

Building a National Agenda for Simulation-based Medical Education

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Overview: Medical Simulation

The United States is facing a health care crisis:

- Medical errors kill as many as 98,000 people annually at a total national cost of between \$37 to \$50 billion for adverse events and between \$17 to \$29 billion for preventable adverse events;¹
- Nursing shortages, which are expected to reach 20% by the year 2020, are forcing some health care facilities to implement mandatory overtime for nurses and increased patient care loads, contributing to an already high number of stress-related errors;
- Medical residents are operating under strict new rules that limit a resident to an 80-hour work week leaving less time for direct interactions between students and instructors; and
- Bioterrorism threats and concerns are forcing institutions and governments to reconsider how quickly providers can be trained and ready to react to a health crisis.



Currently, there are hundreds of schools in the United States providing “hands on” health care education to medical, nursing, and allied health students. These schools predominately use the apprenticeship model as its main teaching style, often referred to in medicine as “do one, see one, teach one.” Until recently, practicing on cadavers, laboratory animals, or real patients has been the only way to teach doctors, nurses, and other health professionals about anatomy and how to practice medicine. Of course, using anesthetized animals for medical training is challenging – the animals do not have the correct anatomy for realistic training, they are expensive, and they are not reusable. While cadavers have the correct anatomy, their use presents other challenges, including expense, difficulty in procuring the cadaver, and tissue degradation. In both instances, ethical issues are raised as well.

A health care provider’s ability to react prudently in an unexpected situation is one of the most critical factors in creating a positive outcome in a medical emergency, regardless of whether it occurs on the battlefield, freeway, or hospital emergency room. This ability, however, is not a skill that one is born with, but rather it is learned and developed with time, training, practice, and repetition. Today, advances in technology have created new and better, methods for teaching the practice of medicine and reinforcing best practices. One of the most exciting innovations in health care is in the field of medical simulation. Employing medical simulation techniques can help move medicine from the old “see one, do one, teach one” method to a “see one, practice many, do one” model for success.

In fact, advanced medical simulation technologies are revolutionizing the way medical education is provided to students and to experienced practitioners as well as helping to ensure clinical competence long after one has finished his or her medical residency or internships. Just as airline pilot simulator training dramatically improved airline safety by reducing pilot errors, the use of medical simulators to teach new skills or procedures, team training, or test competencies is reducing medical errors, improving patient safety, and reducing health care costs overall.

According to the Institute of Medicine (IOM) report, “To Err Is Human: Building a Safer Health System,” preventable adverse events are a leading cause of death in the United States. In fact, health experts estimate that **“at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year from medical errors.”** Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th-leading cause of death. Deaths due to preventable adverse events exceed deaths attributable to motor vehicle accidents, breast cancer, or AIDS.”²

Institute of Medicine - Principle 4

Health care organizations and teaching institutions should participate in the development and use of simulation for training novice practitioners, problem solving, and crisis management, especially when new and potentially hazardous procedures and equipment are introduced. Crew resource management techniques, combined with simulation, have substantially improved aviation safety and can be modified for health care use. Early successful experience in emergency department and operating room use indicated that should be more widely applied.

The IOM report made several notable recommendations with regard to medical simulation:

1. “Establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management.”³
2. “Health care organizations should use and rely on proficiency-based credentialing and privileging to identify, retrain, remove, or redirect physicians, nurses, pharmacists, or others who cannot competently perform their responsibilities.”⁴
3. Use procedures to mitigate injury through simulation training.⁵
4. Create a learning environment. “Use simulations whenever possible.”⁶

“Do I think [medical simulation] is a wave of the future? No question. This is a major goal of the medical education and evaluation system.”

...Stephen H. Miller, MD, MPH, American Board of Medical Specialties

Medical Simulation Defined

Simulation is a training and feedback method in which learners practice tasks and processes in lifelike circumstances using models or virtual reality, with feedback from observers, peers, actor-patients, and video cameras to assist improvement in skills.⁷

Computer-based medical simulation provides a realistic and economical set of tools to improve and maintain the skills of health care providers adding a valuable dimension to medical training similar to professional training in aviation, defense, maritime, and nuclear energy. Medical simulators allow individuals to review and practice procedures as often as required to reach proficiency without harming the patient. Simulation-based Medical Education (SBME) includes several tools and approaches, for example:



patient simulator

- A full environment simulator is similar to flight simulators used to train pilots. The pilot is immersed in a complete replica of the cockpit environment. In medicine, sophisticated mannequins, known as patient simulators provides health care professionals with a computer-based patient that breathes, responds to drugs, talks, and drives all the clinical monitors in the operating room, e.g., blood pressure and pulse rate.
- Task trainers provide a simulated subset of functionality, such as how to give a smallpox inoculation or how to insert a chest tube.
- Computer-based training provides software programs that train and assess clinical knowledge and decision-making skills.
- Simulated/standardized patients allow students to interact with actors trained to act as patients providing students with valuable feedback on, among other things, bedside manner.

Improving Physician Education

“Medical simulation is state of the art education that allows us to create new and realistic methods of learning without putting patients at risk. It is particularly valuable during the crucial early phases of medical training.”

....Steve Dawson, MD, program leader, Simulation Group at the Center for Integration of Medicine and Innovative Technology, Massachusetts General Hospital-CIMIT

Smallpox Inoculators

By the 1980s, the World Health Assembly declared that smallpox had been eradicated and recommended that vaccinations cease. Providers who had been trained in providing smallpox inoculations have since retired, left medicine, or died. Following the September 11, 2001, attacks, however, concerns about terrorists using the smallpox virus has created the need for a new generation of providers skilled in providing the inoculation.

The **Smallpox Inoculation Training Unit (SITU)** was developed by The Simulation Group at Massachusetts General Hospital to provide training for future inoculators. The objective is to deliver a system that simulates smallpox inoculation, provides facts about smallpox, and demonstrates safe handling procedures. The expected outcome is a trained population of skilled, informed, and confident inoculators.



Smallpox Inoculation Training Unit

Developed by the Simulation Group at the Center for Integration of Medicine and Innovative Technology at Massachusetts General Hospital-CIMIT

Table 1. Simulation Tools and Approaches Used in Simulation-based Medical Education⁸

| Type | Description |
|----------------------------------|---|
| Low-tech simulators | Models or mannequins used to practice simple physical maneuvers or procedures |
| Simulated/standardized patients | Actors trained to role-play patients for training and assessment of history taking, physicals, and communication skills |
| Screen-based computer simulators | Programs to train and assess clinical knowledge and decision making, e.g., perioperative critical incident management, problem-based learning, physical diagnosis in cardiology, acute cardiac life support |
| Complex task trainers | High-fidelity visual, audio, touch cues, and actual tools that are integrated with computers. Virtual reality devices and simulators that replicate a clinical setting, e.g., ultrasound, bronchoscopy, cardiology, laparoscopic surgery, arthroscopy, sigmoidoscopy, dentistry |
| Realistic patient simulators | Computer-driven, full-length mannequins. Simulated anatomy and physiology that allow handling of complex and high-risk clinical situations in lifelike settings, including team training and integration of multiple simulation devices |

Benefits of Medical Simulation

As providers spend more time learning and improving their skills, they also enhance patient safety.

As mentioned earlier, training for health care providers follows a methodology of observation and repetition. This process has shortcomings. The trainee only learns from those cases and situations that present themselves within a short period of time a health care provider is in school. Further exacerbating this issue is the recent decision to reduce the workweek for residents to 80 hours per week.

Simulation-based medical training allows for realistic training in communication, leadership and team interaction as well as observation and repetition until the student has mastered the information.

The simulation-based medical training benefits all of us:

- Patients benefit from improved health outcomes and reduced errors.
- Patients with rare or unusual conditions benefit from better-trained providers.
- Consumers benefit from reduced health care costs and enhanced quality.
- Taxpayers benefit from tax dollars spent on equipment used for different skill levels.
- Businesses benefit from the creation of high-tech jobs and greater productivity.
- Physicians, nurses, and health professionals benefit from better skills and lower malpractice rates through demonstrated clinical competence.
- Health care organizations benefit from reduced adverse events.
- Insurers benefit from defending fewer malpractice claims.
- Students benefit from a flexible training curriculum set at their pace, need for repetition, and schedule. Students have the opportunity to practice, make mistakes, and improve their skills and knowledge on the simulated patient *without consequence to the patient*.

Medical simulation-based training provides better-trained health care providers, reduces medical errors, saves money, and improves the quality of patient care overall.

Medical Simulation Improves Patient Safety and Reduces Cost

“Emerging technologies in medical simulation make a critical difference that ranges from helping a patient who is seeking relief from a phobia to training a surgeon who is rehearsing and perfecting a difficult procedure prior to surgery. The use of medical simulation training increases proficiency while greatly reducing training costs for physicians just as the aviation industry experienced with flight simulators. The field for medical simulation technology is simply burgeoning. We have an incredible opportunity to improve medical education and enhance patient safety.”

*Bob Waters, General Counsel, Center for Telemedicine Law, and
Partner, Gardner Carton & Douglas LLP*

What Is Needed?

While the use of medical simulators has the potential to save lives and reduce health care costs, the funding for such efforts is a small portion of what is needed. Bringing medical simulation leaders together to develop funding strategies, create public-private partnerships, and coordinate resources is a necessary next step to leverage and expand the currently available resources.

Working closely with members of the medical and simulation community, Telemedicine and Advanced Technology Research Center (TATRC), U.S. Army Medical Research and Materiel Command, the Uniformed Services University, and the Center for Telemedicine Law (CTL) joined together to convene a one-day meeting in Washington, DC on May 10, 2004 to discuss the state of medical simulation and the challenges it is facing. A summary of that meeting is included at Appendix A.



In an unrelated, but equally important meeting, CTL hosted an exhibition on Capitol Hill on May 11, in which over 30 simulators were on display for Members of Congress, Congressional and Agency staff, associations, medical and nursing schools, and the general public.

Simulation projects are occurring all around the world. Medical simulation research, development, and training are being conducted at many of the major universities, including Harvard University, Massachusetts Institute of Technology, Stanford University, University of Pittsburgh, and many others. In fact, over half of the nation's 120 medical schools already use simulators in their training curricula, as does the US military.

To date, the projects have largely been funded by the US Army through TATRC. Since 1997, TATRC has funded 44 projects totaling \$12,555,000 in funding and by 2007 expects to fund a total of 174 projects totaling \$74,811,000. Again, this is a small portion of what is needed, and the potential of medical simulation is far from being realized.

TATRC and others recognize, and rightfully so, that simulation-based medical training can address the acute need identified in a 1998 General Accounting Office that states that the military's approximately 100,000 medical personnel, excluding reserve members, do not have adequate opportunities to practice battlefield trauma care skills. As more reserve members are used to complement and supplement active duty military, it is important for the country to have a way to train and update medical skills in a time efficient and cost-effective manner.

Who Is Interested in Simulation-based Medical Training?⁹

Many groups, organizations, and individuals are interested in medical simulation and the science behind it, including:

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| Military and Law Enforcement | Army, Navy, Marines, Air Force, Coast Guard, Special Forces, National Guard, Homeland Security, law enforcement agencies, emergency responders |
| Agencies | Department of Defense, Centers for Disease Control, Department of Health and Human Services, Food and Drug Administration, Human Resources Services Administration, Agency for Healthcare Research and Quality, National Academy of Sciences/Institute of Medicine, National Institutes of Health/National Library of Medicine, Department of Veterans Affairs, Department of Commerce, National Institute of Standards and Technology |
| Regulatory and Credentialing Organizations | Food and Drug Administration, State Boards of Medicine, Joint Commission on the Accreditation of Health Organizations, Accreditation Council for Graduate Medical Education, National Board of Medical Examiners, American Board of Medical Specialties, Association of American Medical Colleges |
| Industry | Health care systems, hospitals, medical corporations, high-tech companies, medical device manufacturers, health insurers and underwriters, venture capitalists |
| Providers and Professional Societies | American College of Surgeons, Society for Interventional Radiology, Radiological Society of North America, Society of Anesthesiology, American College of Cardiology, orthopedic surgeons, nurses and many more... |
| Academia and Related Groups | Teaching hospitals, medical schools, nursing schools, academic health centers, community colleges |
| Interested Groups | Institute for Healthcare Improvement, Center for Telemedicine Law |
| Patients | Patients |

APPENDIX A - MEETING SUMMARY

Building a National Agenda for Medical Simulation

Monday, May 10, 2004

Summary

The promise of simulation-based medical training offers incredible opportunities to:

- Improve patient safety;
- Train large numbers of people needed to respond to public emergencies;
- Ensure provider competency; and,
- Reduce health care costs.

There are several obstacles, however, limiting the expansion of simulation training, including:

- Funding for research, development, and acquisition;
- Support from the medical establishment to move to a competency training model; and
- A community-wide effort to communicate the importance of medical simulation technology and training to a broader audience, including patients, policymakers, industry, and the general public.

Currently, federal research and development funding is primarily occurring in the Department of Defense's TATRC, US Army Medical Research and Materiel Command. Simulation-based medical education is or at least fundamentally should be a function of the Department of Health and Human Services (HHS). An agency within HHS should be charged with funding research and development activities for simulation-based medical education.

Medical simulation requires a significant investment from federal government for basic research in areas, such as soft tissue modeling, interoperability standards, cost-effectiveness, and validation studies while private sector funds are needed to move the basic research to market. In related fields, the market place has been unable to fund basic research because the time horizon on which the company will see a return on investment is too long.

The simulation community should identify targets for the next decade, focusing on:

Funding

- Medical simulation will require a significant investment:
 - Federal funds are needed for basic research; and
 - Private sector funds are needed to move the basic research to market.

- An agency within HHS should be charged with funding research and development activities for simulation-based medical education from medical school through life-long maintenance of competence.
- Simulators need to be developed that simulate multiple procedures at different levels. Hospitals and universities cannot afford to buy thousands of simulators to simulate the thousands of individual surgical procedures that students need to learn.

Curriculum Development and Delivery

- Define the education and assessment objectives.
- A substitute is needed to make up for the lost experience for residents who are exposed to fewer training hours as a result of the 80-hour workweek.
- Integrate simulation into all levels of the curricula.
- Focus on a multidisciplinary approach.
- Transition from traditional medical training to competency-based training.
- Develop regional centers or a national center for procedural simulation and assessment, whose primary mission is education and training. Develop regional centers to maximize the use of and investment in the equipment.

Research

- Prioritizing the research agenda and setting research goals.
- Develop a taxonomy of what is needed in the field to advance the field:
 - Create appropriate haptics interface;
 - Representing normal and diseased tissue;
 - Soft tissue modeling; and
 - Interoperability standards.
- Establish a committee or meeting to develop consensus for standards of interoperability, as existing simulators are not interoperable and curricula are not complementary.
- Perform studies
 - Initiate a multi-institution validation study. Validation studies are critical to establish the credibility of simulators – to show that simulators teach what they should teach and will improve the educational process and to demonstrate the efficacy of simulation to payers, insurers, and medical boards;
 - Studies on the impact of simulations on performance improvement, knowledge transfer, or knowledge structure;
 - A cost-benefit analysis of the value of simulation must demonstrate the return on investment; and

- Request the National Academy of Sciences/Institute of Medicine (IOM) to conduct a national study like the *To Err is Human* report focusing on simulation as an adjunct to traditional educational methods.
- Research and development considerations:
 - End users need to be involved from the very beginning of concept design; and
 - Input is needed from experts, institutions, and boards in setting up protocols for testing criteria.
- Focus on the creation of products that address procedural skills and how procedures will be developed 10 years in the future.
- Needs assessment complemented by a meta-analysis of resources available, including simulators and curricula.

Relationship Development

- Greater acceptance needed from the medical community, industry, and the federal government:
 - Consensus on what needs to be done;
 - Collaboration, both national and global, is key to success;
 - Communications, teamwork, and episode management;
 - Greater buy-in from the medical community; and
 - Gathering representatives from different interest groups.
- Medical simulation community must consider how it will organize itself as a community, e.g., pooling resources, developing seed money, and raising the community's visibility
 - Leverage or build relationships with others;
 - Convening a multidisciplinary group to enhance dialogue among engineers, developers, educators, and medical users;
 - Defining and building consensus for industry and government;
 - Coordinate agencies so that they work jointly to find a solution; and,
 - Address intellectual property issues.

Enhanced Communications

- Serving as a communication vehicle - bringing the community together through the Web, journals, and meetings with the general public and members of Congress.
- Develop a concept video or vision statement that could be used as an educational tool to highlight the benefits of simulation.
- Develop the medical equivalent of the National Transportation Safety Board to investigate and analyze errors without punitive action.

- Make a national agenda on simulation-based medical education meaningful and understandable to the average person.
- Focus on patient safety as a meaningful and understandable cornerstone of a national simulation agenda.
- Differentiate between device manufacturers and the educational companies that develop simulators.

Building a National Agenda – May 10, 2004 Meeting Agenda

Forest Glen Annex, Walter Reed Army Medical Center, Silver Spring, MD 20910

| Topic | Speakers & Panelists |
|---|--|
| Welcome | <p>ADM James Zimble, MD, Uniformed Services Univ., Silver Spring, MD</p> <p>Gerald Moses, PhD, TATRC, US Army Medical Research and Materiel Command, Ft. Detrick, MD</p> <p>Mark Bowyer, MD, FACS, Colonel, USAF, MC, Surgical Director of Simulation, National Capitol Area Medical Simulation Center, and Chief, Division of Trauma and Combat Surgery, Uniformed Services University, Silver Spring, MD</p> <p>Steve Dawson, MD, Program Lead, Medical Simulation, The Simulation Group, Massachusetts General Hospital-CIMIT, Boston, MA</p> <p>Jackie Eder-Van Hook, MS, Executive Director, Center for Telemedicine Law, Washington, DC</p> |
| The Promise of Simulation: The American College of Surgeons' Perspective | Gerald Healy, MD , Chair, Otolaryngology, Children's Hospital of Boston; Regent, American College of Surgeons, Boston, MA |
| Challenges Facing Simulation and How a National Agenda Would Solve the Problem | Richard Satava, MD, FACS , Program Manager, Defense Advanced Research Projects Agency (DARPA), DOD and Professor, Surgery, University of Washington, Seattle, WA |
| Practical Advice: What Does it Mean to Create a National Agenda in Medical Simulation | Robert Waters, JD , General Counsel, Center for Telemedicine Law, Washington, DC; Partner, Gardner Carton & Douglas LLP |
| Crew Resource Training: The Anesthesia Perspective | David Gaba, MD , Director, Patient Safety Center of Inquiry, VA Palo Alto Health Care System, and Associate Dean for Immersive & Simulation-based Learning, Stanford University, Palo Alto, CA |
| Lessons Learned: The Israeli Experience | Amitai Ziv, MD , Director, Israel Center for Medical Simulation, Chaim Sheba Medical Center, Tel Aviv University, Tel Aviv, Israel |

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| <p>Incorporating Simulation into Training: Experience in the Harvard Medical School Curriculum</p> | <p>James A. Gordon, MD, MPA, Director, MEC Program in Medical Simulation, Harvard Medical School, Boston, MA</p> |
| <p>State of the Science: Researcher Panel</p> | <p><u>Moderator</u></p> <p>Randy Haluck, MD, Penn State Milton S. Hershey Medical Center, Hershey, PA</p> <p><u>Panelists</u></p> <p>Dale Alverson, MD, University of New Mexico Health Science Center, Albuquerque, NM</p> <p>Steve Dawson, MD, Program Lead, Medical Simulation, The Simulation Group, Massachusetts General Hospital-CIMIT, Boston, MA</p> <p>Alan Liu, PhD, National Capital Area Simulation Center, Uniformed Services University, Silver Spring, MD</p> <p>Carla Pugh, MD, PhD, Gastrointestinal and Endocrine Surgery, Northwestern University School of Medicine, Chicago, IL</p> |
| <p>State of the Science: Producer Panel</p> | <p><u>Moderator</u></p> <p>Mark Bowyer, MD, FACS, Colonel, USAF, MC, National Capitol Area Medical Simulation Center, Silver Spring, MD</p> <p><u>Panelists</u></p> <p>David Hananel, METI, Cincinnati, OH</p> <p>Yael Friedman, PhD, Symbionix USA Corporation, Cleveland, OH</p> <p>Gerald Higgins, PhD, Laerdal Medical Corp., TX</p> <p>Kevin Kunkler, MD, Immersion Medical, Gaithersburg, MD</p> |
| <p>Importance of Validation in Simulation</p> | <p>Anthony Gallagher, PhD, Assistant Professor, Surgery, Emory University School of Medicine, Atlanta, GA</p> |
| <p>Fitting Medical Simulation into Hospital-based Practice: The JCAHO Perspective</p> | <p>Robert Wise, MD, Vice President, Standards, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Chicago, IL</p> |
| <p>The Medical Simulation Community Perspective</p> <p>Breakout Groups; Seeking Consensus Solutions</p> | <p><u>Moderator</u></p> <p>Robert Waters, JD, General Counsel, Center for Telemedicine Law, Washington, DC; Partner, Gardner Carton & Douglas LLP</p> <p><u>Facilitators:</u> COL Mark Bowyer, MD, FACS, Steve Dawson, MD, Gerald Healy, MD, Richard Satava, MD, FACS</p> |

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| <p>The Military Perspective</p> <p>Funding for Medical Simulation: The Department of Defense Perspective</p> | <p>GEN Lester Martinez-Lopez, Commanding General, US Army Medical Research and Materiel Command, Ft. Detrick, MD</p> <p>Gerald Moses, PhD, TATRC, US AMRMC, Ft. Detrick, MD</p> |
| <p>The Regulatory Perspective</p> <p>View on Simulation and New Device Approval: The Food and Drug Administration's (FDA) Perspective</p> | <p>Peter B. Carstensen, Food and Drug Administration (FDA), Center for Devices Radiological Health, Rockville, MD</p> <p>Sandy Weininger, PhD, Food and Drug Administration (FDA), Center for Devices and Radiological Health, Rockville, MD</p> |
| <p>Society for Medical Simulation Update</p> | <p>Lisa Sinz, MD, Director, Simulation Laboratory, Penn State Hershey Medical Center, Hershey, PA</p> |
| <p>Closing</p> | <p>Robert Waters, JD, General Counsel, Center for Telemedicine Law, Washington, DC; Partner, Gardner Carton & Douglas LLP</p> <p>Steve Dawson, MD, Program Lead, Medical Simulation, The Simulation Group, Massachusetts General Hospital-CIMIT, Boston, MA</p> <p>Mark Bowyer, MD, FACS, Colonel, USAF, MC, National Capitol Area Medical Simulation Center, Silver Spring, MD</p> <p>Gerald Moses, PhD, TATRC, US AMRMC, Ft. Detrick, MD</p> <p>Jackie Eder-Van Hook, MS, Executive Director, Center for Telemedicine Law, Washington, DC</p> |

Welcome

ADM James Zimble, MD
Gerald Moses, PhD, TATRC
COL Mark Bowyer, MD
Steve Dawson, MD
Jackie Eder-Van Hook, MS

Col. Mark Bowyer opened the meeting by explaining that its purpose was to engage the community of simulation experts in creating a national agenda for simulation.

Adm. James Zimble characterized this meeting, as the first of what he hoped would be many meetings. When Adm. Zimble went to medical school 50 years ago, medical simulation consisted of using an orange and a needle to practice giving an injection. Those days are long gone: patients do not stay in the hospital long enough any more for medical students, interns, or residents to do a complete workup.

Medical education has always consisted of “see one, do one, teach one,” and medical students did their first spinal taps on actual patients. Recently, the Institute of Medicine (IOM) released its report *To Err is Human: Building a Safer Health System*, which discusses the number of deaths attributed to medical errors. This problem could be resolved by enhancing physician proficiency

in other ways than “see one, do one, teach one.” The technology is available to move ahead, but the medical community must be convinced that this is the right way to go. Medical simulation will require a significant investment and the medical simulation community must be able to articulate the ways in which that investment will have a great return in the form of lives saved.

The next wave of the future is to train not only physicians and medical teams using simulation, but also first responders. Medical simulation will make it possible to train the large numbers of people needed to prepare for and respond to the next disaster.

Col. Bowyer noted that the IOM report showed how costly the many adverse medical events in the United States are in terms of both lives and dollars. The way to minimize errors may be through medical and surgical simulation. Medical simulation needs to emulate what has happened in the aviation industry, where flying a simulator is almost like flying a plane. The difference between medical and aviation simulation is the investment of billions of dollars. It is time for policymakers to realize that this is as important as aviation simulation or genomics projects. It is a matter of patient safety and lives.

The simulation community encompasses academia, industry, regulatory agencies, organized medicine across provider groups, end users, and the military. Representatives from all of these organizations attended the meeting.

Col. Bowyer suggested that the way forward for simulation is through:

- Collaborating, building community;
- Integrating existing and future technologies;
- Validating and verifying;
- Innovating;
- Staying on the “bleeding edge” of technology; and
- Creating a national agenda, which will require funding.

Steve Dawson, MD explained that this meeting came together through the collaboration of four primary groups: Emory University, Massachusetts General Hospital, Stanford University, and the Uniformed Services University of the Health Sciences.

This team was joined by the US Army Telemedicine and Advanced Technology Research Center (TATRC), American College of Surgeons (ACS), and the Center for Telemedicine Law (CTL).

Dr. Dawson explained that what those present were trying to accomplish was much greater than what could be accomplished by any single group. He hoped that this meeting would result in the creation of a national agenda that could capture national attention, including educating public policymakers about medical simulation.



Steve Dawson, MD

On behalf of the CTL, Jackie Eder-Van Hook thanked participants for making the commitment to participate in the meeting and to the AIMS Planning Committee and to AIMS co-chairs Steve Dawson, MD and Col. Mark Bowyer, MD. Ms. Eder-Van Hook stated that CTL was founded in 1995 by a consortium of the Mayo Foundation, Cleveland Clinic Foundation, Texas Children's Hospital, and the Mid-West Rural Telemedicine Consortium. CTL is committed to overcoming barriers to the use of telemedicine and supporting emerging technologies in health care.

Gerald "Gerry" Moses, PhD said that about a dozen of those present had attended a meeting in February 2000 that attempted to develop a strategy for managing funded research projects related to simulation. Over the last four years, the quality of simulators has increased substantially, and today's simulators are much more believable, thus, more useable by the community at large.

Dr. Moses thanked those organizations and individuals involved in medical simulation. Stating that the organizations, such as ACS, are helping the field move forward because they are listening to end users, people in need of medical simulation for medical training, military readiness training, and improvements in surgery. Validation studies have been initiated, as they are critical to establish the credibility of simulators.

For Dr. Moses, the "best news" has been the development of collaborations and relationships among those in medical simulation. However, not all the news is good. Although some investments have been made in medical simulation training, the resulting improvements are not good enough and the potential is far from being realized. Medical simulation has not made an impact at the national level. That is, it has not been noticed nationally.

The Promise of Simulation – The American College of Surgeons Perspective

Gerald Healy, MD

Gerald Healy, MD characterized this as the most important meeting he would attend this year. Although most health care discussions are related to paying for health care, today's agenda centers on patient safety. Participants will discuss ways to ensure that American patients are cared for in safer settings. The way to do that is through medical simulation.



Dr. Healy described many serious challenges in ensuring that doctors are qualified and up to date throughout their lives as physicians. Today, medical students are no longer given a needle and an orange because they do not have enough time for this. Students are leaving medical school without knowing how to insert an intravenous (IV) line because patients are not in the hospital long enough to give students opportunities to practice.

Students are also sent out of medical school without anyone knowing their aptitude. In many cases, aptitude is not assessed until the third year of residency. Because residents with little

aptitude have put so much time into the process, they are typically allowed to complete their programs and move on to become someone else's problem.

Simulation could help identify aptitude early on. Students could then be guided away from fields in which they lack aptitude and toward areas in medicine where those aptitudes are not needed. Errors start early when providers' careers begin to be developed in medical school. ACS is very interested in simulation because the future of surgery lies in beginning to nurture the student in medical school.

Because of the 80-hour rule, surgical residents are exposed to fewer operations. A substitute is needed for that lost experience.

Dr. Healy suggested that if he were a pilot whose skills had last been checked in 1972, no one would want to fly in his plane. However, 1972 is the last time Dr. Healy was checked by the American Board of Otolaryngology, which provided him with lifelong certification. This practice has stopped, and all 24 boards of the American Board of Medical Specialties now require maintenance of certification. The process of lifelong certification has a serious deficiency - the inability to test the technical capability of the doctors who take care of us daily.

Dr. Healy reminded participants that everyone we meet with is or will be a patient or a family member of a patient. All of the issues discussed at this meeting affect all of us.

ACS has taken a vigorous stand on this issue. It wants to ensure that its 60,000 members are qualified to take care of patients. ACS plans to dedicate an entire building in Chicago as a patient safety center. The college has also developed a task force that had its first meeting ever with the Association of Operating Room Nurses. It has also met with the associations of anesthesiologists and nurse anesthetists around one issue: patient safety. All of these groups recognize the need to work together toward the safe outcome of the surgical patient.

"I look forward to the day when simulation can be leveraged to its fullest extent to reduce medical errors, improve medical skills, and, above all, improve medical care for patients."

*General Lester Martinez-Lopez, Commanding General,
US Army Medical Research and Materiel Command, Ft. Detrick, MD*

Challenges Facing Simulation and How a National Agenda Would Solve the Problem

Rick Satava, MD

Rick Satava, MD listed several challenges for a national agenda on simulation:



- **Scientific:** No new great ideas or breakthroughs have been proposed in recent years, as experts have been competing for “low-hanging fruit.”
- **Standards:** Existing simulators are not interoperable and curricula are not complementary.
- **Availability:** Few simulators are available and too many do the same things. These simulators teach about normal conditions, but trainees need to learn about abnormal conditions.
- **Validation:** Validation is needed to show that simulators teach what they should teach and will improve the educational process. This will be very expensive.
- **Curriculum:** Every simulator simulates one thing at one level and does one procedure. Our universities and hospitals cannot afford to buy thousands of simulators to simulate the thousands of individual surgical procedures that students need to learn.
- **Return on Investment:** The return on investment must be demonstrated.
- **Funding:** Funding is a grand challenge because hundreds of millions of dollars are needed to move it forward. No federal agency is currently funding medical simulation. Acceptance from the medical community, industry, and the federal government is necessary.

Dr. Satava reported that funding for medical simulation has traditionally been provided through the Department of Defense with a small amount through National Institutes of Health (NIH).

| <i>Survey of Federal Government Awards for Medical Simulation* (FY04)</i> | |
|---|----------------|
| Department of Defense (DoD) | \$ 1.2 million |
| National Institutes of Health (NIH) | \$ 0.4 million |

* Excludes Congressional Special Interest (CSI) programs through DoD or other agencies.

Dr. Satava stated that medicine is still in the industrial age and simulation will help bring it into the information age. Simulation can be used to train, assess preoperative planning, rehearse surgical procedures, and assess performance and outcomes.

Dr. Satava explained that a new national agenda is needed because the incentive for new ideas or breakthroughs must come at a higher level. Someone with authority is needed to set standards. A national agenda would provide the incentive for long-term investment. If a national agenda were established, those in the field could focus on the areas that suited them best. Congress does not need to provide additional money to support simulation, because agencies have money that could

be reprogrammed for this worthy project. Congress, however, could provide some matching or incentive funds to accelerate the process and entice agencies to fund medical simulation. Having a national agenda would make it easier for agencies to justify investing in medical simulation.

Dr. Satava argued that a national agenda would:

- Call to national attention the needs and opportunities;
- Identify simulation as a national effort and priority;
- Legitimize simulation as a science to be developed;
- Empower consensus conferences for standards;
- Signal to federal agencies that this is an important area in which to fund research;
- Accelerate the development of simulators;
- Indicate a long-term commitment to business; and
- Facilitate multi-institutional validation studies.

Medical simulation could benefit from a report equivalent to the IOM's report, *To Err is Human*. Since that report's publication, the federal government alone has spent \$100 million on a national patient safety agenda, which was developed as a result of the report. A national medical simulation agenda would focus the community's efforts on patients and not providers just as flight simulation helped the aviation industry focus on passenger safety and not pilots.

MEDICAL SIMULATION: ~~DOCTORS~~ :: FLIGHT SIMULATORS: ~~PILOTS~~
PATIENTS PASSENGERS

Practical Advice: What Does it Mean to Create a National Agenda in Medical Simulation?

Robert J. Waters, JD

Robert "Bob" Waters, JD characterized this as the beginning of a very important period for the medical simulation community. Attention needs to be focused on developing a national agenda.



The current level of federal spending on medical simulation projects is very small. However, the potential payoff is huge and presents enormous opportunities for our society. Major initiatives, such as the "Race for Space" or the Human Genome Project were launched by individuals who had the foresight to look into the future.

Members of Congress and policymakers in the Executive Branch must be educated on the exciting developments in this field and its impact on training for new and existing medical and health care professionals. These new training technologies will not only enhance the proficiency of our providers, but they are also likely to draw more young people into medicine and the health sciences.

The stakeholders in this endeavor, include patients, physicians, nurses, medical schools, nursing schools, the allied health professions, public and private insurers, and the health care industry. However, the most important stakeholder is the patient. Our objective must be to improve quality of care and reduce medical errors through enhanced training tools. All of the stakeholders need to look at the big picture, if this vision is to be realized.

The National Institutes of Health (NIH) budget was doubled, because a few well-placed Members of Congress made this a national agenda item. Participants in the medical simulation community need to begin to identify and recruit their own champions.

Mr. Waters stated that it new medical simulation technologies will inevitably find their place in the medical educational environment, but the simulation community can ensure that these tools are developed sooner and in a much more rationale way by becoming actively involved in the public policy process. Rather than simply letting this field develop in a haphazard fashion, the leaders should take control over their own destiny. This community should identify a series of goals, some simple and some complex. The simple goals will provide immediate feedback to policymakers and others interested in the field, and they will provide the foundation and help build support to sustain investments in more complex initiatives, such as soft tissue modeling. As goals are accomplished, there will be inevitable spin-offs that cannot be anticipated.

Participants in this meeting will need to consider how to organize themselves as a community, such as by pooling resources, developing seed money, and raising the community's visibility. A common message needs to be developed and the community needs to work with decisionmakers on an ongoing basis, not just once or twice a year. Periodic exhibitions and events need to be developed and held to ensure that public policymakers and their staffs see the value and potential of medical simulation.

Mr. Waters reminded participants that they are involved in changing people's minds. The key is to identify who needs to be reached and what the message is, and to be persistent. By doing this, the medical simulation community will accomplish more than it could possibly imagine.

The User's Perspective

Crew Resource Training: The Anesthesia Perspective

David Gaba, MD

David Gaba, MD, Associate Dean for Immersive and Simulation-based Learning at Stanford University School of Medicine, pointed out that the successful management of health care crises requires expert knowledge and technical skills. It also requires sound decision-making skills and optimal teamwork behaviors. Although the medical field has done well in developing expert knowledge and technical skills, it has done less well with decision-making and teamwork skills. However, the aviation industry has shown that an effective way to develop these skills is through crew resource management (CRM).



Challenging situations happen much more often in health care than in commercial flights. For example, 20% of anesthesia cases involve an unexpected incident. The principles in CRM apply not just to anesthesia or surgery, but also to a wide range of clinical domains and practitioners. A CRM-based approach focuses on the integration of behavioral skills with medical skills. Simulation is a key component of a CRM-based approach in health care, because it lets teams and team-members actually practice these skills in the context of plausible time-critical challenging situations.

Simulators provide many of the features of real patients, including eye blinks, active pupils, and pulses. They also generate data streams for patient monitoring systems that are critically important in anesthesia, intensive care, and emergency medicine. Dr. Gaba showed photos of a simulation room and control room at VA Palo Alto/Stanford University. The simulation room replicates various actual hospital settings as much as possible. Participants are presented with scenarios that are very challenging not only medically and technically, but also in terms of the principles of decision-making and teamwork. After the simulation, participants take part in a detailed debriefing where they can see a video of what actually happened and discuss the pros and cons of their actions. This has worked well in aviation and it works well in medical simulation.

CRM can be taught to individuals from a single discipline (using instructors and retired personnel to play other team roles), which makes it possible to focus on the behavior skills most needed in that discipline. CRM can also be taught to actual combined teams of individuals from different disciplines in one work unit. This approach facilitates cross-training and building cohesion of real working teams. These two techniques are complementary, and both can be pursued to achieve greater impact.

Lessons Learned: The Israeli Experience

Amitai Ziv, MD

Amitai Ziv, MD reported on the activities of the Israel Center for Medical Simulation (MSR) www.msr.org.il. MSR is a national comprehensive, multidisciplinary simulation center that provides a broad range of simulation-based medical training utilizing a wide range of simulation modalities. The center can simulate all clinical environments, including pre-hospital field environments as well as hospital set-ups like emergency and operating rooms, intensive care units, ward rooms and outpatient clinics.



COL Mark Bowyer, MD,
CAPT Joseph O. Lopreiato,
MD, Amitai Ziv, MD

MSR has built curricula around extreme and challenging clinical scenarios (“nightmares”) that arise in caring for patients. Teams of health professionals – from physicians and nurses to paramedics and military medics come to the center for training. The training includes clinical, humanistic and communication skills and all of the training centers on the trainee’s needs.

MSR has trained more than 13,000 health providers in the last two years. The center has several testing and certification contracts. It has formed a strategic partnership with Israel's National Institute for Testing and Evaluation, the Israeli equivalent of the Educational Testing Service based in the US. In June 2004, it will be involved in the first ever simulation-based admission assessment of students seeking entry to medical school based on their interaction with simulated patients. Another innovation instituted last year was the requirement that medical interns participate in a five-day, mandatory course before entering the hospital.

Dr. Ziv concluded that collaboration, both national and global, is a key to success and that the high cost of simulation is an ongoing challenge that further emphasizes the need for centralized and collaborative efforts in this field.

Incorporating Simulation into Training: Experience in The Harvard Medical Curriculum

James Gordon, MD

James “Jim” Gordon, MD, MPA, director of the G.S. Beckwith Gilbert and Katharine S. Gilbert Medical Education Program in Medical Simulation at Harvard Medical School, noted that never before in the history of medical education have trainees been able to realistically practice in a risk-free environment. Now high-fidelity patient simulators built around computerized robot-mannequins offer remarkable opportunities for novices to gain early clinical exposure before progressing to actual patient care.



One important goal of any training curriculum is to ensure that every student has experience with all types of relevant cases. In traditional medical curricula, however, clinical education is largely dependent on “time and chance”; students gain personal experience only with those cases that happen to present during their individual work hours. Simulation promises to mitigate this inherent variability in training, ensuring that all students have experience with all types of important cases—either real or simulated.

Dr. Gordon argued that although traditional medical education has been remarkably successful, a new paradigm is required to meet the conflicting demands of exponentially growing medical knowledge and ever-decreasing contact time with individual patients. If simulated cases can recreate the cognitive dynamics of real encounters, then important educational moments can be controlled and efficiently replicated in a safe environment. For example, an intern who makes a mistake in real patient care will never forget it—and likely never repeat it. But, this is helpful only for the NEXT patient. Simulation promises to provide such instructive encounters in an artificial environment, thereby, accelerating the development of expertise while minimizing patient risk.

Among Harvard medical students, simulation is used to animate existing curricular material in both pre-clinical and clinical years of training. The simulated cases are realistic enough to engage the students emotionally, thus, providing a unique experiential learning platform where the “patient” actually talks, breathes, blinks, and moves like an actual patient. Dr. Gordon and his colleagues hypothesize that giving students an emotionally heightened, yet safe experience allows them to process material at a level previously accessible only to practicing physicians. After a single brief exposure to a simulation of session lasting 30 to 60 minutes, over 80% of students say that simulation should be a *mandatory* component of their medical education. Building on early work done with students at the Center for Medical Simulation, hundreds of students per year now participate in simulation exercises across the Harvard curriculum.

Harvard has also set up a medical education service that is similar in concept to all other hospital services -- a “patient” is always available in the simulator laboratory, and attending faculty and residents “cover” the service. Students can page the educator on-call at any time to meet in the lab and explore a wide variety of case material “on demand.”

The Research Perspective

State of the Science: Researcher Panel

Panel Members: Dale Alverson, MD
Steve Dawson, MD
Alan Liu, PhD
Carla Pugh, MD, PhD

Moderator: Randy Haluck, MD



Randy Haluck, MD asked the panelists to respond to the following questions:

1. What are the major roadblocks to moving the field of medical simulation forward?
2. What are the areas of research in simulation that need the most attention?
3. What are the gaps or limitations of the current technology?

Alan Liu, PhD suggested that what is missing in the current technology is a good haptics interface. Minimally invasive techniques are easy to simulate, which is why this area is progressing so rapidly. Current research is driven by what can easily be addressed. However, no one is trying to simulate many aspects of the sense of touch, which is actually more than one sense. Open surgery requires many senses and a good open surgery simulator has not yet been developed.

Dale Alverson, MD expressed his interest in virtual reality. Trainees and instructors can enter virtual worlds regardless of location. Dr. Alverson suggested that technologies should be based on needs and organizational requirements. He hoped that this meeting would define more clearly what is needed. Dr. Alverson also stressed that more multi-institutional, multi-center, multi-disciplinary collaboration is needed. Finally, little data is available on the impact of simulations on performance improvement, knowledge transfer, or knowledge structure. Impact of use must be demonstrated.

Carla Pugh, MD, PhD noted that many of the most important lessons that students learn in the operating room are not verbalized, because these are individual surgeons' tricks of the trade. Surgeons model these procedures and residents learn surgery by observing and attempting. All of the steps required to develop expertise need to be identified to develop curricula. Simulation should not drive the agenda; instead, the educational objectives must be defined first and these include more than just procedural skills.

Steve Dawson, MD noted that many existing simulators were designed and developed before they were taken to the medical community. Instead, development should start with the users, the people who will teach what needs to be known. A major gap is in the area of pathology, as no simulators are available to teach pathology. Another gap is interoperability. Dr. Dawson argued that a "Windows for biology" is needed, so that all of the systems being developed can work together.

Dr. Dawson also suggested that haptics might not be needed, because much of medicine today is based on visual cues rather than touch. The emphasis now should be on good visuals, and haptics can be addressed later.

Audience Discussion

Dr. Healy suggested that by the time an open surgical simulator is available, open surgery would no longer be performed in this country. Minimally invasive surgery is becoming more popular. Instead of recreating the way procedures are done today, developers should focus on how these procedures will be performed in the future.

Dr. Liu pointed out that trauma is still the second or third leading cause of death in individuals under age 40 and it involves messy, open wounds and not enough time for minimally invasive procedures. In many parts of the world, such procedures are a luxury. Open surgery is not likely to go away for a long time, and haptics is still important in simulation. Dr. Pugh agreed that open surgery is still needed, for example, when laparoscopic surgery does not work, and laparoscopy is of questionable efficacy for appendectomies or hernias.

Dr. Haluck suggested that different people might mean different things by the term “haptics.” When users ask for haptics, they should set learning objectives for haptics. He asked, would providing haptics “tip the scales,” so that leaders would accept simulation?

Dr. Gaba agreed that good procedural simulators are needed, but more work also needs to be done on good patient simulators. Existing mannequins and systems are quite poor for many applications. The challenge is to “recreate actual humans in their full glory.”

Dr. Satava suggested that the next generation of surgical systems might not require a sense of touch. Haptics are needed to replicate today’s procedures, but not necessarily those of 10 or 20 years from now. Dr. Satava added that haptics are not needed in minimally invasive surgery, as other clues are used.

Dr. Satava asked whether the Harvard medical education service could use more simulators so that it requires fewer personnel. Dr. Gordon explained that at Harvard, simulation is thought of not as a new curriculum, but as a change of venue. A faculty member who is scheduled to give a lecture can do so in front of a blackboard or in a simulation laboratory. The curriculum and people are the same, but the information that is provided using medical simulation is more effective.

Dr. Alverson pointed to the need to identify opinion leaders who understand the importance of integrating simulation into the curriculum. This will require demonstrating that simulation can help the novice become more like an expert, and identifying what requirement is met through integration.

William “Bill” Dunn, MD stressed the importance of a multidisciplinary approach to simulation. Dr. Dunn has been struck by how slow the critical care professional societies have been to follow the lead of the anesthesia education community and others in supporting simulation. Many adverse events in the American medical system are happening in a range of medical and surgical

environments. Cross-specialty appreciation of simulation's potential is needed in both professional societies and regulatory agencies.

Col. Bowyer, MD asked how the vendors could help move the simulation agenda forward. Dr. Pugh suggested that vendors collaborate with end users. Surgeons have little flexibility to meet with vendors because much of their time is scheduled for the operating room. Vendors, therefore, should meet with surgeons at the hospital at times when surgeons are available. Dr. Alverson added that appropriate arrangements would be needed to address intellectual property issues in collaborations between vendors and users.

John Schaefer, MD supported the creation of a national agenda based on a goal, such as patient safety or medical education, rather than on the technologies that are available. He asked the panel members to identify the top medical education agendas for medical technologies. Dr. Dawson suggested that the emphasis should not be on technical aspects of procedures, but rather on communications, teamwork, and episode management. He also suggested that simulation be used to eliminate behavioral patterns that lead to errors early on. The focus should be on residents, as they spend a great deal of time with patients and make many errors. Eventually, however, simulation should be used for medical school applications. Dr. Pugh suggested that simulation should focus more broadly on procedural skills. Cognitive knowledge can be assessed, but not procedural knowledge.

Mandayam Srinivasan, PhD stated that he agreed haptics is not necessary in simulations of all procedures, but it is applicable to some of the procedures as they are done today. In procedures involving very complex tissue mechanics, vision and hearing cannot convey information as quickly as haptics. It is important to evaluate which cases require haptics and to develop virtual reality systems with and without haptics.

The Producer Perspective

State of the Science: Producer Panel

Panel Members: *David Hananel, METI*
 Yael Friedman, PhD, Simbionix
 Kevin Kunkler, MD, Immersion
 Gerry Higgins, PhD, Laerdal

Moderator: *COL Mark Bowyer, MD*

Panel members were asked to respond to the following questions:

1. What are the major roadblocks to moving the field of medical simulation forward?
2. What are the gaps in current research?

3. What areas of medical simulation are the most promising from a business perspective?
4. How can the academic/research community work with the producers to collaborate and build a medical simulation community given, for example, intellectual property issues, open source goals, and interoperability standards?

Col. Bowyer, MD asked panel members to identify the major roadblocks to moving the field forward.

Gerry Higgins, PhD referred to the relatively poor buy-in from the medical community. Simulation has not yet been adopted by medical professional organizations as a basis for certification. When physicians are required to demonstrate their proficiency, simulation will be more broadly accepted.

Yael Friedman, PhD pointed out that when surgeons see simulators, they do not need to be convinced of their value. Yet it is difficult for them to convince their administrators to purchase the equipment because of limited education budgets.

David Hananel explained that although the simulation industry understands the technology involved in simulation, it needs the medical community to define clearly the educational and assessment objectives. If the industry is provided with the problems, it can come up with solutions. Mr. Hananel said he believed that the medical societies need to support simulation.

Col. Bowyer, MD asked for suggestions on how to create a community in which all parts work together. He also asked panelists to address concerns about interoperability and intellectual property.

Kevin Kunkler, MD explained that commercial developers are wary of interoperability standards, because it is difficult to generate revenues by incorporating interoperability standards into their products. However, with more interactions like this meeting in which academic and commercial developers talk to each other, it will become easier to achieve the community's goals.

David Hananel suggested that if one large customer group mandated interoperability, the industry would have to follow suit. Otherwise, it has no reason to move in that direction.

Col. Bowyer, MD asked how could end users help vendors make a business case for simulation.

Kevin Kunkler, MD explained that medical simulation is an emerging, not established, marketplace. Industry is primarily interested in protecting its property and is somewhat opposed to developing interoperable systems, because vendors compete with each other for the end user.

Dr. Kunkler emphasized that vendors are business people trying to sell their products, first and foremost. They want a close relationship with end users. Users are often treated by development

companies purely as subject matter experts and are not well integrated into the team, but companies that hire physicians as part of the development team will be successful. The vendors would like a sense of the future direction of the medical simulation field, and whether medicine will embrace it.

Yael Friedman, PhD is optimistic about the field's future because the simulators are immediately appealing to users.

David Hananel noted that the medical community needs to differentiate between device manufacturers and the educational companies that develop simulators.

Gerry Higgins, PhD said that vendors need input from experts, institutions, and boards in setting up protocols for testing criteria, so that their comments are integrated into medical curricula.

Audience Discussion

Sandy Ressler explained that institutions want interoperability, because vendors may become bankrupt and purchasers will lose the value of their investments. This business side needs to be addressed.

Kevin Kunkler, MD noted that interoperability is also an issue in academic settings where many codes are not developed with the goal of interoperability. However, vendors would be happy to include some elements in their products that are needed for interoperability.

Sandy Ressler suggested that companies get together to discuss interoperability, because it would allow them to make major sales to large institutions, instead of waiting for interoperability to be forced on them. David Hananel pointed out that if an interoperable system is of greater value to the user and would drive more business, then industry might be interested.

Chris Cates, MD reported that carotid stenting is about to receive approval from the U.S. Food and Drug Administration (FDA), which has said that metric-based training is necessary for this approval.

Charles "Chip" Steiner recalled a time when radiology manufacturers were not interested in having their scanning devices be interoperable. He suggested that the core components of the simulation technology do not need to be interoperable, but if components at some level were made available to competitors and end users, the dividends would more than pay for the short-term challenges.

Kevin Kunkler, MD suggested that the incentives and demand for interoperability must come from the user community, or interoperability must be "dictated on high" for it to happen.

An unidentified participant suggested that profits and interoperability are not always mutually exclusive. He pointed to Microsoft as an example of a producer of profitable interoperable products. He urged participants to form a committee or task force to get the work done.

Miles Kitching works for a company that makes an arthroscopy model costing approximately \$3,000. Simulators can be developed for 50 cents or for hundreds of thousands of dollars. He would like some consensus about what level of simulation is needed.

Another participant suggested that interoperability is not all or nothing, because it can exist at different levels. What may be needed are ontologies that represent consensus from the community, such as the meaning of the word “carotid” or where a certain tissue starts and stops. This level of interoperability should not be threatening to vendors.

Kevin Kunkler, MD reported that ontology models are being developed. Accepted standards are being produced for anatomic, structural, and pathological ontologies. He suggested that those in educational research and technologies should talk to medical educators, as this is not occurring.

An unidentified vendor stated that he lacks good solid performance objectives or outcomes for residents. Simulators are great training tools, but they need a good systematic approach to instruction. Interoperability makes sense for large teams, but not for small teams.

Importance of Validation in Simulation

Anthony Gallagher, PhD

Anthony “Tony” Gallagher, PhD reported that studies have shown that complications from surgical procedures drop dramatically with increasing experience.



Much of the validation work for virtual reality simulation of minimally invasive surgical procedures has been done with the Minimally Invasive Surgical Trainer (MIST VR). It was designed by a surgeon, a psychologist and a computer engineer and provides remote training and assessment. Instead of replicating tissues, it replicates the psychomotor skills needed to perform the procedure.

Dr. Gallagher described a randomized controlled trial with surgical residents half of whom were required to train on the simulator until they had reached an objectively determined level of proficiency. The proficiency level was set based on the frequency of errors and other performance factors of five expert surgeons performing on the same simulator. The standard training group received the training that they would normally have. All of the students were assessed to make sure that they knew what they were supposed to do before completing a two-handed minimally invasive surgical procedure. The performance was video recorded and assessed later by attending surgeons blinded to training status. The attending surgeons had also had been trained to identify intra-operative errors with greater than 80% inter-reliability.

The investigators found that the virtual reality training group made six times fewer objectively assessed intra-operative errors than the standard training group. The virtual reality residents also performed procedures 30% faster although speed of operating was specifically identified during training as being unimportant.

A very large US owned multi-national, medical, for-profit company has developed carotid stenting with embolic protection device as a new way to reduce the risk of strokes in patients with carotid artery disease. A double-blinded trial showed that the procedure was as safe, even better than the current standard of care, which is endarterectomy. The FDA liked the procedure and the device, but argued that physicians should not be allowed train to on actual patients due to the already high risk of strokes as demonstrated in the clinical trial (e.g., 4.4% at 30 days and 11.9% at 3,690 days). The panel of experts advising the FDA voted for conditional approval, but approval will require that physicians to be trained on a simulator until they achieve an objectively established level of proficiency. This is the first time that virtual reality training has been mandated (by default) by a government organization.

Dr. Gallagher summarized by saying that simulation works and the surgical community knows how to use it for both training and assessment. He concluded that we are at a historic moment in medicine, because for the first time we can train medical skills to a very high level without exposing the patient to risk. Appropriate use of simulation will produce better physicians who can deliver better quality and safer care to patients.

Fitting Medical Simulation into Hospital-based Practice: The JCAHO Perspective

Robert Wise, MD

Robert “Bob” Wise, MD reported that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) formed a national task force to investigate current processes that hospitals and other healthcare organizations use to assess the competency of practitioners. The issue of simulation has come up in these discussions even though the greatest experience in this technology still is connected to training of residents and medical students. A particular issue that has been noted is the difficulties that organizations face trying to determine whether practitioners are competent to do a procedure that they have never done before or a procedure that they have not done for a long time. Options for assessing competency typically include letters of reference and evidence of completion of a quality program, with proctoring being used on occasion.

Dr. Wise wondered whether simulation could be used to help determine if someone is ready to do a procedure independently. JCAHO is currently writing standards to improve credentialing and these standards are likely to suggest the use of simulation when appropriate. Although simulation is unlikely to be required, it will be suggested as an option that should be considered to determine competency.

The Medical Simulation Community Perspective

Breakout Groups and Report Out: Seeking Consensus Solutions

Moderator: Bob Waters, JD

Participants were randomly assigned to a breakout group that was to address one of the following questions:

1. How do we build a simulation community, break down barriers, and integrate existing and future technologies?
2. What are the major research initiatives or research areas that we need to focus on as a community?
3. How do we build a national agenda that benefits patients?
4. How do we “legitimize” simulation - get buy-in from regulatory agencies, organized medicine, patient safety advocates, etc.?

How Do We Build a Simulation Community, Break Down Barriers, and Integrate Existing and Future Technologies?

Steve Dawson, MD, Facilitator, Group 1

After considering several options, Breakout Group 1 proposed a federation model parallel to the Learning Federation. This federation should have several different roles, including:

- Lobbying for funding;
- Gathering representatives from different interest groups;
- Prioritizing the research agenda and setting research goals;
- Identifying targets for 10 years from now;
- Serving as a communication vehicle - bringing the community together through the Web, journals, and meetings with the general public and members of Congress;
- Convening a multidisciplinary group;
- Demonstrating the efficacy of simulation to payers, insurers, and boards;
- Transitioning from traditional medical training to competency-based training; and
- Defining and building consensus for industry and government.

One organization that could start this is the Society for Medical Simulation (SMS), which shares some of these goals.

As a six-month goal, Group 1 suggested bringing many participants in the current meeting to the SMS meeting in January. In one year, the group proposed defining the national agenda using a small government grant.

Audience Discussion

Several participants said that a Learning Federation model for simulation would work, and that they would participate in a work group on this issue. Mr. Waters suggested that to draw Congress's attention, the group needs to present a concrete national agenda that will not just benefit a single congressional district, company, or institution.

One participant pointed out that patient advocacy groups, especially those with patient safety interests, might be very supportive of the federation model and should be included. Dr. Alverson suggested that the working group include representatives from industry. A breakout group member explained that the federation would be composed of the simulation community, the medical specialties societies industry, patient advocate groups, education groups, and the insurance industry.

Dr. Alverson stated that the federation model presents opportunities for international collaboration. Although this meeting focused on a national agenda, a great deal can be learned by continuing to work with international partners, because many of the issues involved are global.

Since Congress is interested in national security, showing them how simulation is used in places, such as Israel, would be very effective and address immediate needs.

What Are the Major Research Initiatives or Research Areas That We Need to Focus on as a Community?

Rick Satava, MD, Facilitator, Group 2

Dr. Satava reported that Group 2 suggested beginning with multi-scale modeling, which is supported by National Science Foundation and the National Institute of Biomedical Imaging and Biomedical Engineering. The group suggested prioritizing the user group on which to focus, e.g., students, residents, professionals seeking to maintain certification, and the research areas to look at, e.g., team training, or individual task training. Perhaps a taxonomy should be developed of what is needed in the field.



They further suggested a needs assessment complemented by a meta-analysis of resources available, including simulators and curricula. It has been two years since such reports were published and they were incomplete. The results of this assessment should be published in a pamphlet.

By six months, the following should occur:

- Initiate a multi-institution revalidation study;
- Develop a concept video or vision statement that could be used as an educational tool;
- Develop the medical equivalent of the National Transportation Safety Board to investigate and analyze errors without punitive action;
- Establish a committee or meeting to develop consensus for standards of interoperability;
- Coordinate agencies so that they work jointly to fund a solution; and
- Request the National Academy of Sciences or IOM to conduct a national study like the *To Err is Human* report.

By 12 months, Group 2 suggested that the following could be developed:

- A cost-benefit analysis of the value of simulation; and
- A national center for procedural simulation and assessment, whose primary mission is education and training.

Audience Discussion

The military has conducted a fair amount of research on simulation, e.g., what level of simulation is needed. This can lead to a road map of what needs to be done in simulation.

The specific problems that need to be solved by simulation must be identified. More dialogue is needed among engineers, developers, and medical users.

Mr. Waters suggested that Congress could be expected initially to resist any new spending initiatives. Congress should be engaged at the “big picture” level by the medical simulation community -- giving Congress a vision and some examples of the value of medical simulation. Some committee members may eventually want additional detail, but, first, their buy-in must be sought on the basic points.

How Do We Build a National Agenda That Benefits Patients?

COL Mark Bowyer, MD, Facilitator, Group 3

Col. Bowyer, MD suggested that to make the national agenda meaningful to the average person, it is important to point out the benefits to current and potential patients of receiving treatment from someone whose skills can be trusted. The patient will benefit from simulation through enhanced safety and decreased errors and cost. Simulation will ensure that providers are competent. A higher level of uniform standards can be set to which all physicians must adhere.

The leverage for creating excitement for a national simulation agenda can be found in the responses to the events of September 11, 2001. A national agenda has been created to train people to take care of others in the event of an emergency. Simulation also addresses the problems created by risky procedures, such as the declining numbers of obstetricians who have stopped practicing in large part due to high malpractice insurance rates. By improving training and reducing errors and adverse events, the cost of malpractice insurance will decrease.

A new entity may be needed to manage this new initiative. Regional centers should be developed, because individual institutions cannot support the high cost of simulation.

The short-term goal is to build on the enthusiasm of this meeting by establishing a working group that will develop a road map. This group should articulate the need and develop a vision statement that links simulation with safety, error reduction, and cost reduction.

Audience Discussion

Dr. Alverson suggested that in the short term, a working group should be formed to help define the future road map.

Under the national agenda, groups other than the government should be included. Certifying boards should be encouraged to incorporate this technology into their certification processes. Once physicians are required to be certified using simulation, this will move the agenda forward. Perhaps the government can be encouraged to tell certifying boards that they are not doing enough and simulation can help.

To build on enthusiasm, it should be pointed out that simulation can involve situations that physicians might not encounter during their training, but may be encountered in trauma care.

The military's medical training program should be used to showcase the value of simulation. The program involves many people, but is run by a single organization. This is an appropriate population from which to learn. This might be an early place on which to focus.

Simulators might provide a unique solution to the problem of providing training in systems-based practice.

How Do We “Legitimize” Simulation - Get Buy-in From Regulatory Agencies, Organized Medicine, Patient Safety Advocates, etc.?

Gerald Healy, MD, Facilitator, Group 4

Dr. Healy noted that in some cases, a national event could be used to draw Congress’s attention to a cause. The conflicts in Afghanistan and Iraq have shown the military medical corps and the Department of Defense that critical deficiencies exist. Some of these deficiencies can teach important lessons about medical care for civilians. The lessons learned from these situations should be parlayed into the agenda for simulation.



The nursing shortage affects every congressional district. Simulation could help train nurses more quickly.

Group 4 concluded that patient safety should be the cornerstone of the national simulation agenda. The reason to develop simulation programs is to improve the quality of care for patients. Training facilities are needed that use simulators to address actual situations. Congress should be asked to develop regional patient safety training centers with simulation programs to address these critical needs.

Many hospitals have invited congressional aides to see their hands-on training. When lay people see medical simulators, they recognize its value. Congress and aides need to become invested in existing simulation centers.

Audience Discussion

Mr. Waters stressed the importance of communicating with Members of Congress and their staffs. Although staff members might not understand the nuances, they will understand the basic concept. Policymakers are most likely to visit projects in their own states, so supporters of simulators should begin with their own Representatives.

One focus should be on the use of medical simulation to address the reduced experience created by the 80-hour workweek for medical residents.

The WebMD is interested in simulation and their website receives 22 million hits every day from individuals who are interested in medicine. Posting the simulation message on the similar sites might encourage constituents to tell Congress about the need for medical simulation.

The Military Perspective

Funding for Medical Simulation: The Department of Defense Perspective

GEN Lester Martinez-Lopez and Gerald Moses, PhD

In his videotaped remarks, General Martinez-Lopez, Commanding General of the US Army Medical Research and Materiel Command stated that simulation makes it possible to provide better training and care for patients. The Department of Defense (DOD) and industry have been using simulation for many years and are now moving to a new frontier of simulation for medical care. The military has over 70 medical simulation programs that use haptic and information technology to provide medical training. General Martinez-Lopez looks forward to the day when simulation can be leveraged to its fullest extent to reduce medical errors, improve medical skills, and, above all, improve medical care for patients.



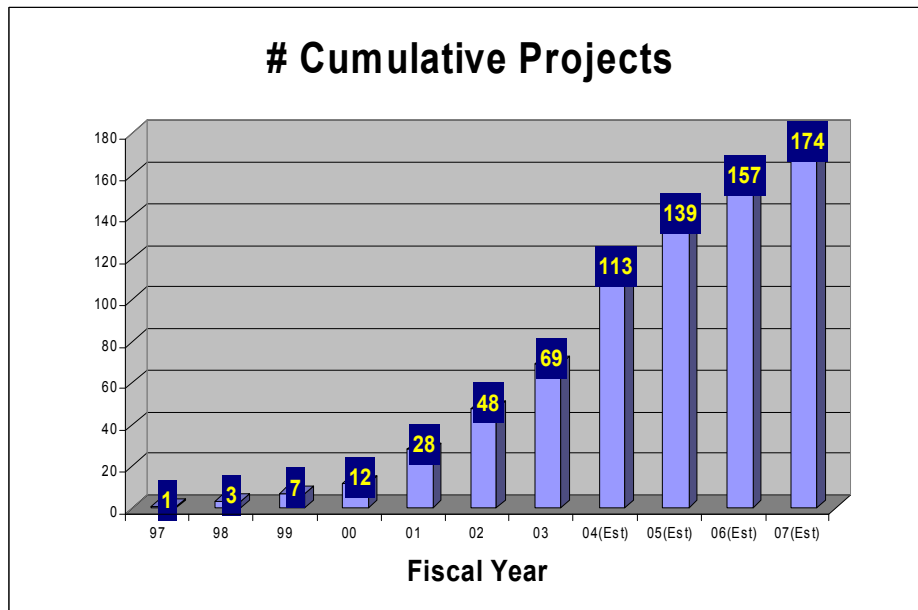
Dr. Gerry Moses emphasized Dr. Martinez-Lopez's support for medical simulation. At TATRC, the funding for research has increased over the last few years. However, the pace of the increase has not been fast enough. Dr. Moses stated that several sources of funding for medical simulation exist, including congressional special interest dollars and the federal Small Business Innovative Research program.

TATRC Medical Modeling & Simulation Portfolio

| in Thousands (000) | FY 1997 | FY 1998 | FY 1999 | FY 2000 | FY 2001 | FY 2002 | FY 2003 | FY 2004 | Total To Date |
|--------------------------------|---------|---------|---------|---------|---------|---------|----------|----------|---------------|
| # Projects Actual or Projected | 1 | 2 | 4 | 5 | 16 | 20 | 21 | 44 | 113 |
| Dollars Invested | \$910 | \$2,477 | \$2,013 | \$6,195 | \$7,713 | \$4,950 | \$10,588 | \$12,555 | \$47,401 |

| in Thousands (000) | FY 2005 | FY 2006 | FY 2007 | Total Projected | Total Overall |
|--------------------------------|----------|---------|---------|-----------------|---------------|
| # Projects Actual or Projected | 26 | 18 | 17 | 61 | 174 |
| Dollars Invested | \$13,470 | \$7,470 | \$6,470 | \$27,410 | \$74,811 |

TATRC Medical Modeling & Simulation Cumulative Projects by Fiscal Year



The Regulatory Perspective

Simulation and New Device Approval: The Food & Drug Administration's Perspective

Peter Carstensen

Sandy Weininger, PhD

Peter Carstensen reported that the Food and Drug Administration's (FDA) device program requires manufacturers to validate that their device meets the needs of the user. This presents a challenge to manufacturers, who might benefit from simulators that allow them to test their devices in realistic environments.

Sandy Weininger pointed out that the uses of simulation range from assessing the performance of a device to evaluating its proficiency. Current simulators do not use cutting-edge technology. If the simulation community wants this to change, they must develop a national agenda.

One participant asked about validating simulators, as opposed to using simulators to validate devices. Mr. Carstensen replied that this requires a comparative study. Until simulators are validated, it will be difficult for the FDA to encourage manufacturers to take on the expense of using them. Mr. Carstensen hoped that validation studies would be conducted soon.

Dr. Weininger suggested that it would be unlikely that the FDA would require that manufacturers use specific types of simulators. The FDA requires good science and engineering to be applied and the best tools will win.

Dr. Ziv suggested that simulators will be needed to train providers to use the new carotid stenting device. In the aviation industry, when a new aircraft is developed, the industry also develops a simulation device. When the carotid stenting device is approved, the accompanying simulation should become standard. Dr. Weininger agreed that many recognized standards incorporate simulators.

A participant wondered whether a simulator might be considered a medical device by the FDA under any circumstance, such as when a provider uses data from an actual patient in a simulator to practice a procedure before treating the patient. Mr. Carstensen said that whether this use makes the simulator a medical device depends on the legal definition of medical device, but the use described by the participant would probably not fall under the definition. Dr. Weininger explained that the FDA usually does not regulate simulators, since they do not treat or mitigate, and, therefore, are not medical devices. However, to use devices safely and effectively, providers must be trained. If a simulator is part of a treatment protocol, it is possible that it could be considered an accessory and, hence, regulated as part of the parent device.

Society for Medical Simulation Update

Lisa Sinz, MD

Lisa Sinz, MD reported that the Society for Medical Simulation (SMS) was created to serve health care educators and researchers, and focuses on education, assessment, research, and patient safety. The society is interested in all types of simulators and simulation, including computer-based programs, surgical and procedural trainers, and human patient simulators.



SMS began in 1995 with a meeting in Rochester, Minnesota of people interested in simulation. This meeting evolved over the last nine years to the point where 350 individuals attended the last annual meeting. The society now includes all types of providers, including paramedics, nurses, dentists, etc., in a range of medical specialties from around the world. Simulation represents a paradigm shift in health care, and SMS is interested in improvements in simulation technology and educational methods to promote better patient care.

Closing

Robert J. Waters, JD

Steve Dawson, MD

COL Mark Bowyer, MD

Jackie Eder-Van Hook, MS

Gerald Moses, PhD

Mr. Waters characterized the meeting as “historic and invaluable.” The meeting will serve as the beginning of a strong effort to develop a national agenda. The meeting organizers will ask participants to help implement some of the recommendations made at the meeting. The activities must be broken down into smaller tasks.

Mr. Waters urged participants to invite Members of Congress at every possible opportunity to visit their institutions. If decisionmakers become involved in this issue, their imaginations and enthusiasm for medical simulation will be ignited.

Dr. Dawson and Col. Bowyer thanked the members of the planning committee that made the meeting possible and for TATRC’s sponsorship. A real opportunity exists to move the simulation community forward, and the way to do that is through collaboration. Col. Bowyer encouraged all participants to continue their collaborations to find similar interests.

On behalf of the TATRC and the Center for Telemedicine Law, Dr. Moses and Ms. Eder-Van Hook, respectively, thanked the participants and speakers for attending and working to build the medical simulation community. Through collaboration across specialties and disciplines, the community can improve patient care by improving training and reducing medical errors.

AIMS PLANNING COMMITTEE

The work of the Advanced Initiatives in Medical Simulation (AIMS) was completed with the hard work of AIMS Planning Committee:

- **COL Mark Bowyer, MD, FACS**, National Capitol Area Medical Simulation Center, Uniformed Services University; *Co-Chair*
- **Steve Dawson, MD**, Massachusetts General Hospital; Partners Healthcare; *Co-Chair*
- **Jackie Eder-Van Hook, MS**, Executive Director, Center for Telemedicine Law
- **Anthony Gallagher, PhD**, Emory University School of Medicine
- **Gerald Healy, MD**, Children’s Hospital of Boston; American College of Surgeons
- **Thomas Krummel, MD**, Stanford University Medical Center
- **Gerald R. Moses, PhD**, TATRC, US Army Medical Research and Materiel Command
- **Robert J. Waters, JD**, General Counsel, Center for Telemedicine Law; Partner, Gardner, Carton, & Douglas LLP

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Telemedicine and Advanced Technology Research Center, US Army Medical Research and Materiel Command. <http://www.tatrc.org/>.



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AIMS Sponsors & Co-Chairs

Co-Chair Steve Dawson,
Bob Waters, Gerry Moses,
Co-Chair COL Mark Bowyer,
and Jackie Eder-Van Hook

¹ *To Err Is Human: Building a Safer Health System*, Institute of Medicine. National Academy of Sciences. (1999).

² Ibid.

³ Ibid. pp. 156.

⁴ Ibid. pp. 169.

⁵ Ibid. pp. 176.

⁶ Ibid. pp. 178-9.

⁷ Ibid. pp. 176.

⁸ Ziv, A, Wolpe, P, Small, SD, Glick, S., *Simulation-Based Medical Education: An Ethical Imperative*. Academic Medicine. 78, 783-788 (2003).

⁹ This list was compiled from a variety of sources.