 p.m. – Simulation as an Agent of Change for Education**

- Introduction by Steve Dawson, MD, Chair, AIMS
- Neal Seymour, MD, Baystate Medical Center
- Elizabeth C. Poster, PhD, RN, FAAN, University of Texas-Arlington, School of Nursing
- Gerry Moses, PhD, University of Maryland Medical Center and School of Medicine

**3:30 – 4:15 p.m. – The Business of Medical Simulation: The AIMS Industry Council Update**

- Industry Council Presentation, Elizabeth Sanchez, SimMedical
- Industry Council Panel: B-Line Medical, CAE, EMS, Forterra Systems, Gaumard Scientific, Haptica, Immersion Medical, IngMar Medical, Laerdal, Limbs & Things, Inc., Medic Vision, METI, Pocket Nurse, Simbionix, SimMedical, SimQuest, Simulab Corporation, Touch of Life Technologies, Verefi Technologies

**4:15 – 4:30 p.m. – Closure and Adjourn**

**4:30 – 6:00 p.m. – Reception at National Capital Area Simulation Center**

**5:00 – 6:00 p.m. – Medical Team Training in the Wide Area Virtual Environment (WAVE) Demo**

## **Appendix B – Accomplishments**

The efforts undertaken by the Center for Telehealth & E-Health Law to advance medical simulation and leverage the work already performed by the Federal government has been tremendously successful.

- Educated professional licensing boards about the value of medical simulation
- Provided opportunities for key national leaders to state their interest, declare their intentions, and offer their experiences with regard to medical simulation – one key accomplishment related to this is the public acknowledgement that malpractice claims for simulation-trained clinicians declined over a five-year period based on claims data which resulted in a 35% decrease in premiums for anesthesiologists
- Informed the military, medical, nursing and allied health communities, academic, and others about the current state of medical simulation
- Supported the further coalescing of the medical simulation community
- Articulated the value of medical simulation
- Showcased the research and commitment of the US Army, TATRC as well as the US Agency for Healthcare Quality and Research, an agency of the Department of Health and Human Services and the National Institute of Biomedical Imaging and Bioengineering, an institute of the National Institutes of Health, , an agency of the Department of Health and Human Services
- Offered a networking opportunity for those interested in advancing the field