Simulation in Health Care: A Model for Improving Patient Safety and Ensuring Quality

Building a National Agenda

for Simulation-Based Medical Education

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

November 2005
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Simulation in Health Care: A Model for Improving Patient Safety and Ensuring Quality

Building a National Agenda for Medical Simulation

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Meeting summary of the Second Annual Advanced Initiatives in Medical Simulation held May 2005.
Building a National Agenda for Simulation-based Medical Education

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Overview

In 2004, the Telemedicine and Advanced Technology Research Center (TATRC) in the U.S. Army Medical Research and Materiel Command undertook efforts to raise awareness about the value of simulation-based medical training to improve health care quality and reduce medical errors. To that end, TATRC provided partial funding to convene a national agenda setting conference. This meeting brought together key leaders in medicine, government, and regulatory officials with medical simulation and patient safety experts. In 2005, TATRC continued its support of this effort and convened a second conference, the title of which was “Simulation in Health Care: A Model for Improving Patient Safety and Ensuring Quality.” This report provides a brief overview of medical simulation and a summary of that meeting.

Medical Simulation Defined

Simulation is a training and feedback technique in which learners practice tasks and processes under realistic settings and circumstances using tools and models, such as virtual reality, and utilizing feedback from observers, such as professors, peers, actor-patients, and video cameras.

Since the advent of advanced computer technology in the 1970s, simulation training in aviation has allowed pilots to experience and practice high prevalence, high-risk, or frequently occurring situations without endangering the life of the pilot, instructor, or those on the ground. In fact, simulators have become so realistic and effective that the Federal Aviation Administration certifies pilots to receive a type rating to fly new aircraft based solely on the results of the simulator without the pilot flying the actual aircraft. Like aviation, medical simulation allows students and experienced clinicians to learn or improve a skill or demonstrate competency without harming the patient.

Types of Simulators

Simulators allow students to make decisions in real time, see the effects of those decisions, consider their actions, receive feedback about those actions and decisions, understand the decisions they made, benefit from those decisions, and start all over again without harming the patient.

In general, simulators fall into the following categories: (1) mannequin-based, high fidelity, or realistic patient simulators, (2) partial or complex task trainers, (3) web- or screen-based computer simulators, (4) standardized patients, (5) crisis resource management or multi-disciplinary team training, and (6) virtual reality.
• **Mannequin-based, High Fidelity, or Realistic Patient Simulators.** In medicine, students and experienced practitioners alike, use sophisticated mannequins to practice and hone their clinical skills. Simulation provides health care professionals with computer-based patients that breathe, respond to drugs, talk, and drive all the clinical monitors in the operating room, e.g., blood pressure and pulse rate.

• **Partial or Complex Task Trainers.** Task trainers provide a simulated subset of functionality, e.g., chest tube insertion, ultrasound, and bronchoscopy, or training for rare life-threatening events, such as anaphylaxis, hyperthermia, or complex events, such as apnea testing for the assessment of brain death. Both novices and experienced practitioners can benefit from training using partial task trainers.

• **Web- or Screen-Based Computer Simulators.** Computer or web-based software programs provide students with clinical knowledge and critical decision-making skills, e.g., taking a history, examining a virtual patient, ordering laboratory tests, and generating clinical hypotheses. This type of training can be made available on demand, which allows students and clinicians to enhance their skills at times and places of their choosing in the most cost-effective manner possible.

• **Standardized Patients.** Simulated or standardized patients allow students to interact with “actors” specifically trained to present their medical histories, simulate physical symptoms, and portray emotions as specified by each case. Students perform focused physical examinations based on the patient case and, which include: listening to heart and lungs with a stethoscope; pressing on abdomen, neck, face, and limbs to assess tenderness; using a scope to look in ears, eyes, nose, and throat; taking pulse and blood pressure; checking muscle strength, reflexes, range of motion, and gait. Standardized patients provide students with immediate, one-to-one feedback on their performances, e.g., interview effectiveness and bedside manner.¹

• **Crisis Resource Management or Multi-disciplinary Team Training.** Crisis resource management or multi-disciplinary team training allows groups to learn to work together and addresses “human factors”, that is, non-technical issues, such as communication, leadership, planning, workload distribution, status, and culture.

• **Virtual Reality.** Virtual reality is a simulated, immersive environment constructed by a set of computer-generated stimuli in which an individual perceives that he or she has entered another “world.” A virtual reality environment uses sensory that may include visual, sound, motion, and smell, among others. Virtual reality is being used both for training and in treatment purposes, as in the case of overcoming phobias.

**Table 1. Simulation Tools and Approaches Used in Simulation-Based Medical Education**
<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Tech Simulators</td>
<td>Models or mannequins used to practice simple physical maneuvers or procedures.</td>
</tr>
<tr>
<td>Standardized Patients</td>
<td>Actors trained to role-play patients for training and assessment of history taking, physicals, and communication skills.</td>
</tr>
<tr>
<td>Web- or Screen-Based Computer Simulators</td>
<td>Programs to train and assess clinical knowledge and decision making, e.g., perioperative critical incident management, problem-based learning, physical diagnosis in cardiology, and acute cardiac life support.</td>
</tr>
<tr>
<td>Complex or Partial Task Trainers</td>
<td>High-fidelity visual, audio, touch cues, and actual tools integrated with computers. Virtual reality devices and simulators replicate a clinical setting, e.g., ultrasound, bronchoscopy, cardiology, laparoscopic surgery, arthroscopy, sigmoidoscopy, dentistry.</td>
</tr>
<tr>
<td>Mannequin-Based or Realistic Patient Simulators</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Table 2. Comparing Traditional & Simulated Teaching Methods: Bronchoscopy Example**

Bronchoscopy is a diagnostic procedure in which a tube with a tiny camera on the end is inserted through the nose or mouth into the lungs. The procedure provides a view of the airways of the lung and allows doctors to collect lung secretions or tissue specimens.

**Traditional Training Method:** students practice inserting a bronchoscope on live patients or human cadavers.

Pros: Airway anatomy in human cadavers is accurate and ventilators can mimic breathing. 
Cons: Human cadavers are expensive, difficult to procure, experience tissue degradation, do not cough, secrete fluids, or provide variable pathology; ethical issues; no feedback. 

**Simulated Training Method:** Using a realistic simulated bronchoscope, video monitor, and haptic interface, it allows students to insert a bronchoscope until a specified level of proficiency has been achieved.

Pros: Simulated bronchoscopy provides realistic anatomy and movements, e.g., vocal cord spasm, cardiac pulsations, cough, and variable pathology. System evaluates trainees on their performance and offers suggestions for improvements. Studies indicate better clinical outcomes for both novices and experts. 
Cons: The availability of simulators for clinical education and certification.
Benefits of Medical Simulation

Traditional training for health care providers follows a methodology of observation and repetition allowing the trainee to learn from those cases and situations presented within the short period of time a clinician attends school.

In addition to clinical skill development, simulation or training-based medical training provides realistic training in communication, leadership and team interaction and observation providing the student with the opportunity to repeat the materials until the student has mastered the information.

The simulation-based medical training benefits all of us, as follows:

- Patients benefit from improved health outcomes and reduced errors and deaths.
- Patients with rare or unusual conditions benefit from better-trained providers.
- Patients and clinicians benefit by increasing the number of procedures and type of complex, risky procedures addressed and experienced during training.
- Consumers, patients, and families benefit from reduced health care costs and enhanced quality.
- Taxpayers benefit from tax dollars spent on equipment that can be tailored to different skill levels.
- Businesses benefit from the creation of high-tech jobs.
- Businesses benefit from greater worker productivity due to better health care.
- Physicians, nurses, and health professionals benefit from having better skills.
- Society, health care systems, and physicians benefit from 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 that is tailored to their pace, learning comprehension, 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.

Where Is Simulation Being Used?

Simulation-based medical training provides better-trained health care providers, reduces medical errors, saves money, and improves the quality of patient care overall – all good reasons for using medical simulation.

While no definitive study has been undertaken to catalogue where simulation is occurring, the following organizations are or have engaged in simulation. Institutions interested in adding or removing their names to the list should contact info@medsim.org. This list does not include companies engaged in simulation manufacturing, research, development, or activities occurring outside the United States. (The next iteration of this list attempts to include such information.)
<table>
<thead>
<tr>
<th>State, City, Organization</th>
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<td>Alabama, Anniston, Center for Domestic Preparedness</td>
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<td>Alabama, Birmingham, University of Alabama Birmingham</td>
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<td>California, Long Beach, Long Beach Memorial Center</td>
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<td>Colorado, Denver, Air Life Denver</td>
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<td>Illinois, Chicago, Rush University Medical Center</td>
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The Future of Medical Simulation

The future of medical simulation is bright, as evidenced by the growing level of interest in federal and state governments, accrediting organizations, the medical and nursing communities, within public policy circles, and the health care system in general.

Federal Government

In 2004, the Food and Drug Administration’s (FDA) decision to require virtual reality simulation as a component of a training package provided explicit approval of the training protocols required for FDA approval of the carotid stenting and implicit validation for the use of simulation training. The FDA’s decision to require the use of simulation before a physician can perform a carotid stenting procedure will result in “the largest and most important investigation of the role of virtual reality for procedural skills training ever conducted.” The subsequent decision by Medicare to pay for carotid stenting performed by appropriately trained personnel...
for a defined group of high-risk patients marked another paradigm shift. With this recognition of the value of simulated training by regulators and payers, carotid stenting is ushering in widespread use of virtual reality simulation as a required training tool. Mandated training using simulation now exists as a reality. Organizations representing the majority of physicians who will perform carotid stenting, which include the Society of Cardiovascular Angiography and Interventions (SCAI), the Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS), have all expressed their support for the use simulation and jointly issued a competency statement.  

**Oregon Simulation Alliance**

In 2004, Oregon Governor Ted Kulongoski’s Healthcare Workforce Initiative formed the Oregon Simulation Alliance. The Alliance’s initial members included Oregon Center for Nursing, Oregon Consortium for Nursing Education, Community College Healthcare Action Plan, Oregon Association of Hospitals and Health Systems, Oregon Health and Science University, and Oregon Health Careers Center.  

Using seed money from Oregon Workforce Investment Board, the Alliance hopes to attract public and private resources. In FY 2003-2004, the Oregon Workforce Investment Board committed $600,000 to the Alliance to build a statewide network of health care coalitions that will use simulation as a training tool, and expedite the training of health care workers in multiple disciplines and occupations.

**Oregon Simulation Alliance - 2005 Goals**

**Goal 1** Provide access to equipment required for simulation programs to meet education and training needs of the state.

**Goal 2** Create a system for sharing information related to simulation, including the best practices, training, scenario development, and evaluation.

**Goal 3** Establish Oregon as a leader in simulation.

**Goal 4** Develop and promote a multi-sector community based simulation coalitions around the state.

**Goal 5** Be a clearinghouse of information for simulation funding opportunities and provide a system for coordinating funding requests to avoid duplication of efforts in Oregon.

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**Joint Clinical Competence Statement on the Use of Simulation in Carotid Training**

By SCAI/SVMB/SVS

In an effort to assist physicians with differing backgrounds and skills to reach a common benchmark of proficiency, metric-based simulation should be incorporated into training. This will provide skills acquisition in an objective manner, based on real-world situational experience, while removing specialty-based biases from the training process. Prior studies have demonstrated that using this training modality for surgical procedures has been beneficial.
**Patient Safety**

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. Health experts estimate that “at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year from medical errors (some health policy experts estimate the actual number is much higher). Deaths in hospitals due to preventable adverse events exceed the number attributable to the eighth-leading cause of death. Deaths due to preventable adverse events exceed deaths attributable to motor vehicle accidents, breast cancer, or AIDS.”

As patient safety expert and AIMS keynote speaker, Jeffrey Cooper, Ph.D., points out, “Numerous calls for action and almost countless programs for improving patient safety, from both the top down and the bottom up, are now found in all manners of health care organizations. Tools and approaches are presented by many organizations, including the Agency for Healthcare Research and Quality (AHRQ), JCAHO, National Patient Safety Foundation, the Institute for Healthcare Improvement, and many state medical and public health organizations.”

Cooper identifies the following key elements as essential for creating a patient safety environment: routine training for emergencies, training for teamwork, establishing an environment for discussing error without punishment, testing new procedures, evaluating competence, usability testing of devices, investigating human performance, and providing skills training for novices. While not an exhaustive list, it is easy to see how simulation can help to foster a culture of safety in medicine just as it has in other domains, such as nuclear energy, aviation, chemical manufacturing, and military operations.

As health care consumers demand better outcomes and more accountability in medicine, simulation will benefit. Health systems, insurers, and certifying boards will embrace simulation as an efficient and effective way to provide training and certification for health care professionals.
Media and Scholarly Articles

A bibliographic search has shown that since 1996, 1,662 articles referencing simulation were published in medical journals, and in the past two years alone (2003-2004), 540 journal articles were published, indicating an increase over the historical average of approximately 30%.

<table>
<thead>
<tr>
<th>Simulation Citations</th>
<th>Medical Journals</th>
<th>Newspapers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citations 1996 to 2004</td>
<td>1,662</td>
<td>926</td>
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<td>Citations 2000 to 2004</td>
<td>1,142</td>
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<td>Citations 2003 to 2004</td>
<td>540</td>
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While the number of citations for newspaper articles generally was flat, Jerome Groopman, M.D. published a noteworthy article in the *New Yorker* Magazine (May 2005) entitled, “A Model Patient, How Simulators Are Changing the Way Doctors Are Trained.”10 The article – totaling approximately 5,500 words – does an admirable job of outlining the history and current state of medical simulation.

Certifying Boards

A number of medical boards are currently discussing ways in which simulation can demonstrate performance for examination purposes.

For example, ABVM, which offers certification in vascular and endovascular medicine, expects to include simulation in its board exam in 2006. According to a member of ABVM’s Board of Directors, Michael R. Jaff, D.O., “We feel quite strongly that if metrics can be developed to actually provide some quantitative feedback on a simulator that would be a critical component to the endovascular exam. It’s one thing to ask people questions and put them in scenarios, but another to actually make them perform a procedure and have them scored on that procedure. For example, how long does it take you to realize that there is a perforation from the guidewire to the kidney? Did you use the wrong stent? Have you overdilated the lesion? Did you recognize the symptoms of a complication?”11

Historically, the targets for simulation-based medical training have been combat medics and medical and nursing students. Other health care workers, however, such as emergency medical personnel and allied health professionals, now are utilizing simulation in increasing numbers for students and experienced clinicians alike. These numbers will continue to grow as more certifying boards use simulation as a part of their certification process.

Risk Management

The pace of litigation and the need to manage risk is causing health care institutions to find innovative solutions to reduce the associated financial burden. These institutions and their medical liability carriers are using simulation as a means to respond to these challenges by providing incentives or discounts on premiums.

According to the Risk Management Foundation’s (RMF) website,12 the Center for Medical Simulation and RMF of the Harvard Medical Institutions jointly offer a Labor and Delivery
Crisis Resource Management (CRM) course specifically for obstetrical nurses, obstetricians, and anesthesiologists. This Labor and Delivery CRM course qualifies as one of the required elements that RMF’s Controlled Risk Insurance Company (CRICO)-insured obstetricians must complete to take advantage of a 10% per year discount of annual malpractice premiums for three years. Qualification requirements of CRICO insurance premiums rate reductions are available at http://www.rmf.harvard.edu/obincentive.

“We were particularly interested in the simulator because the simulation scenarios are based on our own malpractice claims. We’ve compiled the medical incidents and then they’ve been turned into simulation scenarios. So, it gives the providers a very realistic setting to practice in. We became interested in this based on our own claims review in the obstetrical area. As you know, awards and judgments and settlements in obstetrics can be in multiple millions of dollars, so it’s a very serious loss area for us. We also noted through the claims review that many times the vulnerabilities in the claims resulted from either poor team coordination or poor monitoring and reaction times by providers when patient vitals showed signs of trouble. So, the simulator really helps to develop teamwork and refine the reaction when the monitoring shows there’s a need to intervene.”

Jack McCarthy, President, Risk Management Foundation

It is plausible that at some point, perhaps in the not-too-distant future, insurers may even consider disincentives, such as refusals to provide liability coverage to those who did not adopt or utilize simulation training.

Summary

Communities of individuals and organizations interested in simulation have coalesced over the past several years, due at least in part to TATRC’s support of the Advanced Initiatives in Medical Simulation efforts. The Society for Medical Simulation, established in 2004, recently launched the first scholarly periodical devoted to medical simulation, The Journal of the Society for Medical Simulation. In 2005, The U.S. Congress’ Modeling and Simulation Caucus added medical simulation to its portfolio. In that same year, the Federation of American Scientists’ brought together educational researchers, medical practitioners, and video game developers for a workshop to discuss trends in simulation–based education and training programs in medicine and how best to make these learning systems easier to build. Clearly, there is a wide range of interested parties and simulation-related activities.

Ultimately, it is likely that governmental regulators and non-governmental accrediting agencies will drive simulation training first though voluntary and later through requirements. The simulation community, therefore, should endeavor to educate key decision makers in government and non-government entities alike.

Simulation has been on the path toward acceptance for the past 20 years; its future has never been brighter.
MEETING SUMMARY

Simulation in Health Care:
A Model for Improving Patient Safety and Ensuring Quality

National Naval Medical Center
Bethesda, Maryland
May 11, 2005

SUMMARY

On May 11, 2005, the Advanced Initiatives in Medical Simulation (AIMS) met to discuss and strategize on how to move the simulation field forward. One goal of the AIMS effort is to create a unified voice from among the range of interested parties including, academia, industry, regulatory agencies, organized medicine, end users, military, societies, the insurance industry, allied health, and federal and state governments. The AIMS goals also include defining the message; fostering champions; encouraging discussion; and securing support for medical simulation.

The ultimate goal of simulation is to improve patient safety and improve the quality of care. Patient safety involves the basic premise that no patient should be injured as a result of health care intervention. A basic principle is not to “practice” (learn how to do) risky or less painful, with experience procedures on patients without developing a minimum level of competency first.

Simulation can improve and provide:

- Safety;
- Efficiency in high-cost clinical settings;
- Optimal conditions for learning (learner-centered at the pace of individual);
- Objective and immediate feedback;
- Integration of multiple skills;
- Utility as an assessment tool; and
- Test-bed for research.

Simulation is an effective, efficient way to learn skills and teamwork behaviors. It is a way to provide consistency in training; objectivity in feedback and assessment; transparent, credible credentialing; a real-world evaluation of technologies and techniques under stressful conditions; and experience delivering services for the entire health care organization.

A number of elements, which include: the fact that training on patients is becoming too expensive and socially and politically untenable, and the potential impact of the 80-hour workweek limit for residents, are likely to promote the use of simulation in health care and
provide the economic incentive for using simulation in education. The economic model to fund simulation, however, remains murky.

The FDA approval of the carotid stenting procedure last year included a requirement that physicians be trained using simulation, and marked a watershed for medical simulation as a training methodology. The subsequent decision by Medicare earlier this year to pay for carotid stenting performed by appropriately trained personnel for a defined group of high-risk patients marked another paradigm shift. With this recognition of the value of simulation training by both regulators and payers, carotid stenting is ushering in widespread use of virtual reality simulation as a required training tool. Mandated training using simulation now exists as a reality.

Simulation also plays an important role in the broader medical field beyond carotid stenting, including nursing, EMTs, paramedical personnel, mass casualty preparedness, and military training. Professional societies in practices such as surgery, radiology, cardiology, and anesthesiology are becoming increasingly focused on incorporating simulation into curricula, residency training, and even testing.

Unfortunately, simulation faces obstacles from the medical community, such as acceptance from the medical industry – the lack of research and development resources, and inadequate funding from federal agencies. These obstacles require solutions at the national level, with input from sources such as AIMS, the Association of American Medical Colleges, and professional boards. For the field of simulation to progress, it is crucial that key national decision-makers take the lead. In addition, the simulation field must overcome the hurdles it faces with respect to validation interoperability.

To address these impediments and generate possible solutions, organizations, such as AIMS, have a unique and important role in educating key decision makers about the benefits of medical simulation.

As some in the health care industry have already come to understand, simulation will fundamentally change the practice of medicine, by providing for the first time genuine “practice.” We are moving toward a tipping point in which simulation becomes a standard form of teaching and evaluation in health care.

**WELCOME AND INTRODUCTION**

Jackie Eder-Van Hook, M.S., Center for Telemedicine Law  
Capt. Joseph Lopreiato, M.D., National Naval Medical Center  
Col. Mark Bowyer, M.D., Uniformed Services University of the Health Sciences

Jackie Eder-Van Hook, Executive Director of Center for Telemedicine Law, convened the meeting and introduced Capt. Joseph Lopreiato, M.D., Medical Director of the National Capital Area Medical Simulation Center of the Uniformed Services University of the Health Sciences (USUHS). Dr. Lopreiato welcomed participants on behalf of Rear Adm. Adam Robinson, Commander, National Naval Medical Center (NNMC) who was not able to attend the meeting.
Dr. Lopreiato presented a brief overview of the NNMC facility and its history. Opened in 1942 as the flagship of Navy medicine, the NNMC has become known as the presidents’ hospital. President Franklin Roosevelt, who served as Undersecretary of the Navy during World War I, selected the site, which at the time was pig farm on rural Wisconsin Avenue. Roosevelt is credited with sketching Center’s tower. Since the NNMC’s completion, several presidents, members of Congress and Supreme Court justices have made regular visits to the facility for medical care.

Building 10, the site of the AIMS meeting, first opened in 1995 and is dedicated to Laurel Clark, one of the astronauts killed in the 2003 Columbia shuttle explosion. Dr. Clark was a pediatric resident at the hospital and went on to become a flight surgeon and astronaut. Building 10 serves as the hospital for USUHS, which is the only federal medical school in the nation. The National Capital Area Medical Simulation Center, part of USUHS, is one of the few sites to contain all its simulation technologies in one room.

Colonel Mark Bowyer, M.D., Surgical Director of the National Capital Area Medical Simulation Center. Dr. Bowyer stated that the theme for this second annual conference is the creation of a unified voice with the goal of using medical simulation to improve patient safety and ensure quality care. This year’s meeting goals are to:

- Establish and build the simulation community;
- Define the message of medical simulation;
- Foster champions in the field;
- Build momentum for simulation; and
- Determine the resources needed for a national agenda.

Dr. Bowyer reiterated that the goal of today’s meeting is to move the simulation community forward with a unified voice. The ultimate goal for simulation is to improve patient safety and the quality of care for patients. A national agenda is needed to achieve this. Dr. Bowyer acknowledged that many different perspectives are represented at this meeting and suggested that in order to move the field of simulation forward, each person must be committed to working together as a team for this common purpose.

**KEYNOTE**

**Medical Simulation in the Context of Patient Safety and Quality**

Jeff Cooper, Ph.D., National Patient Safety Foundation

Dr. Jeff Cooper, a professor of bioengineering and anesthesiology at Harvard University and a pioneer in medical simulation, opened his presentation by expressing his support for simulation.

For him the reason is simple: simulation benefits patient safety. He asked participants to consider their motivations for attending the meeting and the fundamental reason they promote simulation. He suggested that there are three general categories of simulation proponents:
• “Techies,” who thrive on their interest in the technology of simulation and are needed for the business of simulation to move forward.
• Medical educators, who hope to improve the “broken system” of medical education by using simulation as a tool to improve health care education; and
• Strong supporters of patient safety who believe simulation can serve as a tool to improve patient safety.

Dr. Cooper conducted an informal poll of the participants and determined that only a few people attended because of their technological interest in simulation, while the majority attended because they are medical educators and a smaller, but significant number, attended who identified themselves as patient safety advocates.

Dr. Cooper stated that his task is to convert all participants into patient safety advocates, regardless of their other interests or specializations. According to Dr. Cooper, emphasizing patient safety is the best way to promote simulation. The oft-quoted 1999 Institute of Medicine (IOM) report “To Err Is Human,” followed by “Crossing the Quality Chasm” in 2001, made it clear that health care is not safe enough, that bad things happen within health care, people are harmed, and people are afraid to talk about it. The reason for inadequate health care is that the health care culture is built on outdated notions that: (1) it is customary to practice on patients; (2) bad things are bound to happen because those coming into hospitals are subject to preexisting illnesses and unfortunate results are unavoidable; and (3) routine training is the exception rather than the rule.

Patient safety relies on the basic theory that no patient is to be injured as a result of health care intervention. Dr. Cooper, an experienced biomedical engineer, indicated that he was slow to realize the connection between proper medical simulation and patient safety. Earlier in his career, Dr. Cooper conducted experiments at DuPont, a gunpowder manufacturer that was then ranked the safest company in the country. DuPont rates its safety record by length of time between losses of employees to injury, with a billboard on which such information displayed in its lobby. Dr. Cooper suggested that hospitals place safety in such high regard by also posting signs in their lobbies letting the public know it is walking into a potentially dangerous environment. He believes that holding hospitals responsible for patient safety can help people place a higher premium on safety. Dr. Cooper also stressed the importance of constant thought and consideration of ways to promote safety, and suggested that hospitals conduct regular safety discussions, much like DuPont’s daily five-minute and monthly hour-long sessions, to keep safety at the forefront.

Safety is about doing the right thing, with minimal harm. It is also about providing care centered on the patient and striving to gain the trust of patients. It is about creating a culture focused on care and teamwork. It is properly educating health care providers and driving home the message that patient care is of utmost importance.

Further, it is important that the medical field realize that simulation is more important than simulators, and that the focus be on the technique, and not the technology. Although the technology is important and can be used to market the technique, the technology itself is merely the tool that must be designed to fit the objectives, curricula, and applications, and not vice versa.
Simulation promotes patient safety by allowing practitioners to develop a minimum competence before they “practice” (learn how to do) risky or less-painful-with-experience procedures on patients. It provides a more effective, efficient learning tool for the development of skills and a mechanism to foster teamwork. It can also provide consistency in training; objectivity in feedback and assessment; transparent, credible credentialing; a real-world evaluation of technologies and techniques under stressful conditions; and experience for the entire health care organization in delivering services.

Because medical education is grossly underfunded, patient safety can be used as leverage for simulation. The economic model to pay for simulation remains somewhat undeveloped (although it might be on the horizon), while patient safety is something everyone can understand and appreciate. Unlike aviation simulation, which provides a much more cost-efficient learning tool than using real aircraft, the economic model for medical simulation depends on a number of elements to promote the use of simulation, including the cost-prohibitive expense and social and political untenability of training on patients, and the potential impact of the 80-hour workweek rule.

While patient safety remains a fundamental unsolved problem for health care, simulation should be made a big part of the solution, Dr. Cooper concluded. He offered some suggestions for making safety the partner driving simulation:

- Get connected to the people who are responsible for patient safety;
- Connect to those who pay for the absence of safety, i.e., insurers;
- Address safety concerns in objectives and curricula; and
- Enlist patients in making the argument.

**MEDICAL SPECIALTIES**

Randy Haluck, M.D., Moderator  
Daniel Scott, M.D., Tulane University  
W. Bosseau Murray, M.D., Penn State University  
Chris Cates, M.D., Emory University

Dr. Randy Haluck, Director of Minimally Invasive Surgery at Penn State Milton S. Hershey Medical Center, stated that the purpose of this panel is for representatives of three specialty areas: laparoscopy, anesthesiology, and cardiology, to articulate the latest in simulated-related activities and research.

**Laparoscopy—Daniel Scott, M.D.**

Dr. Daniel Scott agreed with Dr. Cooper that the surgical system as an apprenticeship model is outdated. It is important that the laparoscopic medical field lead a national effort to offer an alternative to the current, outdated apprenticeship model, which dates back more than a century to the teachings of Dr. William Halsted. Dr. Scott suggested that the medical field look to the advances in flight simulation for direction, given that it is 50 years ahead of medical simulation technologies.
Surgery certainly has advanced technology. Most of abdominal surgery is now laparoscopic, which requires a new set of psychomotor skills. The rationale for simulation training is clear – it will enhance education, maximize efficiency, and increase patient safety. Dr. Scott cited three studies demonstrating the validity of medical simulation; one published in 2000 provided evidence demonstrating that simulation training improves operating room performance; a subsequent study conducted two years later found that surgical residents who trained on the Minimally Invasive Surgical Trainer-Virtual Reality (MIST-VR) performed better at laparoscopic cholecystectomy than those who did not.

A third study of the performance of 17 basic tasks conducted by surgery interns found that in instances where MIST-VR techniques were used, less time and fewer procedures were needed to properly train interns to become proficient. A study of porcine Nissen fundoplication indicated improvement through practice, but also through MIST-VR training. Therefore, transferability of simulation into proficiency has been demonstrated. It remains to be determined at which point in the training process simulation provides the most significant benefits.

The future of surgical simulation will likely include operation-specific simulation combined with virtual procedures for cholecystectomy, flexible endoscopy, and robotic surgery. Various obstacles exist. For example, currently only 55% of surgical training programs in the United States have laboratory skill programs, and only about half mandate attendance. In addition, setup costs for labs are high, on average approximately $133,000, and often have inconsistent funding sources, a lack of standardization, and inadequate standards for assessment.

Possible solutions to overcome such obstacles include continued research and development, improved interfaces, and the establishment of national standards for laparoscopy through the American College of Surgeons, the Society of American Gastrointestinal Endoscopic Surgeons and others.

**Anesthesiology—W. Bosseau Murray, M.D.**

Dr. Bosseau Murray stated that simulation has become an accepted training tool in anesthesiology, with some of the work initiated at Hershey Medical Center at Pennsylvania State University College of Medicine. There are many dimensions of simulation and educational goals for it within the field of anesthesiology, but much like the other medical fields, it also faces a number of challenges, barriers, and failures. The field uses interactive and often “immersive” activities that recreate experiences of the real world – they prepare for and amplify actual experiences, but do not replace clinical experience. Simulation is a technique, not a goal, and the human being using the simulator must teach. The simulator alone is not the teacher.

Teaching strategies using a simulator can begin with a known case, i.e. the look-here, see-this approach, or an unknown case, which can be diagnosed by slowing down the passage of time and later assessing the situation in “real time” to demonstrate the impact of crisis management and group dynamics. While certification for simulation training is not yet a reality in anesthesiology, it soon will be, Dr. Murray said.
Anesthesiology is using a wide spectrum of simulation approaches: simulation labs, centers, and institutes; partial task trainers, i.e., airway management; and human patient simulators for crisis management and crisis resource management. Some examples of efficient and effective uses of simulation include: the basic lung simulator and sloping capnograph simulation, which is used to maximize ventilation to get a normal capnograph. In addition, certain sophisticated programs, such as the Jim Philips’s Gas Man, use techniques similar to the mathematical models underlying diving computers as a means of simulation.

Non-technical skills in anesthesia include four skill categories with 13 skill elements:

1. Teamwork: Coordination, exchange information, assertiveness
2. Task management: Planning and preparing, prioritizing, using resources
3. Situation awareness: Gathering information, recognition, understanding, anticipating
4. Decision making: Identify options, balance risks, reevaluate

The problems and challenges for departments of anesthesia are both internal and external.

Internally, they include issues of cost, space, curriculum development and integration, which are generally solved by anesthesiology departments themselves. It is important that simulation be incorporated into the curriculum rather than as an add-on. Simulation, however, is still relatively new and older generations on curriculum committees may be reluctant or even resistant to the use of potential of simulation.

Externally, the problems require a solution at the national level, with outside input from sources such as AIMS, the Association of American Medical Colleges, and professional boards. A national list of equipment with ratings similar to those given by Consumer Reports would help lead to the development of improved simulation equipment. Finding simulation expertise, establishing assessment methods, and promoting national acceptance of simulation are also challenges to be faced by the medical field as a whole.

Dr. Murray concluded that objective, validated assessments that are unassailable in court and scoring systems are needed.

Cardiology—Christopher Cates, M.D.

Dr. Christopher Cates, Director of Vascular Intervention at Emory University, is an advocate of simulation training for carotid stenting. Physicians are likely to lose skills after being in practice for a couple of years, he noted, and it is difficult to train them in a new technology while emphasizing patient safety under the traditional physician training methods.

While the procedure of carotid stenting is not well known, stroke, the disorder that stenting is designed to prevent, is a major cause of disability and death in the United States. Stenting removes arterial plaque from the carotid artery in a very complex procedure that includes the inserting of a basket-like device to collect the plaque being removed from the artery and prevent
it from reaching the brain. The stent eventually becomes part of the body. It is important to train doctors appropriately so they will not cause a stroke when performing the procedure. The tighter the carotid blockage, the more likely that a stroke could result.

There is a high success rate in stenting in the past 10 years in which the procedure has been used, with a lower complication rate than carotid endarterectomy, the conventional procedure in which plaque is removed from the carotid artery. In the Sapphire trial of 334 randomized patients, data presented a year and a half ago indicated a nearly 50% reduction in stroke, myocardial infarction, and death in stent procedures, compared to endarterectomy. There is a significant learning curve in stenting with increased numbers of strokes and fatalities in cases performed by less experienced surgeons.

Carotid stenting has represented a “perfect storm” for simulation training, Dr. Cates said, with less than 100 experienced operators for a procedure for which there is great demand. A minimum level of expertise is needed to properly perform carotid stenting on patients, the simulation technology is available, and the political environment is conducive. In late 2004, Cordis, a division of Johnson & Johnson, presented an expedited review to the FDA: the FDA panel voted to approve the application which included simulation training. This decision is a boost for simulation and creates a new market for simulation training.

The subsequent decision by Medicare earlier in 2005 to cover carotid stenting performed by appropriately trained personnel in a defined group of high-risk patients marked a paradigm shift. Although carotid stenting is a high-volume vascular procedure, with high visibility and high patient demand, it is also a high-risk procedure and mistakes happen. Errors and inappropriate training in carotid stenting leads to morbidity. The FDA entry criteria require experience in endovascular intervention, tiered training, online didactic cognitive training and assessment, and metric training, representing an historic shift toward the recognition of the value that medical simulation can provide. In addition to support from regulators, payers and industry is a coalition of professional societies. In fact, the Society for Cardiovascular Angiography and Interventions (SCAI) is creating joint competence/credentialing document with Society of Cardiovascular Angiography and Interventions (SCAI), the Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS) and core curriculum in carotid stenting, formalizing tier training program for SCAI carotid competency and certification, regional simulation training centers, and a national registry specifying “metric-based simulator training to proficiency.”

In the Emory Neuro Anatomy Carotid Training (ENACT), a virtual reality program, Dr. Cates and colleagues piloted simulation training in a group of 125 physicians. They demonstrated the validity and feasibility of the technology and established a learning curve. Dr. Cates reiterated that collaboration represents a major breakthrough in simulator training. Johnson & Johnson has taken the lead in establishing major centers for simulation, and the first 1,500 patients of physicians trained by the tiered program will be reviewed in a post market surveillance study.
Dr. Cates concluded that simulation carotid stenting is ushering in widespread use of virtual reality simulation as a required training tool. The FDA’s mandate is a paradigm shift, establishing a new objective standard for technical skills assessment. Further studies will validate virtual reality simulator training, which medicine and society should be prepared to embrace.

**Discussion**

Noting that the opportunity lies in confronting challenges and problems, Dr. Haluck questioned whether cardiology, due in part because of the carotid stent, has adopted simulation overnight. Dr. Cates responded that simulation will be embraced in carotid stenting because it is mandated by the FDA. With simulation technology, cardiology will measure performance and embrace a way to learn a skill safely without harming patients. As with anything new, there is a pushback; however, acceptance is occurring on a number of fronts.

Rajesh Aggarwal inquired how a standardized approach for proficiency training would be determined. Dr. Scott responded that the methodology has been simple – to begin by examining how experts who perform a procedure well, e.g., surgeons known to be capable of suturing well. The next step is to look at the learning curve and determine whether medical students can achieve these benchmarks, and demonstrate transferability in the operating room. The current struggle is determining whether the same benchmarks can be used for training and assessment.

Dr. John Cardella, an interventional radiologist, questioned whether some people, even after a high number of repetitions, are capable of grasping the technique. Dr. Cates said that he has seen great variability, with some grasping the technique more quickly than others. Simulation allows individual performance to be tracked and evaluated on a case-by-case basis, and not everyone passes. Furthermore, it is not always possible to differentiate between vascular surgeons and cardiologists. In a recently presented study, about 22% of trainees did not meet the established benchmarks. Dr. Haluck stated that a major challenge for the advancement of simulation is the accumulation of measurable data regarding the results of training.

Dr. Gerry Higgins, of Laerdal, commented that it is important to identify objectives. A simulator does not have to be a complete reproduction of the cardiovascular system. A good example is simulated training for landing on an aircraft carrier. Dr. Cates agreed to a certain extent, noting that certain simulators can be used for certain tasks; but for high-stakes assessment of technical skills, he emphasized, enough fidelity is needed, for example, to measure catheter wall/wire interaction.

Rick Severinghaus asked whether or not there is enough expertise at regulatory agencies to assess simulation. Dr. Cates responded that the FDA is looking to the medical community to make statements about suitable training.
The View of Simulation from Organized Medicine

Ajit K. Sachdeva, M.D., American College of Surgeons, Moderator
Gary Becker, M.D., National Cancer Institute
Dick Bell, M.D., Chair, Department of Surgery, Northwestern University
Michael Cowley, M.D., Professor of Medicine, Virginia Commonwealth University
Charles W. Otto, M.D., Professor of Anesthesiology, University of Arizona

Dr. Sachdeva opened by indicating that the Organized Medicine panel would move one step forward from the advances in major fields described by previous speakers to consider how to advance simulation in the areas of training, certification, and accreditation.

Board of Surgery—Richard Bell, M.D.

Dr. Richard Bell, a national leader in surgical education and Chairman of the Board of Surgery, the organization that considers accreditation of surgical residents, expressed his enthusiasm to collaborate with the assembled group and discuss the current state of the field of simulation. He discussed standardized curriculum and the role of simulation. He has been troubled for several years by the tremendous variability in the skill set of graduating U.S. surgical residents particularly given the increasing demand for more uniform performance by surgeons in avoidance of errors. The profession wants to standardize care based on evidence, and the American Board of Surgery’s recognition of variability in graduating U.S. residents has led to increased scrutiny of training by licensing agencies and an acknowledgement of the need to increase efficiency of residency training. This is a positive outcome for both surgery and simulation.

In a November 2004 meeting, a group of organizations, including the American Board of Surgery, American College of Surgeons, American Surgical Association, Association of Program Directors in Surgery, and the Residency Review Committee for Surgery and Association for Surgical Education, endorsed the idea of a national curriculum, a significant shift forward in training. With a national curriculum, training would focus more on the demonstration of competence, rather than merely observing experienced practitioners for several years, as had been the focus in the past. Desirable features of a new national curriculum include:

- Learning measured by the mastery of competencies rather than length of rotations;
- Competencies organized into modules that provide curricular structure and support evaluation;
- Residents learning at their own speed; and
- Utilization of new technology.

The curriculum would require didactic knowledge, simulated clinical skills, and hands-on experience, with hands-on experience comprising the largest portion of the curriculum. Curriculum builders must determine the skills in which general surgery residents should be
proficient, and once they are determined, this list can serve as a template for those creating simulation tools, to develop tools to match those needs. A profile of recertification of general surgeons found that 95% of practice is in a small number of categories, meaning that a limited number of modules are needed.

Didactic and simulation skills must teach the need to learn. Didactic teaching breaks down to books, journals, lectures, and the Internet, and an Internet tool for delivering didactic knowledge is being developed. As simulation becomes more robust, the curriculum must be flexible to accommodate new tools, and simulation is likely to play a large and important role in residency training.

**American Board of Internal Medicine—Michael Cowley, M.D.**

Dr. Cowley discussed the simulation-based assessment of procedural skills in interventional cardiology. The American Board of Internal Medicine (ABIM) establishes requirements for certification and maintenance of certification.

ABIM is considering simulation technology as a means of evaluating procedural and technical skills in specialty and subspecialty areas. The initial ABIM effort to evaluate and validate simulation testing is focused on interventional cardiology, because the subspecialty is procedural-based. A pilot study was to determine whether a valid and reliable evaluation tool can be developed for assessing the technical proficiency of interventional cardiologists using the Medical Simulation Corporation’s SimSuite® technology in 10 clinical centers, with simulator user interface operated by a clinical/technical specialist.

The specific aim is to evaluate whether the SimSuite® system can distinguish among physicians with varying clinical skills in interventional cardiology.

Features of case scenarios within the pilot study include range of difficulty; specific clinical testing points identified and incorporated; and metrics such as stent length and lesion coverage, balloon length and diameter, time to treat, medications and sedation, correct fluoroscopic projections, and responses to complications. A sample case history describes key clinical features and patient characteristics.

Subsequent to the initial beta test, 120 subjects were tested at 10 sites at three levels of expertise—novice, midlevel, and expert. The simulator protocol consisted of a demographic information questionnaire, a practice case on the simulator, six case scenarios for evaluation, a survey about experience with the simulator, and rating of procedural skills by a clinical specialist.

The scoring algorithm is based on the logic of the case, with a checklist of important actions that considers the relative importance and pattern of actions, e.g., sequencing, timeliness. The final score represents an assessment of the combined appropriate and inappropriate actions. The total score is an average of individual case scores and unanticipated incidents are re-evaluated for validation.
In analyzing results, the hypothesis was to determine if there was a difference in performance between the three expertise levels in completing therapeutic interventional cardiac procedures on the simulator. Psychometric characteristics included difficulty and discrimination of each case, reliability and reproducibility of the test, and validity of the instrument. Preliminary results indicated that differences in the percentage of correct responses corresponded to the operator’s experience, signifying that simulation can discriminate differences in expertise and that the magnitude of discrimination varies by specific case scenario.

Data collection has been completed and an automated scoring program adaptable to any case is currently being developed for the program. Process variables are also being analyzed, including scores on cases, overall demographic data, survey findings and clinical specialist ratings. The overall experience has been useful, Dr. Cowley concluded, and further evaluation of simulation for testing is planned. It is expected that once the technique becomes incorporated, it will likely be used in the recertification process.

American Board of Radiology—Gary Becker, M.D.

Dr. Gary Becker is in a unique role in radiology as he serves in leadership positions in three radiology organizations of the Society of Interventional Radiology (SIR), the American Board of Radiology (ARB), and the Radiological Society of North America (RSNA). Dr. Becker stated that all three organizations are working together to determine the appropriate role for simulation in radiology.

A number of forces limiting trainee case exposure, including the 80-hour rule for residents, the diminishing role of angiography as noninvasive diagnostic approaches become increasingly available, interspecialty competition, regulatory factors such as the FDA simulated training requirement in carotid stenting, the need for board exams that emulate practice, the evidence that simulated training reduces error, and the appreciation of the larger potential for this technique are at play in prompting the groups to examine different simulation models.

A host of opportunities lie ahead for simulation, beginning with medical student aptitude testing of image perception and procedural skill; medical student clinical scenarios and modules; and resident clinical modules that could address, for example, conscious sedation, contrast reaction, and basic procedure skills. Residents, fellows, and attending physicians can potentially benefit from the addition of advanced skills, training in new procedures, individual case planning with practice simulations, required practice hours in the future, and preparation for low-volume, high-risk procedures.

Other opportunities to use simulation include individual performance improvement plans, team care simulations (e.g., emergency), maintenance of privileges or recredentialing, and board examinations. Simulation can also play a role with experienced practitioners through the maintenance of certification in individual educational plans. The need for specific, focused simulation training may arise from quality assurance processes, and simulation may play a role in maintenance of clinical privileges, evaluation of performance, individual case planning, and examinations.
Unfortunately, there are also a number of barriers to the full adoption of simulation, including a low level of awareness about simulation; simulation is not yet ingrained in the culture of medical education and training; the applicability of simulation to radiology may not be intuitive; additional resources, including money, expertise, space and time, are needed; and a robust menu of modules need to be developed and validated.

Within RSNA and SIR, increased focus on the value and advancement of medical simulation is developing. Currently, a task force is increasing the simulation visibility of RSNA and SIR annual meetings. Validation testing of a focused module will be considered at RSNA 2005, and the SIR Foundation is planning a research initiative. At the RSNA April 2005 meeting, Teaching & Learning in Radiology, leaders were exhorted to make a major commitment to medical simulation. Future activities include SIR, RSNA, ABR Foundation roles in the development of simulators, increased involvement in validation and applied science, and an active role in the development of standards and metrics for vascular and non-vascular procedures.

American Society of Anesthesiologists—Charles W. Otto, M.D.

Dr. Charles Otto, Vice President for Scientific Affairs of the American Society of Anesthesiologists (ASA) stated the vision for the use of simulation focuses on the fact that critical incidents are rare in anesthesiology, but there are serious crises for which practitioners must be prepared to handle. Simulator training can provide a valuable tool in maintaining best practice and crisis management skills while emphasizing patient safety. Although simulator education is common in residency training, it has not been widely applied in continuing anesthesiology education. The ASA believes that simulator education has the potential to become an important part of their members’ lifelong learning.

The ASA initiative on simulator education seeks to establish a task force on standardized national simulator training; appoint established, respected anesthesiology simulator experts to the task force; establish the goals and objectives of the task force and a timeline for completion; and provide a completed report to the ASA with a blueprint for implementation. The mission is to provide ASA members with a descriptive guide of all aspects and opportunities in simulation education. Brochures and a website will provide locations, duration, dates, goals and objectives, frequency, equipment, instructors, cost, local amenities and continuing education credit information.

The goals of the standardized national simulator training program underway are to determine the current status of simulation offerings available to members, which award CME credit; determine and recommend type(s) of simulation education that best serve the needs of ASA members; develop a process for deciding which simulation centers will participate in this ASA educational activity; and determine training and qualifications of instructors for ASA-sponsored simulator educational offerings.

Further goals include the development of a mechanism for ASA members to select, register, and pay for simulation offerings; a determination of how CME credit will be provided for each
offering; and a financial analysis of program implementation. A task force report is expected by September 2005, with implementation projected to occur by September 2006. ASA’s ultimate goal is to provide simulation programs to members, with participation in such programs recorded in the ASA database and automatically transmitted to the American Board of Anesthesiology for its Maintenance of Certification database.

Discussion

Noting that the approaches presented are serial, one participant questioned whether there has been any attempt at integrating a spiral model. Dr. Bell responded that he does not view the circle as ending with clinical experience. While certain tasks could be frontloaded at the beginning of residency, those with clinical experience will return to some sort of simulation training, which is an ongoing and continual process. Dr. Sachdeva added that typical knowledge transfer consists of knowing, showing, and doing, and simulation has turned this triangle on its side.

Adrianus Houtsma inquired about the role of training throughout careers, and Dr. Bell agreed that the need for continual education is important, and the American Board of Surgery is planning to add someone to its board to manage the maintenance of certification. Dr. Otto added that he also encourages ongoing training and reevaluation in the anesthesiology community, with retraining modeled on the airline industry. Dr. Cowley said that the field has a long way to go in defining the skills to be taught, and Dr. Becker added that these will likely be integrated into recertification requirements. Recertification is a relatively novel idea, and physicians certified prior to the early 1990s are not required to be recertified. However, as new procedures, such as carotid stenting, are developed, they may require the establishment of training modules and separate certification requirements. Dr. Cowley said that in interventional cardiology, there will be critical need for simulation to train new generations of doctors.

Dr. William Dunn of the Mayo Clinic said that the common denominator of simulation is the reality of the patient, not a technological project. He noted that at least four different companies are developing interventional cardiology simulators and inquired about the panel’s perspective on future mechanisms for proficiency assessment of simulation. Dr. Becker responded that different technologies have different applications, and it has been a challenge to integrate the different applications. The medical field must combine the strengths of different systems and recognize that problem and judgment areas are more difficult to assess than technical skill.

Ophthalmologist Dr. Robert Mazzoli asked whether if specialty boards would be able to put an imprimatur on simulators. Dr. Sachdeva expanded the question to inquire as to what boards and specialty societies want from the simulator community to move the field forward. Dr. Otto responded that, while he cannot speak for the American Board of Anesthesiology, he believes that, initially, it is not necessary for each board to improve on individual simulators unless it will be used for a board exam. Anesthesiology’s contribution to advancing simulation has been to establish a task force to develop ideas on ways to tap into the expertise of the simulation community, and he hopes that other disciplines will take a similar approach.
Dr. Cowley said that although simulation’s advancement will be slow as a means of certification, it is making increased penetration as a means of educating. Dr. Becker added that he does not foresee ABR placing a “stamp of approval” on any product, and professional societies must develop and test skill sets while industry must collaborate to develop standards.

Within the field of surgery, Dr. Bell said, the medical skills in which proficiency is needed must first be defined before seeking the proper technology to address such needs. If products are developed jointly, the issue of putting on a seal of approval may not be as significant. Dr. Sachdeva added that the American College of Surgeons will not place stamp of approval on any technology, but will, instead, require certain educational standards, with the goal of establishing a compendium of validated simulators.

GOVERNMENT AND REGULATORY PERSPECTIVE

Gerald Moses, Ph.D., U.S. Army, TATRC, Moderator
James B. Battles, Ph.D., U.S. Agency for Healthcare Quality and Research (AHRQ)
Kenneth J. Cavanaugh, Ph.D., U.S. Food and Drug Administration (FDA)
Usha Satish, Ph.D., Accreditation Council for Graduate Medical Education (ACGME)

Gerry Moses, Ph.D. of the Telemedicine and Advanced Technology Research Center at the U.S. Army Medical Research and Materiel Command noted that the speakers on the government and regulatory panel which provide an update on federal and regulatory efforts outside of the DoD.

Food and Drug Administration—Kenneth J. Cavanaugh, Jr., Ph.D.

Dr. Kenneth Cavanaugh, a biomedical engineer experienced in cardiovascular devices, is the team leader for carotid and renal stents at the FDA’s Center for Devices and Radiological Health (CDRH). He reported on the FDA's perspective on medical simulation-based training for cardiovascular devices and presented an overview of the role of the FDA, the role of simulation in the FDA’s mission, the example of carotid stenting, and ways in which the FDA would like to see simulation develop.

The FDA’s mission is to protect and promote public health and regulate the marketing of food, drugs, biologics, medical devices, and cosmetics. With respect to medical devices, marketing approval is based on safety and effectiveness, with both pre-market and post-market data assessed. The FDA does not regulate the practice of medicine or the credentialing of physicians, or make reimbursement decisions. Once a device is on the market, physicians can prescribe it as they see fit.
Simulation affects CDRH in several ways. The CDRH does not regulate or review medical simulations directly, but it does review training programs for devices prior to marketing approval that can include simulation. Consequently, simulation is likely to become more prevalent in the future.

Carotid stenting, a high-profile interventional procedure that reduces the risk of stroke without invasive surgery and treats patients considered too ill for conventional surgery, provides an example of the proper use of medical simulation in the view of the FDA. The first carotid stent was approved by FDA in August 2004, but devices were used off label long before. Training of physicians was a key consideration in approving carotid stenting, and the training program includes simulation for several reasons. Carotid stenting is a new technology that requires a unique skill set and is performed by interventional clinicians with varied clinical backgrounds, i.e., surgery, radiology, cardiology, and neurology. Because of anatomic and physiologic differences, an animal model does not provide a training model realistic enough to be useful.

In reviewing simulations, the FDA does not look at the actual content, but is more interested in the program structure. Simulations used for training during clinical trials may also be appropriate for post-market use. In the future, simulation is likely to play a larger role in training programs, with more uses and potential credentialing considered.

A number of characteristics for a simulator are ideal for a training program, including:

• Biofidelic (reflecting human body);
• Metric-based (dynamic and static);
• Properly validated;
• Realistic tactile feedback (haptics);
• Uses both real-world and “canned” cases; and
• Proficiency-based progression, in which physicians demonstrate competence before performing the procedures on patients.

In conclusion, Dr. Cavanaugh emphasized that the CDRH utilizes medical simulation as a component of device training programs and the use of properly designed simulations can promote patient safety by improving operator technique. Dr. Cavanaugh invited participants contact him and other FDA personnel if interested in working with the CDRH to incorporate medical simulations into other aspects of medical device regulation.

Accreditation Council for Graduate Medical Education—Usha Satish, Ph.D.

Dr. Usha Satish is an Associate Professor of Psychiatry and Behavioral Sciences at the State University of New York Upstate Medical Center and a member of the Accreditation Council for Graduate Medical Education (ACGME), a private voluntary accrediting body that improves patient care by improving graduate medical education. ACGME establishes standards for 8,100 residency programs housing 100,000 residents. In establishing its standards, ACGME consults with 350 volunteer physician experts sitting on
26 residency review committees, and an institutional review committee. Although ACGME is a private organization, its work is recognized by the federal government, certifying boards, and licensing boards. With an annual budget of $20 million and a staff of approximately 100, it conducts 2,100 site visits annually. Its recent initiatives have focused on competence, duty hour concern, and adequate education.

With a vision to enhance residency education through educational outcome assessment, ACGME operates according to fundamental principles that measurement leads to improvement, programs require flexibility to adapt to their particular environments, and public accountability is a necessity.

Examining a program’s education potential and the amount of required resources, such as time, faculty, lectures, and facilities, are more prescriptive than an outcomes analysis that examines whether a program is actually educating residents and looks for a demonstration of skills.

Models can help understand life, but they are not flawless. Both measurements and models need to be constantly reassessed. Structured dialogue regarding measurement, rules, and context are also needed to make the most beneficial use of models. Because medicine is subjective, residents must learn which rules must always be followed and in which circumstances they can stray from the general rules. Simulation can play an important role in helping physicians differentiate between the two.

Proper assessment of medical procedures must measure actual performance, identify areas for improvement, satisfy a reasonable request for accountability, be practical, and discern growth over a period of time. A variety of evaluation tools can be used to perform such assessment, including multiple choice exams, global ratings, oral exams, chart stimulated recall, computer-based simulations, objective structured clinical exams, portfolios, and 360-degree evaluations. It is hoped, Dr. Satish said, that in years to come, simulators and simulation will become an integral part of these assessment tools.

The first phase of the outcome analysis, which is to form an initial response, has been completed. The subsequent steps of sharpening the focus and clarifying definitions are expected to continue into 2006, with the integration of proper education into health care occurring from 2006 to 2010. Benchmarking and improvement will be an ongoing part of the initiative.

General competencies are the familiar six competencies—patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice. Simulations can fit into any or all learning paradigms. Lessons learned to date are that competence is a habit that develops along a continuum. Developing the habit is not easy, but it involves more than knowledge and skill.

In the Dreyfus Model of Skill Acquisition, those who master specific skills must pass through five levels of proficiency: (1) novice, which emphasizes established rules; (2) advanced beginner, which incorporates rules into specific situations; (3) competency, which incorporates rules into selected contexts and emphasizes accountability; (4) proficiency, which emphasizes
accountability and intuition; and (5) mastery, which involves the immediate assessment of a given situation. Hubert Dreyfus, one of the developers of the model stated that “to become competent, you must feel bad.” As students “feel bad,” they learn. It is much less harmful to “feel bad” after making a mistake in a simulation than with a live patient, Dr. Satish emphasized.

Dr. Satish provided a definition of “phronesis”: knowing exactly which rule to bend and exactly how far to break it to accommodate the reality with which one is confronted. She explained the distinction between a “qualified” practitioner, or one who is a board certified graduate of an ACGME accredited program that emphasizes medical knowledge without any warrants, and a “competent” practitioner, whose experience is derived from habit, actual performance, a balanced set of measures and attributes, implied warrant, and trust. Dr. Satish believes that the competent practitioner is more useful to patients than a qualified practitioner. The measurement system must focus more on competence, which can be created by using simulations.

Dr. Satish concluded by providing the top 10 reasons ACGME promotes simulation:

1. Clinical skills should be learned as far away from the patient as possible.
2. Health care is one of the few high-risk industries that does not conduct routine rehearsals and debriefings.
3. Simulation can be used as a formative tool for resident development.
4. Simulation can be used to determine control for both rules and contexts.
5. Simulation can be used to assess how residents respond in different contexts.
6. Simulation can be used to form a portfolio of assessed experiences to help residents indicate and evaluate the procedures that they have performed.
7. Simulations allow residents to intentionally make mistakes and learn about the consequences.
8. Simulation is a controlled method of learning about system-based practice.
9. Simulation can document how residents think, as well as what residents think.
10. Simulation exposes values, as well as rules.

Agency for Healthcare Research and Quality - James B. Battles, Ph.D.

Dr. Battles, Senior Fellow for Patient Safety at the U.S. Agency for Healthcare Research and Quality (AHRQ), in the U.S. Department for Health and Human Services discussed simulation in the context of patient safety. AHRQ’s stated mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. After the IOM reports on patient safety, AHRQ was directed by Congress to support issues related to patient safety, with a specific mandate that they conduct and support research and build private-public partnerships to identify the causes of preventable health care errors and patient injury in health care delivery; develop, demonstrate, and evaluate strategies for reducing error and improving patient safety; and disseminate such effective strategies throughout the health care industry.
The goals of patient safety are to reduce the risk of health care-associated injury to patients and to remove or minimize hazards that increase such risk. Some risks and hazards are educational, a tightly coupled relationship between clinical training and patient care that often places patients at risk of injury. Accordingly, the medical field must determine how to decouple clinical training and patient care, while remaining cognizant of the ethical challenge associated with putting today’s patients at risk for the benefit of training tomorrow’s physicians.

This dilemma has many facets. For example, medical training and education is a lifelong process that continues far beyond a physician’s residency. In addition, the emphasis to date has been on knowledge acquisition, rather than performance-based acquisition of clinical skills by individuals and teams, and many medical and surgical procedures are potentially dangerous and very difficult to learn and teach. Patients are harmed as steep learning curves are climbed by residents and practitioners under the traditional, but deficient apprenticeship model of “see one, do one, teach one.” Dr. Battles questioned whether any of the attendees would get on a plane with a pilot trained by this method.

Problems with medical training can be compared with the aviation and space industries. Aviation involves more than mere “stick and rudder” skills to ensure safe and reliable flights, and space flight studies by NASA have linked accidents to failures of command, communication, and crew coordination. Accordingly, crew resource management (CRM) was initiated in the mid-1970s to help aviators lacking “the right stuff” to manage aircrews effectively. Parallels between the training methods used in the aviation industry can be drawn to the medical field. Mastering intricacies of team behavior between physicians, nurses, pharmacists, and technicians is different from mastering textbook knowledge, and a predominant focus on knowledge acquisition does not prepare one for the rapid paced clinical environments, distractions, and uncertainties of medicine.

Further, aviation can involve a preoccupation with minor mechanical problems, a failure to set priorities or delegate tasks and responsibilities, inadequate leadership, inadequate monitoring, failure to use available data, and failure to communicate intended plans. Similarly, medical professionals often fail to brief other team members of plans for operation, fail to inform team members of workload or patient problems, fail to establish leadership roles, disagree over the proper course of action, and fail to debrief actions and provide training to residents.

Dr. Battles traced the early beginnings of simulation training in aviation and medicine and went on to list a number of limitations of current medical training practices: (1) aside from applicable ethical issues, cadavers are difficult to procure and tissue degrades; (2) anesthetized animals lack similar anatomy and can be cost-prohibitive; and (3) real patients do not wish to be used as practice material. On the other hand, simulation can promote patient safety; improve efficiency in high cost clinical settings, scheduling and availability; create optimal conditions for learning (learner-centered at the pace of the individual) with objective and immediate feedback; promote the integration of multiple skills and utility as an assessment tool; and provide a test-bed for research.
These benefits correspond to the AHRQ agenda and its priorities of teamwork and simulation. AHRQ supports simulation development through grants, cooperative activities in the development and evaluation of teamwork with the Department of Defense, expanding the evidence base for simulation and teamwork, and a curriculum on team training.

To advance knowledge about simulation, in November 2004 AHRQ prepared a special supplement about simulation and team training for *Quality and Safety in Health Care*, a publication of the *British Medical Journal*. Dr. Battles reiterated the areas where simulation can be useful to: (1) develop professional skills without harming the patient; (2) develop team skills; and (3) teach patient interaction skills using standardized patients.

Although AHRQ is currently funding simulation studies, with quality proposals for simulation scoring well in study sections, AHRQ has limited funding for investigator initiated research, with the expectation that only a few grants will be awarded in Fiscal Year 2006. AHRQ considers simulation and team training an essential element of patient safety and AHRQ staff has extensive experience in the field and understands its importance. Like AHRQ, accrediting and licensing authorities are also advocating simulation, and the Association of American Medical Colleges, ACGME, the American Board of Medical Specialties, and the National Board of Medical Examiners are exploring ways to promote simulation. A simulation-based performance test is currently required for licensure as a physician in the United States.

**Discussion**

Dr. Moses reiterated that for simulation to progress, it must reach a level of national interest with specific partners in its promotion, such medical boards and societies, federal regulatory agencies, and the medical industry.

Dr. Mazzoli inquired whether recognizing the number of simulator surgeries in achieving the requisite number of surgeries has been considered, and if ACGME has contemplated the number of simulator surgeries that are equivalent to one live procedure. Dr. Satish stated that, currently, the focus has been on promoting the recognition that simulations are valuable, without determining specific equivalencies.

In response to a question regarding the need to focus on training for success, rather than merely training to avoid “feeling bad” from errors, Dr. Satish agreed that success should be part of training. However, because simulation provides an opportunity to recover quickly from mistakes, medical trainees can learn with less pain than they would have in actual medical units.

Ivan George of the University of Maryland raised the issue of third-party payers who show interest in carotid stenting, but refuse to pay for such procedures without simulation. According to Dr. Cavanaugh, economics are not considered in FDA decisions, and Dr. Battles added that this has been considered in malpractice coverage.
Dr. LeRoy Heinrichs of Stanford University School of Medicine, indicated that he is beginning to use team training in virtual environments over the Internet, with haptics for distance learning because trainees do not have to be in the physical proximity of a mannequin.

Dr. Moses commented that there should be another agency involved in the discussion—the Center for Medicaid and Medicare Services (CMS)—and perhaps others as well. Dr. Cooper agreed that CMS is critical to a beneficial discussion because the pay for performance movement will likely be a big driver in health care and suggested that several insurers are providing incentives for simulation training.

Dr. Houtsma asked if simulation offers advantages for issues related to hand-eye coordination or perception/action coordination, if there is interest in this type of fundamental research, and, if so, what the proper channels are for obtaining adequate funding. Dr. Battles indicated that there is interest in using simulation to promote hand-eye coordination, but funding is currently limited.

**SYNTHESIS OF MORNING SESSION**

Steven Dawson, M.D., Partners Healthcare

Dr. Steve Dawson of Partners Healthcare and a key leader in the AIMS effort reiterated that the morning’s message was clear—simulation enhances patient safety. Quoting Dr. Richard Satava at the 2004 AIMS meeting, Dawson said “flight simulation did not make flying safer for pilots; it made it safer for passengers.” Evolving technology has the potential to fundamentally change medicine. Although individuals have done a tremendous job of developing and incorporating the technology, it is difficult to chart a course and follow it. AIMS and medical groups are trying to do that; however, the question remains whether medicine is capable of accepting such technology. The FDA’s decision last summer regarding simulation training in carotid stenting represents a major advance, but how this decision affects the field as a whole remains to be seen.

The field of simulation is still in its infancy, and has relied on support from TATRC. Currently, its roles in education and curricula, its role in various specialties and the definition of validation are all yet to be identified. One size does not fit all, as indicated by the morning’s discussions of basic surgery skills, anesthesia, and cardiologic intervention.

Simulation has the potential to fundamentally change the practice of medicine by allowing for the actual initial “practice.” This will affect engineers in the design lab, experienced physicians, novice physicians, medical students, and even high school students who can make valuable use of simulation if they have the necessary manual dexterity and cognitive ability.

At the 2004 AIMS meeting, mandated simulation was the unspoken concern—never mentioned but hard to ignore. Yet, with the recent FDA decision on carotid stenting, mandated training using simulation now exists as a reality. Several questions remain: Is there a course of medical...
care that is too risky to use humans for training? If carotid training is simulated, can heart training also be simulated? What will patients think about simulation?

Basically unstated in the morning session was the fact that simulation plays a large role in the broader medical field, including nursing, EMTs, paramedical personnel, mass casualty preparedness and military is one of the staunchest supporters of simulation training.

Dr. Dawson was saddened to hear Dr. Murray’s comment that current simulation systems have insufficient fidelity to allow certification. Dr. Dawson stated that it is unfortunate that anesthesiology, the specialty with the most experience in simulation, currently does not have a system to allow certification. The lack of certification capabilities has implications for the design of systems, metrics of systems, and evaluation.

Validation seems to be a major hurdle to the widespread acceptance and use of simulation. To properly measure performance, it is necessary to determine the appropriate measurements in designing simulators and to create broadly defined class of “experts” since different institutions have different needs.

Certain forces can be influenced for residents, while other forces cannot. The latter includes the reduced 80-hour work week requirement, which is having a profound effect on training. Decisions by outside agencies, organized medicine’s move to maintenance of certification, corporate-driven agendas and patient demand are other forces that affect the use and acceptance of simulation.

Dr. Bell’s statement that the specialties must define what is important to them summarized an important aspect of the morning session’s discussion. Dr. Dawson added the simulation developer must heed such definitions when designing simulation technology.

In conclusion, Dr. Dawson reiterated Dr. Cooper’s first rule that no patient should be harmed by a medical intervention—the ultimate reason for the participants’ support of simulation.

Discussion

Dr. Carla Pugh of Northwestern University made a self-professed “inflammatory” statement to generate discussion and stated that she believes the fidelity issue is an excuse used by surgeons that haven’t defined what needs to be taught in the operating room. She cited an example of poor training in basic skills—male students attending to female patients often fail to properly use a stethoscope because of the embarrassment to move the patient’s breast as necessary to properly place the stethoscope. By properly assessing the performance of basic skills, it would be easier to determine at the outset those students/physicians who will likely fail.

David “Bart” Bartlett, an aviator and retired Marine Corps Lieutenant Colonel, stated that while he is not a doctor, doctors should be aware of the advancements that the military and the aviation industry have made in the area of simulation and should consult with individuals from those industries when evaluating medical simulations.
Future of Medical Simulation for Patient Safety—Richard Satava, M.D.

Dr. Satava of the University of Washington holds an appointment with the U.S. Defense Advanced Research Projects Agency (DARPA). He began the discussion by making the observation that simulation is now receiving a groundswell of support from a variety of agencies. While it has not yet reached a tipping point, the field is moving forward.

Medical simulation improves patient safety, an a priori fact. Simulation technologies have a proven record in improving safety through decreased errors during technically challenging procedures, such as surgery and other interventions. Technical errors are reduced by improved training with a focus on error identification.

The long-term goal of simulation is to integrate it with assessment into the daily clinical practice; for example, simulation would be used to discover the effect of a drug or procedure before prescribing it.

The current groundswell makes this a unique moment for simulation. Medical education, particularly skills education, is beginning to be redefined. In fact, training and assessment are two sides of the same coin. In other words, training automatically involves assessment. Simulation and modeling need to be incorporated into curricula, as appropriate.

Many challenges remain for medical simulation, as stressed by the previous speakers. Scientifically, fidelity, and realism are necessary, and experts are competing for “low hanging fruit.” Standards are needed for interoperability of hardware and sharing software programs. Variety has been a low priority, and few simulators are developed to work with more than one task. Validation is expensive, with too few simulators available to conduct clinical trials. Curriculum also presents continuing challenges. Clinical use requires preoperative planning, surgical rehearsal, and performance assessment and outcomes. The 80-hour work week requirement for residents leaves little time to combine simulation with traditional training. Moreover, simulation is continuing to struggle to obtain acceptance from the medical community, the medical industry, and federal agencies, but there is hope that this is changing.

Although there has been some funding provided by the Department of Defense (DoD), and the Department of Health and Human Services (HHS), additional funding sources are needed.
Funding for simulation training includes the following:

- $8 billion in the annual U.S. Army Training and Doctrine Command (TRADOC) budget;
- $3 billion for annual simulation;
- $800 million for the FY03 Simulation, Training & Instrumentation Command (STRICOM) budget;
- $1.25 billion for the new naval air warfare system; and
- Approximately $2 million for the federal investment in medical simulation.

Clearly, the investment in medical simulation is minor in comparison to the total military portfolio. Therefore, medical simulation can get lost in the “valley of death” between commercial and government use. Defense Advanced Research Projects Agency (DARPA) funding is no longer available for simulation, and commercial companies lack the funds necessary to move beyond the development of prototypes.

The goals of DARPA are to establish a fundamental infrastructure, increase networks between multiple institutions, gain consensus from the international community, and establish support for the principal competencies.

As other speakers have mentioned, this requires a paradigm shift to correspond skills training to established criterion, as opposed to the duration of training, and students should not perform a procedure on a patient until they have demonstrated proficiency. In a standardized curriculum, anatomy must be taught, followed by procedural steps, error and outcome assessment, and testing and skills training.

Dr. Satava emphasized that simulators are only a tool that must be integrated into a comprehensive, proficiency-based curriculum. Only through stringent validation of simulators and their curricula will it be possible to achieve acceptance by the training and regulation bodies. It is not “build it and they will come,” but rather “validate it and they will come.”

Simulation marks a fundamental change in the scientific method, interjecting modeling and simulation between study design and experiment. One example is the Holographic Medical Electronic Record, or Holomer, a total body scan that establishes a baseline for diagnosis and becomes the electronic record. Dr. Satava suggested that by utilizing Holomer, an international task force to create global interoperability will further advance creating simulation.

**Simulation Validation and Its Impact on Patient Safety—Tony Gallagher, Ph.D.**

The sole way to convince the medical community of the power of technology is to use quality data to support it, said Dr. Tony Gallagher of Emory University. As other speakers, he emphasized the paradigm shift that simulation will bring to procedure-based medicine, reiterating that the Halsted model of training – see one, do one, teach one – is outdated and must be replaced.
Dr. Gallagher said laparoscopic surgery is an interesting case in point. While laparoscopic surgery has been widely accepted, it has a higher complication rate than traditional surgery in gallbladder removal. One study of bile duct injury in laparoscopic cholecystectomy found that probability of injury was a function of surgeon experience. Surgeons have responded slowly to this data, failing to recognize that a radical and fundamental rethinking of training is required.

Surrogate measures of skill are not needed when a skill itself can be measured. Skill is determined by know-how in addition to attending to the subtle detail of the procedure, and simulations have been shown to reduce error, by up to 95%—clearly aiding in the development of “skills.”

The MIST-VR simulator was the first trial of virtual reality to assess whether the skills required for the simulator transfer to the operating room. The prospective, randomized, double-blinded study of Yale surgical residents compared standard training to VR training in performing laparoscopic cholecystectomy. The VR-group was trained until individuals reached an objectively established level of proficiency on two consecutive trials. Didactic training was also included. Observations and analysis convincingly established that virtually trained residents made fewer errors than those who received standard training. VR-trained residents performed the procedure 30% faster and made six times fewer errors. Standard-trained residents were nine times more likely to fail to make progress and five times more likely to injure the gallbladder or burn non-target tissue. Although the study’s size was small, its results were compelling, if not convincing.

Because carotid stenting is now driving the field of simulation, Dr. Gallagher reviewed the features of the latest and most sophisticated VR simulator in this arena—the 3D Full Physics virtual model of the aorta, coronary, and carotid arteries. This device acts like a patient and allows training in subtle details of technical skills. It has dynamic, as well as static, metrics, such as catheter wire movement. The device allows a supervisor to assess the skills of the physician handling the device and fellows can be trained outside the catheterization lab or operating room.

The FDA decision to mandate simulator training for carotid stenting will have tremendous implications for medicine, Dr. Gallagher continued. Perhaps without intending to do so, the FDA mandated a standard of care in its role of ensuring that a new device was introduced safely into the marketplace. Because it stated that four different physician groups—interventional cardiologists, vascular surgeons, interventional radiologists, and neurosurgeons—can perform carotid stenting provided that they have the skills to do so the boundaries between disciplines are beginning to blur and the assessment of technical skills is now required when performing high risk/high profile procedures.
A dozen industry representatives, including Gaumard Scientific, Haptica, Immersion Medical, Laerdal, Medical Simulation Corporation, MedicVision, METI, Simbionix, SimMedical, SimQuest, Simlab, and Verefi Technologies, Inc. have joined together to create the AIMS Industry Council to collaborate around their shared goals of increasing the use of acceptance of simulation. Dr. Moses thanked the industry partners for agreeing to speak and representing the industry together despite their diverse interests and business processes.

**Industry Overview—Fiona Slevin**

Ms. Slevin thanked AIMS for the catalyst role it has played in bringing the industry groups together. In meetings to date, representatives have agreed on several but not all aspects, a sign of a healthy, young and provocative group.

Within AIMS, the objectives of industry are to advance and secure resources for the deployment of simulation, increase appreciation of the need and benefits of simulation by working with the medical community to articulate the case for simulation, deliver high quality products that meet market needs, and working to deliver cross-industry standards. For its part, industry promises a commitment to increasing patient safety by building a credible simulation industry; products that deliver effective learning solutions and return on investment; innovations in technology and learning systems; and listening, collaboration, and sharing a common goal for the long term.

Industry requests that other partners present at this meeting assist with establishing standards and curricula, agree on proficiency requirements, continue to support investment in technology development and novel solutions for simulation, strive to accelerate acceptance and adoption of simulation beyond this group, and continue to partner and collaborate with industry to build beneficial products that deliver the necessary outcomes.

A number of barriers must be overcome. Low research and development for simulation funding has had a detrimental effect on the advancement of simulation, resulting in too few training centers, buyers, and users, as well as a gap between technology vision and development reality. Speed of acceptance and adoption are also barriers, as well as the lack of standards for training, curriculum, and proficiency and current fragmentation of the delivery platform.
Panel Discussion

Dr. Matthew Weinger of Vanderbilt University asked how to work with clinical, virtual reality, and medical record companies to create simulated environments. Dr. Gerry Higgins responded that Dr. Satava’s suggestion to endorse an electronic health record offered some compelling insights. Moving beyond simulations into multimedia training and related scenarios would also help advance the medical field. Mr. David Hananel indicated that a number of companies are attempting to create an underlying multimedia platform with a standardized use of information.

In response to an inquiry regarding the ways in which AIMS can help companies determine the appropriate market for specific technology, Mr. Hananel suggested that many products currently on the market were derived in the academic research environment. Dr. Higgins added that many of his customers express a desire to have more innovative interfaces.

Colonel Bartlett said that some similarities can be found in work with flight simulators, including overlap and redundancies by different companies. It behooves the industry to work together to solve these problems, he said, and take advantage of lessons learned in other arenas. It is difficult, he added, for the industry to collaborate to address standards if there is no single organization, and he asked if there is a medical organization that could address this. Mr. Severinghaus responded that the Simulation Interoperability Standards Organization (SISO) would provide international standards with participant input and, once developed, they will be available to all who want to use them.

Dr. Dale Alverson of the University of New Mexico asked for the panel’s perspective on the potential relationship of academic research and development and the games industry. Mr. Steve Schmitt said that games should be considered as a potential training tool for the current and upcoming workforce. Tomorrow’s workforce, ranging from paramedics to surgeons, will come from today’s generation of multitasking teenagers, and the proper connection between games and education can provide another useful tool to move the industry forward.

Ms. Slevin offered a slightly different perspective. Games will have amazing effect on medical simulation, she said, and will set expectations of what residents can anticipate in training. Her company is hiring employees and consultants with backgrounds in the games industry, but the proper infrastructure and underlying technology is necessary to allow the fields to come together.

Dr. Higgins acknowledged the work of Dr. Victor Spitzer, University of Colorado Center for Human Simulation, who spearheaded a training database and training model of the human. In response to the previous question about the role of games within the medical industry, he stated that, like Ms. Slevin, his company draws on the experience of those from the games industry and believes that the younger generation being trained in medical and allied health professions will expect technology to provide a means of interaction and training.

Mr. Hananel issued a caveat regarding the involvement of the game industry. Following an attempt to collaborate with Nintendo and Microsoft in medical simulation, he determined that if
there was not a plausible market for at least 100,000 units per year, there was little interest from
the games manufacturers.

Dr. Aalpen Patel of the University of Pennsylvania, said that, following last year’s AIMS
meeting, he thought it was possible to develop an open standard, such as Windows or Linux.
Now, however, he believes that serial open standards that perform everything on one simulator
and with different modulators are a better approach. Dr. Higgins said information technology
simulation has a long history, dating back to the open source community developed in 1970s for
the semiconductor industry. A core technology is necessary to allow companies to utilize their
own proprietary applications accessed from a common platform. Dr. Patel questioned whether
the Industry Council, or another standards organization, could possibly determine the appropriate
information technology standards and enforce them industry-wide.

Mr. Schmitt said that standards and interoperability will happen, as the industry takes on a life of
its own. To do so, the industry must express its needs to Congress about its needs by focusing on
the elements of the current “perfect storm” movement. Current macro issues, including the
nation’s huge health care bill, the severe nursing shortage, billions of dollars worth of new
medical devices that go onto the market each year, must be addressed along with the
establishment of strategic funding in order to build infrastructures.

Dr. Alverson said that the real issue is marketing and acceptance by the medical community.
Building a simulation device without specifications laid out by the medical community is
difficult. The initiative needs to be more from the medical side, he said, because the technology
is there.

Sandy Ressler, of the National Institute of Standards and Technology, expressed the opinion that
it is a mistake not to reach out to the games industry, which is seeking a large market, but is
becoming too expensive to produce good games. There is currently a movement called “Serious
Games” and “Games for Health Care,” that will explore the interface between medicine and
gaming. Dr. Higgins added that he will be presenting a conference on games for health care in
the fall 2005, and is also doing related work for the National Science Foundation.

Mr. Meents said that his company, Immersion Medical, has been looking at different levels of
medical simulation, including video games, device trainers, procedure trainers, and patient
simulation.

Dr. Cardella advised participants to heed the analogy of the games industry. There is a sense that
medical simulators may not produce the market share they anticipate, and he wondered if
industry representatives would consider the Airbus experiment in Europe, in which the product
developed as a result of a large government investment and coalescence of companies. A Boeing
or McDonnell Douglas of medical simulators is needed, he said, to devise one simulator by
pooling resources. Ms. Slevin agreed that this is an excellent idea. Ms. Slevin added that there
seems to be an underlying assumption that medical device manufacturers will fund simulation
and inquired whether any attendees from a medical device company could address the
assumption. A representative from Johnson & Johnson, which owns about 60 simulators,
indicated that safety is the industry’s principal driving factor, with the patient being the ultimate priority, and he encouraged AIMS to push forward.

Referring to the Airbus model, Mr. Schmitt questioned whether the U.S. government would potentially fund research and development of a product that the medical industry cannot fund itself. With Medicare and the TRICARE Military Health System, the federal government is the largest health payer, and Mr. Schmitt expressed his belief that the federal government has an incentive to fund initiatives that can potentially solve such problems.

In response to an inquiry regarding ways in which companies can distribute their products to physicians, Dr. Higgins responded that his company uses approximately 40 sales representatives to distribute its products.

AIMS PRINCIPLES AND COLLABORATORS

Dan Raemer, M.D., Society for Medical Simulation, Chair
Steven Dawson, M.D., Advanced Initiatives in Medical Simulation

Society for Medical Simulation—Dan Raemer, M.D.

The Society for Medical Simulation (SMS) is an academic organization that was established to advance simulation in health care. Its mission is to foster improvement in health care through simulation in education, testing, and research, with a multidisciplinary, multispecialty, and international approach. Its current focus is on planning an international meeting on medical simulation, set for January 14–17, 2006 in San Diego, California.

SMS will launch a new journal, *The Journal of the Society of Medical Simulation*, which will publish technical, social science, medical, and any other type of articles related to simulation in health care. Dr. Raemer encouraged meeting participants to consider submitting their papers to this new journal. The society is also working to provide educational and informational resources for the simulation community. Dr. Raemer encouraged attendees to offer input to the society at [www.socmedsim.org](http://www.socmedsim.org).

Principles for Advanced Initiatives in Medical Simulation—Steve Dawson, M.D.

Dr. Steve Dawson of Partners HealthCare began with an explanation of AIMS as both an idea and an organization, with individuals, universities, industry, and others working toward the common goal of encouraging support for simulation as a means of improving patient safety and patient care and educating critical groups about value and potential benefits of simulation. The current focus of AIMS is to increase awareness about medical simulation.

One of the central objectives AIMS is to provide a unifying voice for simulation, with the founding philosophy that a “rising tide lifts all boats.” AIMS does not support any one individual group, but, rather, the simulation field as a whole.
Now only in the middle of its second meeting, AIMS’ structure is evolving, and AIMS seeks representation from all involved parties. An Industry Council, currently consisting of 12 member companies, has been established to ensure adequate industry representation within AIMS, which is essential to providing substantive feedback to AIMS. A Planning Committee, consisting of 16 people, has been established.

The goal of AIMS is not to present science, but, rather, to gather interested parties to encourage adoption of simulation within the medical industry and to the outside world. Recognizing that this is a long-term effort, AIMS’ role in research is to encourage support for simulation from government insurers, philanthropy, and others.

Challenges lie ahead, including expanding the scope of simulation to involve new specialties and conducting trials to prove efficacy. AIMS endeavors to influence the national discussion regarding simulation and encourage a new IOM report about simulation and patient safety. To do so AIMS requires the support of all participants in attendance.

### MAKING THE BUSINESS CASE FOR PUBLIC POLICY INTERVENTIONS

Ryan Adesnik, J.D., Stanford University  
Bob Waters, J.D., Gardner Carton & Douglas LLP

**Talking About Simulation I—Ryan Adesnik, J.D.**

Mr. Ryan Adesnik, Director for Government Relations at Stanford University and a former legislative staff member, believes in the efficacy of a government effort to support simulation. He became a believer in simulation as he observed a response to a simulated situation in a neonatal intensive care unit; an air bubble was put into an “infant” and he watched nurses and physicians respond in an “incredibly realistic” way as they pumped, yelled, and sweated to save the baby, even after the director announced, “scenario over.” His interest grew as he saw what others were doing with mannequin simulation and virtual reality.

Many of the issues related to simulation and the arguments for it have resonance for key decision makers in medicine, academia, industry, and Congress. It will take time, but policymakers will realize, as Dr. Cooper stated earlier, that the cost in treating patients as training materials is just too high. Key messages include:

- Patient safety is an important message and should be emphasized. The American people want to have the best possible health care. The message is that there is a better way, and they can be shown that simulation is that better way.
- Quality of care.
- The impact of the FDA’s decision with regard to carotid stenting.
- The debate on medical malpractice has been focused on tort reform, but the possibilities of simulation represent a positive message about reducing errors.
- Homeland security can be enhanced by using simulation to plan for mass casualty events.
- Simulation as an additional use of technology in health care.
To make the simulation field grow, a coalition of interested parties must be built, including insurance, industry, government, patient advocacy, academia, and professional societies. Working together, this coalition can determine the level and type of resources needed to further validate research, to develop new equipment, and to assist in the purchase of equipment for academic centers.

**Talking About Simulation II—Robert Waters, J.D.**

Mr. Robert Waters, a partner with Gardner Carton & Douglas LLP, stated that rarely in life do people get the chance to be part of something big, and even more rarely do they know it at the time. The people in this room are part of something big, he said, adding that simulation has to become integrated into medicine in the next 10 years for the health care system to advance. Participants at the conference, Mr. Waters believes, have the chance to make that happen sooner rather than later.

Mr. Waters said it is frustrating for most people when they realize they have a good idea but don’t know how to communicate it. He proposed a number of scenarios that would illustrate how to take knowledge about simulation in medicine and get payers, regulators, and policymakers to understand its importance. Mr. Waters further suggested four concrete steps:

- Be succinct and specific about what you want and what you want done
- One-page handouts are helpful. While complicated issues are hard to explain, it may be all the time the reader has to consider.
- Invite decision makers to visit your company, center, or lab.
- A picture is worth a 1,000 words.

**CLOSING AND ACKNOWLEDGEMENT**

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Jackie Eder-Van Hook, Center for Telemedicine Law  
Col. Mark Bowyer, M.D., National Capital Area Simulation Center, USUHS

**TATRC Medical Modeling & Simulation Portfolio - Gerald Moses, Ph.D.**

Dr. Moses presented a brief overview of the TATRC portfolio, noting that the Department of Defense is joining with the simulation community in its efforts. Dr. Moses is often asked how much money is needed for simulation, but he seeks to determine how much patient injury is costing the nation before answering how much is needed.

DoD mandates the training (either new or retraining) of approximately 80,000 to 90,000 people per year. DoD works on advanced technology in support of military and civilian medical applications. When DoD became interested in simulation, it developed a portfolio comprised of PC-based interactive multimedia, digitally enhanced
mannequins, virtual workbenches, and total immersion virtual reality. In the past five years, the field has made continual advancements, several that were even dramatic.

Because the field is advancing so rapidly, building the next generation simulator requires looking beyond present simulator technology. Enabling technologies for advanced simulation-based training systems include real-time in vivo tissue property measurement, tissue-tool interactions, graphics and visualization, learning systems, metrics development and learning transfer assessment, and open source architecture.

TATRC’s funding portfolio for simulation is currently a combination of appropriated dollars and funds from various other granting sources. Unfortunately, it is insufficient to achieve the necessary improvements. Large investments in developing simulators and purchasing simulators for training institutions are needed, as well as a national agenda for support.

Finally, collaboration is essential for success. Dr. Moses closed the session with a recollection from a meeting on simulation in February 2000, in which all but one participant pledged to work together and trust each other, to believe that the rising tide would lift all boats. Today, all who made such pledge have profited, gained and improved, with the lone dissenter departed from the industry—a powerful object lesson that collaboration is absolutely essential to success.

Acknowledgements—Jackie Eder-Van Hook and Col. Mark Bowyer, M.D.

Ms. Eder-Van Hook thanked participants, speakers, and moderators, with special appreciation to the AIMS Planning Committee and the Industry Council, which came together in a mere three weeks to collaborate in a new way. She invited everyone to attend the medical simulation exhibition the following day, and indicated that the AIMS 3rd annual conference and exhibition is already being planned.

Dr. Bowyer thanked Dr. Moses, TATRC, and Ms. Eder-Van Hook and her staff for their support.
More information on standardized patients can be found at the Association of Standardized Patient Educators (ASPE) Website at http://www.aspeducators.org, which promotes and supports the development and advancement of standardized patient education and research in the health sciences and provides support, resources and educational opportunities to medical educators.


Oregon Simulation Alliance draft document.


Search terms included: medical simulation, simulation-based medical training, simulation-based training, standardized patients, surgery simulation, clinical simulation, simulated scenarios, education and training simulators.

http://www.newyorker.com/fact/content/articles/050502fa_fact
http://www.vascularmanagement.com/vdm/displayarticle.cfm?articleID=article3544
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