Missouri Medicine

The Journal of the Missouri State Medical Association www.msma.org March/April 2013

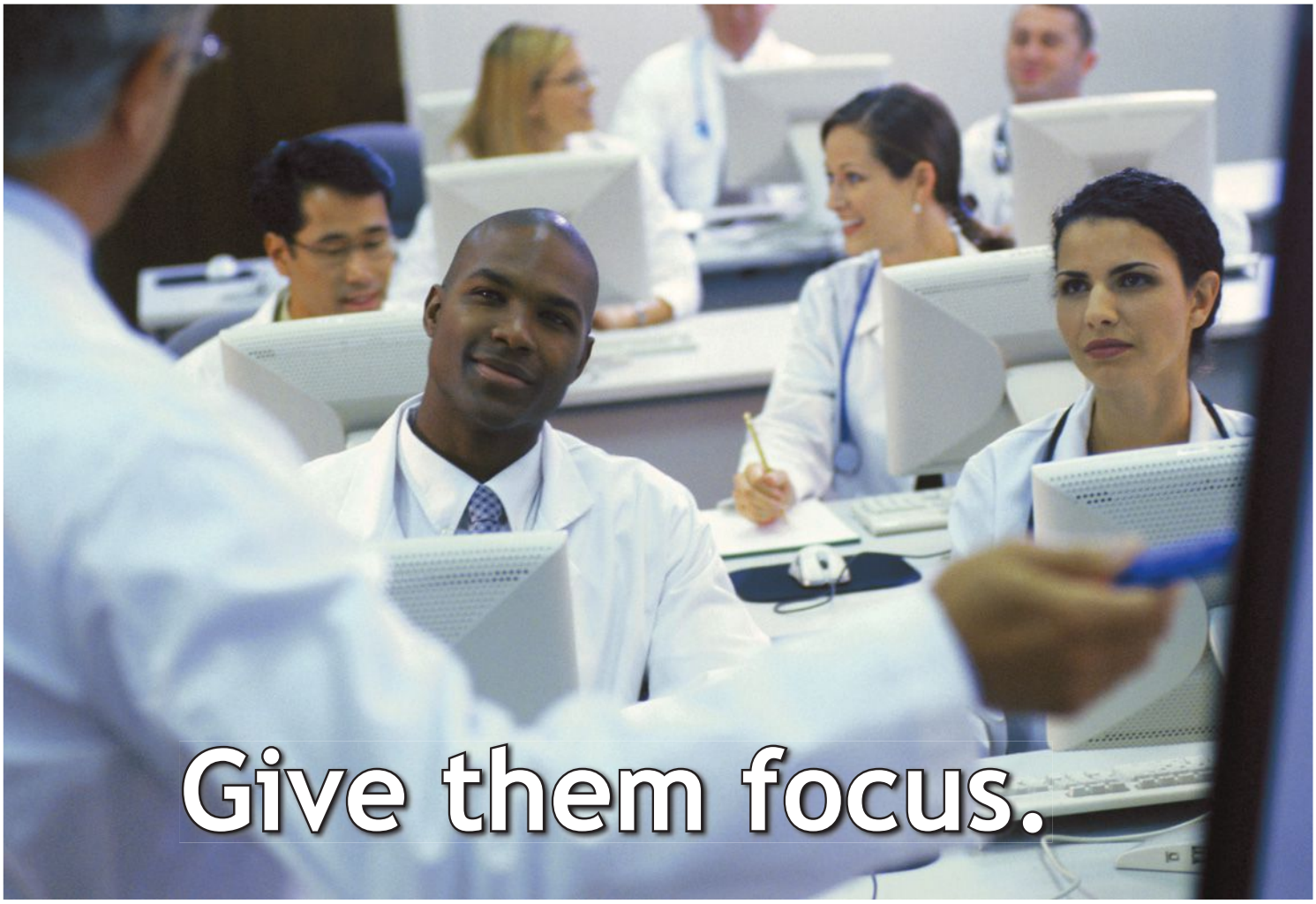
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About Missouri Medicine

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Judgement Day: The Hospital Corporation of America Decision

by Charles W. Van Way, III, MD

Greater Kansas City Health Care Foundation awarded $162 million in ruling against HCA.



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You've heard of the HCA decision. You've read the headlines. If you are anything like me, your reaction was, "What just happened?" Well, here it is. Please note that I'm not a lawyer (obviously), nor am I close to any of the parties in this business. But, I do have friends, some in high places, and I'm a news junkie. So here, with the help of certain sources, and heavy reliance on the decision itself, is what I have been able to learn.[1, 2, 3]

On January 24, 2013, Jackson County, Missouri Circuit Judge John M. Torrence awarded a judgment against Hospital Corporation of America (HCA), which, the judge noted, is the largest hospital chain in the United States. The amount was a "minimum" of $162 million, and seems, says the judge, certain to grow much larger.[3] The case was filed against HCA in 2009 by the Health Care Foundation of Greater Kansas City (http://hcfgkc.org), so it's been in progress for nearly four years.

This story begins with the collapse of the Health Midwest System in 2002. With twelve acute care hospitals, many clinics and affiliated physician practice groups, it was Kansas City's largest health care provider. Health Midwest began soliciting bids to sell its assets. They alerted potential bidders that, because of strained finances, "substantial infusions of capital were necessary for the existing facilities to simply bring those facilities up to a level necessary to provide high-quality health care to the residents of the Kansas City community."[1] They eventually sold Health Midwest to HCA, in a transaction that was the largest sale up until then of a non-profit hospital system to a for-profit system.

The Chief Executive of HCA at that time was Jack Bovender. Mr. Bovender described HCA's purchase offer as follows:

"I am very pleased to inform you that today HCA is submitting an offer to purchase Health Midwest at an enterprise value ranging between $850 million and $1 billion. As part of our proposal, we are also committing to make an additional $400 to $500 million of capital investments in health care facilities and equipment to the Health Midwest system over the next seven years. This capital investment could go substantially higher should we ultimately decide to build replacement hospitals in Independence and/or Lee's Summit. This places the total value of HCA's offer within a range of $1.25 billion to $1.5 billion excluding any replacement hospitals."[3]

The Judge found that Mr. Bovender made similar representations in a separate September 5, 2002 letter:

"In addition, HCA envisions making capital expenditures over the next seven years with respect to the Health Midwest system of $400 to $500 million, with the amount and timing depending on the ability to obtain regulatory approvals, the needs of the facilities and other factors. This amount could go higher if we decide,

after consultation with the local medical staffs, community boards, and employees, to build a replacement facility in Lee's Summit or Independence." [4]

On November 14, 2002:

"*Although we are not yet in a position to give a specific breakdown of how the $450 million in capital investments in the Health Midwest facilities will be spent, we fully expect a significant portion of those funds to be allocated to improvements in the Research and Baptist Facilities*." [5]

The core of Judge Torrence's ruling was that HCA did not fulfill its commitment to spend at least $162 million of the $300 million in the first two years following the sale on capital improvements to the hospitals it purchased. Instead, it made plans to build new hospitals in Eastern Jackson County. These were in areas more affluent than those served by the hospitals. The Judge went further, noting that HCA was obligated to spend $50 million a year on capital improvements during the next three years following the sale. He ordered a court-supervised accounting to determine whether HCA spent any of the rest of the $450 million capital improvement commitment (that is, $288 million).

Then, there was an issue with charity care. HCA made written commitments to continue to provide charity care for ten years, at the pre-sale level. The Judge concluded that this charity care commitment was at least in the amount of $650 million, or $65 million per year. These commitments appeared in documents signed by HCA and Health Midwest, and were submitted to the Attorneys General in both Missouri and Kansas. Both approved the purchase, after legal battles.

To resolve this issue, Judge Torrence also ordered that court-supervised accounting be done to determine how much charity care HCA actually provided over the ten years after the sale (ending in early 2013). That means that on top of the "$162 million immediate award", the Court's independent auditor is going to be combing through over a billion dollars of expenditures that HCA claims it made and will make up his own mind how much, if any, of those claimed expenditures met rigorous accounting standards.

In short, the audit will deal with both capital improvements and charity care. The results could significantly increase the amount awarded to the foundation. Since over $900 million will be audited, the amount may be increased by a fairly large sum.

Judge Torrence's ruling didn't give the Foundation quite all it asked for. Most significantly, the Judge denied the Foundation's request for interest on the $162 million from 2005, when the capital improvements were to be complete, to the present. At the statutory rate of 9% per year, compounded, that would have almost exactly doubled the amount. Nor did the Judge agree with the Foundation's alternative theory on capital expenditures that HCA's planning and expenditures for new hospitals in Eastern Jackson County "materially detracted" from the required maintenance and necessary improvements of the hospitals it purchased.

And then, HCA has stated that they plan to appeal the verdict.[1, 2, 6] As the saying goes, "It ain't over 'till it's over."

But these issues shouldn't detract from the size of the victory in this case. The entire Kansas City health care community, indeed the entire U.S. healthcare system, owes a big "thank you" to the Foundation. Because of its leadership and diligence, these funds have been recovered, and will be spent on behalf of the hundreds of thousands of uninsured, underinsured underserved members of our community. The Foundation was established, in part, to be a civic watchdog after the Health Midwest sale. It has fulfilled its civic responsibilities admirably.

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MM



Every year, your MSMA leadership makes its annual pilgrimage to the nation's capitol to advocate for our patients and our profession.

MSMA Goes To Washington

by Stephen Slocum, MD

Legislators have for years told us that they agree with us that the SGR is a flawed formula, and needs to be replaced, but that the cost to fix the formula is too expensive.



Stephen Slocum, MD, MSMA member since 1979, is MSMA's President for 2012-2013. He is an Ophthalmologist in St. Louis.
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When I've flown into Washington, D.C. in years past, when landing from the north especially on a clear night, I've always been struck by the beauty of the city and the illuminated historic buildings and monuments. Then the reality sets in that the city is home to a multitude of greedy, corrupt, manipulating, selfish politicians. Okay, maybe I exaggerate. Some people in D.C. aren't politicians. And some politicians do not fit into those categories.

I recently returned from D.C., where your MSMA leadership has just made its annual pilgrimage to the nation's capitol to advocate for our patients and our profession. With the political climate that exists today, it was only fitting that my flight was diverted from Reagan National Airport to Dulles due to excessive fog. I assumed that the fog was coming from the Capitol, since the dome was shrouded in a thick mist.

We travelled to D.C. to participate in the AMA's annual National Advocacy Conference. We usually spend most of our time during the conference on Capitol Hill, visiting the offices of the Missouri Congressional Delegation. This year was not unlike any other.

For the most part, we were treated graciously and receptively by the legislators and/or their staffs. A couple of offices did not seem overly glad to see us again, but we were at least given time to discuss our issues.

This year, we once again presented our objections and dismay over the continued presence of the Sustainable Growth Rate Formula for Medicate reimbursement. But for the first time we were able to express optimism that the SGR formula may be legislated out of existence. Two pieces of legislation are circulating this year which would permanently dismantle the formula.

As everyone knows, this formula has been around for over a decade, and threatens each year to drastically cut our Medicare reimbursements. If the SGR cuts would go into effect at the end of 2013, our reimbursements would be slashed by 30%, which would force many physicians out of the Medicare program and decrease medical care access for millions of Medicare recipients.

Legislators have for years told us that they agree with us that the

SGR is a flawed formula, and needs to be replaced, but that the cost to fix the formula is too expensive. The truth is the longer Congress waits to permanently erase the formula, the higher the cost. At least that has been true in the past. This year, apparently due to a change in "physician behavior,",the cost has actually come down to a mere $138 billion. With this Dollar Store pricing, maybe Congress will act before we go back to our usual excessive, irresponsible utilization of resources.

The Affordable Care Act was passed amidst tremendous controversy. The merits of this legislation were not even agreed upon among our various medical organizations.

One important caveat we left with our legislators is that fee-for-service medicine must be retained, at least for the short term. One of the SGR bills would actually immediately end fee-for-service, and transition payments to be only through new, innovative health care delivery models such as Accountable Care Organizations. We are all in favor of innovations in payment models in order to achieve fiscal savings, but too many practices would be unable to transition out of fee-for-service abruptly. Many rural practices and small solo practices would likely be forced out of the Medicare program if this change were to happen. Hopefully, Congress will find a reasonable alternative to immediately canceling fee-for-service.

Another topic we discussed in D.C. was that of the looming crisis in graduate medical education. Since 1997 there has been a cap on the number of residency positions supported by the Medicare program. AMA statistics indicate a growing shortage of physicians in this country relative to the growing population. This trend is particularly troubling in the primary care sector, where there is already a shortage of physicians. The bottom line is that patients will be increasingly denied access to primary as well as specialty medical care.

We are coming into an era in medical education where more physicians are graduating from medical schools than can match into a residency program. Medical students frequently graduate with debts of $150K-200K. It becomes difficult paying off loans of that size without suitable employment.

We realize that the state of the federal budget is in limbo at present. Will the sequestration cuts take place? Will there be a budget? Will the can be kicked down the road once again? We asked our legislators to, in any event, keep in mind the importance of medical education in general and graduate education in particular.

The Affordable Care Act was passed amidst tremendous controversy. The merits of this legislation were not even agreed upon among our various medical organizations. There are some aspects of this law, however, upon which we in medicine are in agreement. A couple of these are an error of commission and an error of omission.

The error of commission was the establishment of the Independent Payment Advisory Board. This fifteen-member government agency has the authority to make changes to the Medicare payment system. IPAB's decisions can be overruled only by a supermajority of Congress. Since IPAB is charged with the task of achieving savings to the Medicare system, it would seem that physicians will be put into "double jeopardy" ("triple" if you consider the possible 2% sequestration cuts), with decreased reimbursement already threatened by the SGR formula.

We are pleased to see a bill introduced this year in Congress which would eliminate IPAB. We have encouraged our legislators to support (some have already co-sponsored) this bill.

One of the glaring omissions of the ACA is the failure to address national tort reform, one of the most significant drivers or increased health care costs.

As you know, MSMA is waging its own battle on tort reform in Missouri. The Missouri Supreme Court struck down as unconstitutional our 2005 legislation which, among other things, set a cap of $350,000 on noneconomic damages in malpractice actions. We are now working diligently to recover the cap in the current legislative session.

Our 2005 legislation was tremendously successful. Malpractice claims against physicians dropped by 58%, but in addition there has been a yearly savings of $44 million overall in decreased liability insurance

premiums. That is money which can be put back into the health care system, and is not spent on the defense of lawsuits.

Think of the savings that would accrue nationwide if such caps on noneconomic damage were in effect in every state.

Of course, we realize that there is a danger in a national piece of legislation setting a cap higher than a state such as Missouri can negotiate in its own state legislature. The wording of a national bill would have to be carefully crafted.

In any event, we discussed tort reform with our federal legislators. In the current political climate, there is virtually no chance of this happening. We felt it important, though, to voice our concerns on this very important issue.

Our legislative visits in the nation's capitol always allow us to reinforce the message that we represent the physicians of Missouri, and that our federal legislators should always use us as their primary resource for health care issues. We and our very capable staff are always willing and able to offer our assistance and guidance to those in charge of making our laws and influencing regulations.

So, did we accomplish our mission on this trip to D.C.? Maybe some of the offices we visited were increasingly motivated to help us further our objectives. It is always difficult to read the responses of those legislators and staffers from whom we solicit so much when they have so much else on their plates.

I like to keep a positive attitude that our message has been heard, and that we will have improvement in all of the issues which concern us. That is exactly what I was thinking when my plane was taxiing to the runway (at National) in preparation for departure from D.C. That is when I noticed the first snowflakes of an approaching winter storm. I tried to consider whether the snow was a symbol of the cleansing of the filth and fog for which Washington is known. Or was the snow the symbol of another "job" we had just received in the halls of Congress?

I guess we'll have to wait to find out.

MM



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Healthcare Business Solutions

Kansas City Metropolitan Physician Association: An Alternative for Independent Physicians in Kansas City

by Nathan Granger, MD & Nate Kelly, MBA

A physician-led group in Kansas City is striving to offer physicians in the area an alternative to hospital employment in the form of an independent physician association.





Nathan Granger, MD, MBA, MSMA member since 1997, is the KCMPA-ACO President, and Nate Kelly, MBA, is the Director of Strategy and IT, KCMPA and Director of Population Health Strategy, Cerner Corporation.
Contact: info@kcmetrophysicians.com

Independent physicians in the U.S. are declining as more and more physicians seek employment by health systems. According to a 2012 Accenture Consulting report, 57% of physicians were independent in 2000. By 2012 only 39% of physicians were in independent practices. Accenture estimates that number will decrease to 36% in 2013, a 5% annual decline after considering the increase in the total number of physicians.

A physician-led group in Kansas City is striving to offer physicians in the area an alternative to hospital employment in the form of an independent physician association. The Kansas City Metropolitan Physician Association (KCMPA) was formed in late 2011 with the goal of empowering independent physicians to be leaders in the Kansas City health care landscape. A little more than a year later the organization has more than 200 physician members in many different specialties dedicated to the creation of a clinically integrated, coordinated care system consisting solely of independent physicians. MSMA member Nathan Granger, MD, MBA, and his physician colleagues at Clay Platte Family Medicine Clinic, cultivated the broad physician involvement and commitment to the vision. According to Dr. Granger, a family physician and the President of KCMPA, the time for action is now.

"Of all of the health care delivery organizations in Kansas City, independent physicians are in the best position to make health care more affordable for our patients and community while focusing on patient-centered care and new reimbursement models," Granger said. "It feels like the regulatory environment and market forces should favor independent physicians, but the sheer number of regulations, ever-changing local health care landscape, and the demands of operating a small business make it hard for independent physicians to see the mountains through the trees. With so many independent physicians in Kansas City choosing employment, our opportunity to be leaders in the Kansas City health care marketplace is beginning to dwindle."

Barriers to Independent Practice

Just why do physicians seek employment in the first place? Physicians surveyed by Accenture cited business cost and expenses, prevalence of managed care, electronic medical record requirements, maintaining and managing staff, and the number of patients required to financially break-even as the chief reasons for seeking employment. All of these concerns, according to Granger, can be addressed with the formation of a

strong, supportive independent physician association.

"Looking across the country, independent physician associations have become essential to a large number of independent physicians seeking to control costs while being innovative and working to act in the best interest of their patients and community. Like the KCMPA, they also seek to help physicians navigate new regulations and participate in the new reimbursement models."

Kansas City Metropolitan Physician Association: Preserving Independent Practice

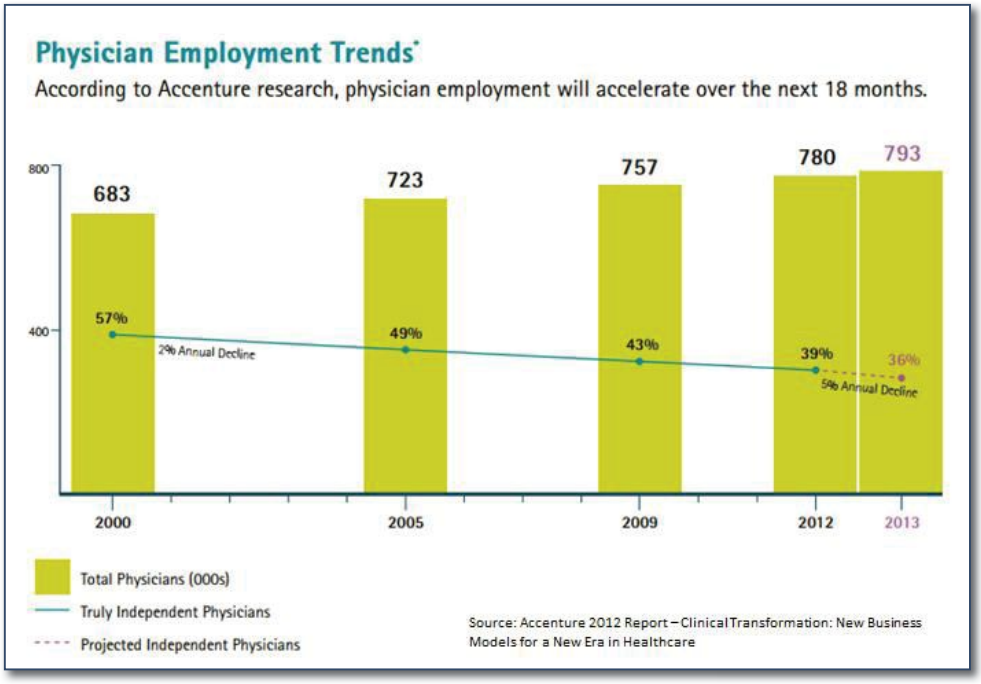
If recent announcements from CMS are any indication, the KCMPA is walking the walk when it comes to reform. On January 10 the KCMPA-ACO, the primary care subset of the KCMPA, was announced as one of the new Medicare Shared Savings Program Accountable Care Organizations – the first Medicare ACO based in the Kansas City metropolitan area. KCMPA-ACO was also named one of the Centers for Medicare and Medicaid Innovation's 15 new Advance Payment ACOs, making them one of 35 such ACOs in the country. Essentially, Medicare placed a bet that KCMPA's ideas about how to reduce costs will work, and the group will receive funds upfront from Medicare to enable the innovation described in the application. Within this program, KCMPA-ACO physicians are incentivized to reduce healthcare costs while improving the quality of care for nearly 12,000 Medicare patients.

The KCMPA views the ACO recognition as a beginning of a journey. "The KCMPA-ACO is an important step as we seek to prepare independent physicians for new reimbursement models in Kansas City," Granger said. "We will look to engage other payers in similar models as we grow and learn from each step of this process."

Dr. Granger and many other KCMPA physicians are career-long members of MSMA and Kansas City Metro Med. Dr. Granger served as Treasurer of Kansas City Metro Med for the past three years. A.J. Delaney, MD, MBA served as one of MSMA's Alternate Delegates to the American Medical Association. Kansas City Metro Med has supported KCMPA-ACO's from the beginning, making introductions to local CMS staff and offering its board room for KCMPA's monthly board meetings. Jill Watson, Metro Med's long-time Executive Director, left Kansas City Metro Med at the end of February to become KCMPA-ACO's CEO, and first employee.

"I've spent my career understanding the health policy goals and best practices, where we'd like health care to go, and what keeps physicians from getting there," Watson said. "I think the time is right, with aligned goals and resources in place to finally make it happen."

Those interested in learning more about the Kansas City Metropolitan Physician Association may visit www.kcmetrophysicians.com or contact by emailing info@kcmetrophysicians.com. MM



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Physicians of the Future

by Margaret Wilson, DO

ATSU-KCOM prepares students for success in an ever-changing healthcare environment



Margaret Wilson, DO, '82, MSMA member since 2012, is the Dean and a Professor of Family Medicine at A.T. Still University - Kirksville College of Osteopathic Medicine.
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Today's health care environment is constantly changing and becoming increasingly complex. With challenges like rising health care costs, an aging population, fewer primary care doctors for rural and underserved patients, and of course, health care reform, it is more important than ever for health sciences universities to better prepare their graduates for the future.

While many of today's challenges are beyond our control, we can control the quality and experiences of our students' education. At A.T. Still University's Kirksville College of Osteopathic Medicine (ATSU-KCOM), we ensure our students not only succeed academically, but also receive the hands-on training necessary for success in their professional careers.

Before discussing ATSU-KCOM's curriculum and initiatives for student success, it is important to better understand our University, our College, and our strategies that effectively contribute to ATSU's long-term goals.

The University

Since 1892, ATSU has grown from a single-discipline school on one campus in Kirksville, Mo., to a multidiscipline university on two campuses in Kirksville and Mesa, Ariz. Our students and faculty are part of a distinguished heritage of humanistic health care based on an integrated approach that begins with a belief in the interactions of the body, mind, and spirit, and continues with an understanding of how these dimensions can be treated holistically.

The University provides an environment in which students and faculty are continually challenged to cultivate a lifestyle of whole person health care through education, wellness training, nutrition, emotional wellbeing, problem-based learning, and co-curricular activities. Each program, from audiology to dentistry, family practice to public health, integrates the principles of whole person care into its curriculum.

The College

As the founding college of osteopathic medicine, ATSU-KCOM remains committed to educating osteopathic physicians and related health professionals and preserving and advancing osteopathic principles, practice, and philosophy. Offering both a Doctor of Osteopathic Medicine (DO) and a unique research thesis-based Master of Science degree in biomedical sciences, ATSU-KCOM provides students with many special experiences and opportunities to better prepare them for the future.

Strategies

Moving forward, one major objective for ATSU-KCOM is anticipating and responding to changes in health care delivery and medical education. This includes several mechanisms such as faculty and program development, tracking and evaluating changes in health care, and developing strategic partnerships with community health centers.

As part of our strong commitment to the education of the most competent osteopathic physicians, ATSU-KCOM



The campus of A.T. Still University - Kirksville College of Osteopathic Medicine in Kirksville, Mo.

also plans to focus on refining and enhancing student learning outcomes. This requires an innovative academic environment that promotes diversity, interprofessional education (IPE), learning-centered health education, use of technology, expansion of student and faculty scholarship, and establishment of a culture that supports student learning by rewarding faculty and staff development.

In order to maximize the effectiveness of our programs it is necessary to identify and cultivate mutually beneficial strategic partnerships to advance ATSU-KCOM's mission, vision, and identity. With much uncertainty concerning the future of our economy, it is imperative that the College optimizes existing revenue use and enhances infrastructure.

The Curriculum

The DO curriculum at ATSU-KCOM is a patient-centered model, which uses a systems approach and patient cases. Numerous presentation styles are used, including problem-based scenarios, case presentations, web-based instruction, small-group labs, workshops, lectures, and early clinical experiences. Osteopathic theory and methods are taught throughout the first two years and align with the basic science, clinical, and physical exam courses.

The course, The Complete DOctor, teaches communication skills, physical exam skills, professionalism, difficult topics, and medical ethics. As part of this course, students participate in standardized patient encounters, early clinical experiences with community agencies, school physicals for local school children, and case presentations.

Training in Osteopathic Manipulative Medicine techniques occurs throughout all four years. During the first two years, didactic instruction with supervised hands-on training prepares students for integration of the osteopathic approach into clinical practice.

Block testing, which mimics board exam testing, is implemented into the first two years. Tests are completed electronically with all disciplines and content integrated into one exam. At the end of each year, one through three, students also complete a performance skill assessment with standardized patients and OSCE stations.

For third and fourth years, students complete clinical rotations at one of 10 regional sites across the country. The didactic curriculum is delivered on-site with standardized assessment completed by a number of methods, including shelf exams, case presentations, and online modules.

ATSU-KCOM developed a Humanities Center that offers many electives including those that focus on spirituality, literature in medicine, vulnerable populations, global health, and ethics. These electives give our students the opportunity to grow, not just as physicians, but as individuals.

With a philosophy that promotes community involvement, our students are very active in service to the community through their social clubs and professional organizations. Activities include local health fairs, fundraisers for breast cancer, presentations to local school children, collections for the food pantry, coordination of the local soup kitchen, and holiday gifts to children in need.

Students at ATSU-KCOM are also involved in a faculty

mentor program. Each member of the entering class is assigned to a small group with a faculty mentor who gets to know their students better, providing advice and mentorship. These groups have informal discussions on topics such as specialty selection, the health care system, residency match, or just the day-to-day challenges of medical school.

ATSU-KCOM's graduate-level biomedical sciences program provides individuals aspiring for a career in health sciences an opportunity to prepare for professional studies in the areas of medicine, research, and education. The program combines didactic core coursework with electives and unique, individualized research projects to create an integrated approach to biomedical sciences education. Most importantly, graduates gain the skills they need to make an impact on the discovery and treatment of disease as future physicians, academicians, and/or researchers.





Above, ATSU-KCOM students learn procedures on human patient simulators. Below, first-year ATSU-KCOM students receive iPads.

The biomedical sciences track is a thesis-based, research program in which graduate students have the opportunity to work across different disciplines or to concentrate in one specialized area. Areas of study include anatomy, biochemistry, cell biology, histology, immunology, microbiology, molecular biology, neuroscience, pharmacology, and physiology. Faculty work one-on-one with students to advise research, provide educational resources, and assist in developing research-related skills such as evaluating literature, procuring funding, designing and performing experiments, analyzing and presenting data, and writing and submitting work for publications.

It's clear ATSU-KCOM takes great pride in its students. Faculty members actively engage with our students to ensure they are successful in the classroom and are well-rounded outside of the classroom. ATSU-KCOM provides a multitude of opportunities and experiences for students to get involved, inside and outside their field of study. As our College continues to grow and build on our traditions and history, we are always looking ahead and taking advantage of opportunities to improve and innovate.

Initiatives for success

To keep pace with changes in health care delivery and to provide the best learning experiences possible, ATSU-KCOM continually looks for ways to improve its curriculum, particularly integrating current technology and IPE.

One of the most exciting new curricular initiatives is clinical ultrasound training. Beginning in 2011, clinical ultrasound was integrated into the first-year curriculum as part of the anatomy course. ATSU-KCOM purchased 18 portable ultrasound units that are used to enhance learning of living anatomy through identification of structures coupled with physical examination. Medical students learn how to perform bedside ultrasound with different scanning methods, interpret findings, and correlate the findings with physical diagnosis at the point of care.

Ultrasound laboratory sessions and web-based learning modules are conducted in conjunction with clinical cases presented by clinical faculty. An ultrasound elective is offered during the second year to further develop skills and learn special examinations, such as the FAST exam. With knowledge of this technology, our graduates will be ahead of the curve as residents and physicians.

ATSU-KCOM students are also in the forefront with the implementation of an electronic medical record (EMR) system. The National Health Care Act requires all practices

to move patient records from paper to a confidential electronic system – EMR. Recognizing this shift in practices, the College introduced an EMR curriculum that focuses on patient-centered communication, clinical decision support systems, and information entry.

At ATSU-KCOM, EMR is introduced during the first semester of class, and students work on patient cases throughout the first two years. Currently, ATSU-KCOM is the only medical school in the country to implement EMR at this level.

ATSU-KCOM also has a fully-developed human patient simulator center with 12 full-sized mannequins. The simulator mannequins are used to teach exam skills and procedures such as CPR, intravenous access, intubation, ventilation, and cathertization. In addition, the center has a pelvic exam simulator, colonoscopy models, and a newborn simulator. Students have the opportunity throughout their tenure to learn skills and apply their knowledge by experiencing clinical scenarios in the simulation lab.



ATSU-KCOM students learn to use ultrasound.

The latest development at ATSU-KCOM is the iPad implementation for all first-year students. The class of 2016 was the first full class to receive iPads to use in their coursework. iPads not only provide students with convenience, organization, and additional resources, but they also help reduce the University's carbon footprint and create cost savings.

As physicians begin using iPads at patient bedsides, our students will hit the ground running in clinical experiences, rotations, and residency. They will already have the know-how to pull up EMRs, x-rays, and charts; explain procedures and symptoms to patients; and complete charts before leaving the patient's room.

It is important to note that these advancements in technology are not simply implemented for the sake of being "cool." These technologies are strategically added to ATSU-KCOM's program to further build upon a tradition of an innovative academic environment dedicated to preparing highly competent professionals for the future health care environment.

As for IPE initiatives, ATSU-KCOM continues to incorporate interprofessional experiences to help students learn more from and about other health professions. For instance, ATSU-KCOM participates in the annual Interdisciplinary Biomedical Research Symposium. The symposium serves as a wonderful opportunity to bring together students and faculty, not only from the ATSU and Truman State University campuses, but also from other undergraduate colleges in the Midwest to share their research activities and presentations.

Over the past several years through a home visit program, House Calls, many of our students have partnered with Truman State University nursing, health science, and communication disorder students to team visit senior and vulnerable patients in the community. Additionally, other interprofessional experiences are in development to help students gain a better sense of teamwork, roles, and responsibilities.

Another IPE opportunity for students is the IPE Collaborative Case Competition. Teams of students from a variety of disciplines and schools across the University are given the opportunity to teach, share, and learn from each other while conducting an analysis of a hypothetical case developed by faculty advisers. At the end of the case, students present their findings and recommendations for enhanced collaboration to a panel of judges representing leaders from various disciplines.

Opportunities like these, along with familiarization of modern technology, will become more important for our students as they enter a health care field that requires health care providers to be more flexible, adaptable, and tech savvy than ever. Focusing on strategies and initiatives that will make us stronger and more efficient as a college and university will help us continue our tradition of educating competent and compassionate health care professionals.

So much rides on the success of our students. Our students are our future. As educators and administrators, we must continue to actively create a learning-centered environment that better prepares our graduates for success in an ever-changing health care system, despite the challenges and uncertainty ahead. MM



Headed For a Fall: Over the Social Security Disability Fiscal Cliff

by Arthur Gale, MD

Oklahoma administrative judge Howard O'Bryan personally awarded an estimated $1.62 billion in life time disability benefits to claimants in just three years!



Arthur H. Gale, MD, MSMA member since 1976, is a *Missouri Medicine* Contributing Editor. He practices Internal Medicine in St. Louis.
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Some 455,000 workers received Social Security disability in 1960[1]; by 2011 over 18 million people were receiving some form of benefits from Social Security disability. In the past four years alone the numbers have increased by a staggering five million. In 2011 the Social Security Administration disbursed over $130 billion for its two disability insurance programs. There is an additional $80 billion cost for Medicare for which a disability recipient qualifies after two years.[2] The money set aside by the Social Security Administration in the disability trust fund is projected to run out by 2016.[3]

In the past, the disability program focused on serious illnesses such as stroke, incapacitating heart, and pulmonary disease and cancer. Now nearly half of the beneficiaries are disabled because of "mood disorders" or disorders of the "musculoskeletal system and connective tissue,"mainly back pain. It is very difficult to objectively disprove a person's claim to be suffering from depression or back pain.[4]

In 2011 alone there were nearly 3.4 million first time disability claims (See Figure 1). The average age of new disability recipients is a mere 49. A major driver of disability is employment-unemployment rates. When there is a downturn in the economy, as in recent years, and unemployment benefits run out jobless people start applying for disability. Another major driver is health insurance.[5] A person on disability for two years becomes eligible to receive health insurance under Medicare. This increases the average financial value of security disability by nearly 50%.

Congress has begun to address the disability problem in hearings chaired by Senator Tom Coburn, an obstetrician-gynecologist from Oklahoma. Coburn's interest in disability was piqued when he found that a man he had hired to cut down trees on his property was on social security disability.[6] Coburn has been mainly concerned with the process by which administrative law judges determine disability. These judges

are expected to rule on about 5,002 cases per year. Nevertheless, there is a huge backlog of cases. In 2008 the national wait for a disability hearing was 538 days. In testimony before Congress the Commissioner of the Social Security Administration boasted that because of improved efficiency, even with a smaller staff, the wait had been reduced to 354 days in 2012.[7]

But this so-called improved efficiency comes at a price. One administrative law judge, Howard O'Bryan of Oklahoma City, ruled on over 1,800 cases per year without a hearing. This is an astonishing, indeed suspicious, record considering that each case is nearly 500 pages long. O'Bryan personally awarded an estimated $1.62 billion in life time disability benefits to claimants in just three years![8]

Approximately one-half of the applicants make it onto the disability rolls. In Puerto Rico this figure[9] has jumped to 69%; one Puerto Rican administrative law judge reportedly approved 98% of the cases. There is a huge disparity in the disability rolls in different states. In West Virginia 9% of the population is on disability. In Utah and Alaska it is 2%.[10] Coburn says that you could flip a coin and get it about as right as the judges. Coburn believes that up to 40% of claims may be fraudulent.[11]

Disability has become big business for the legal profession (See Figure 2). Lawyers now advertise their ability to get disability for clients on every national and local media outlet. These attorneys can be very aggressive. A few years ago I sent the records of a patient to one such attorney. But that was not enough. He sent me a letter written by him stating the cause and extent of the patient's illness with my name printed at the bottom. He expected me to sign the letter. According to the Washington Post, *"the vast majority of disability applicants turn to a network of lawyers to increase their chances of getting aid."* If applicants are turned down, the attorneys will represent them on a contingency fee basis in the appeals process.[12]

A physician's statement is required for every disability application. Most of the time Social Security relies on the information contained in the charts of the physicians who have cared for the applicant. Some of the time Social Security will seek a consultative exam from a physician who has not seen the applicant previously.

How can physicians give an accurate description of the patient's illness? How can physicians detect fraud?

Figure 1

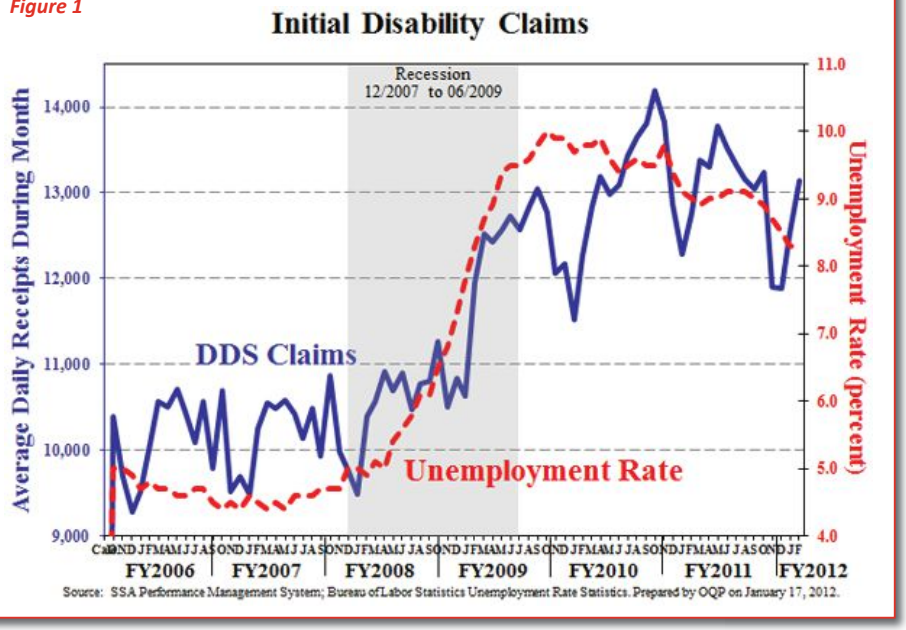


Figure 2

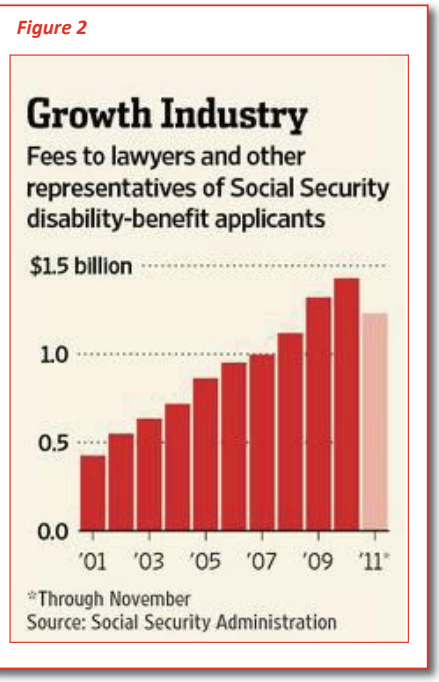
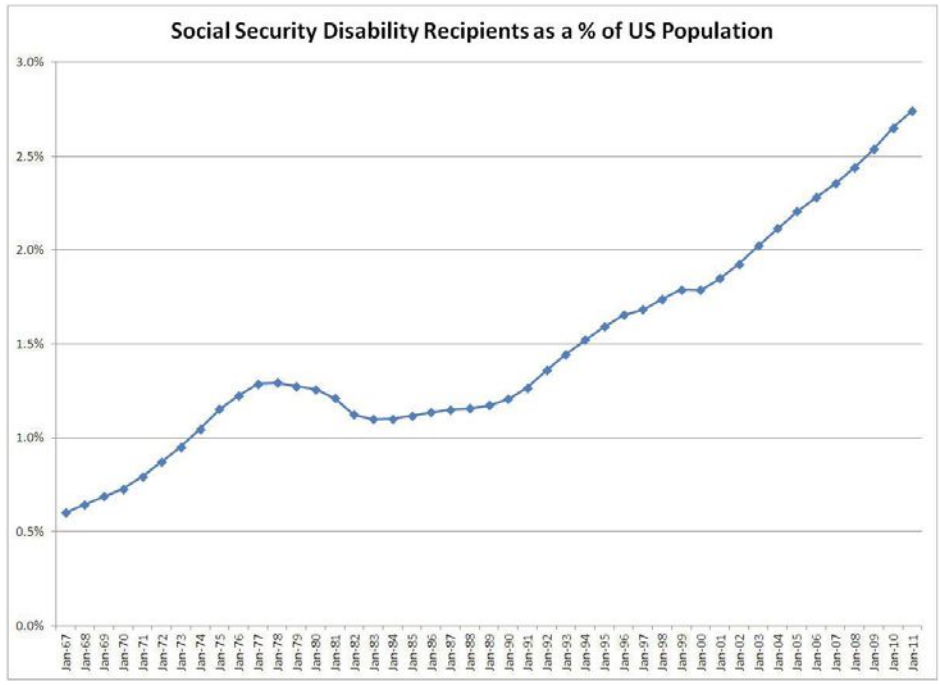


Figure 3 - Source: Wordpress.com



A recent article in *American Medical News*, a publication of the American Medical Association, titled "Detecting Deception,"[13] cited one study that showed "*29% of personal injury cases and 30% of disability claims involved probable malingering and symptom exaggeration*." Another author wrote: "*Faking symptoms of common medical and psychiatric conditions is not difficult. Ninety-seven percent of untrained people can correctly choose symptoms associated with a major depressive disorder on subjective checklists. Sixty-three percent can identify at least five symptoms associated with a brain injury*."

A Harvard psychiatry professor stated that with the availability of all sorts of medical information through the internet anyone can come up with a plausible list of symptoms and complaints. Then when the physician asks," 'Do you have this?' The patient has evey symptom under the sun." A neurophysiologist wrote that the system is being clogged up by people who don't need diagnostic imaging or therapies.

AMA Guides newsletter states, "*When doctors interact with the legal system they are constantly exposed to the legal system's misdirected emphasis on opinions. The issues of malingering and validity can be addressed purely based on fact, without any interference from opinions."*

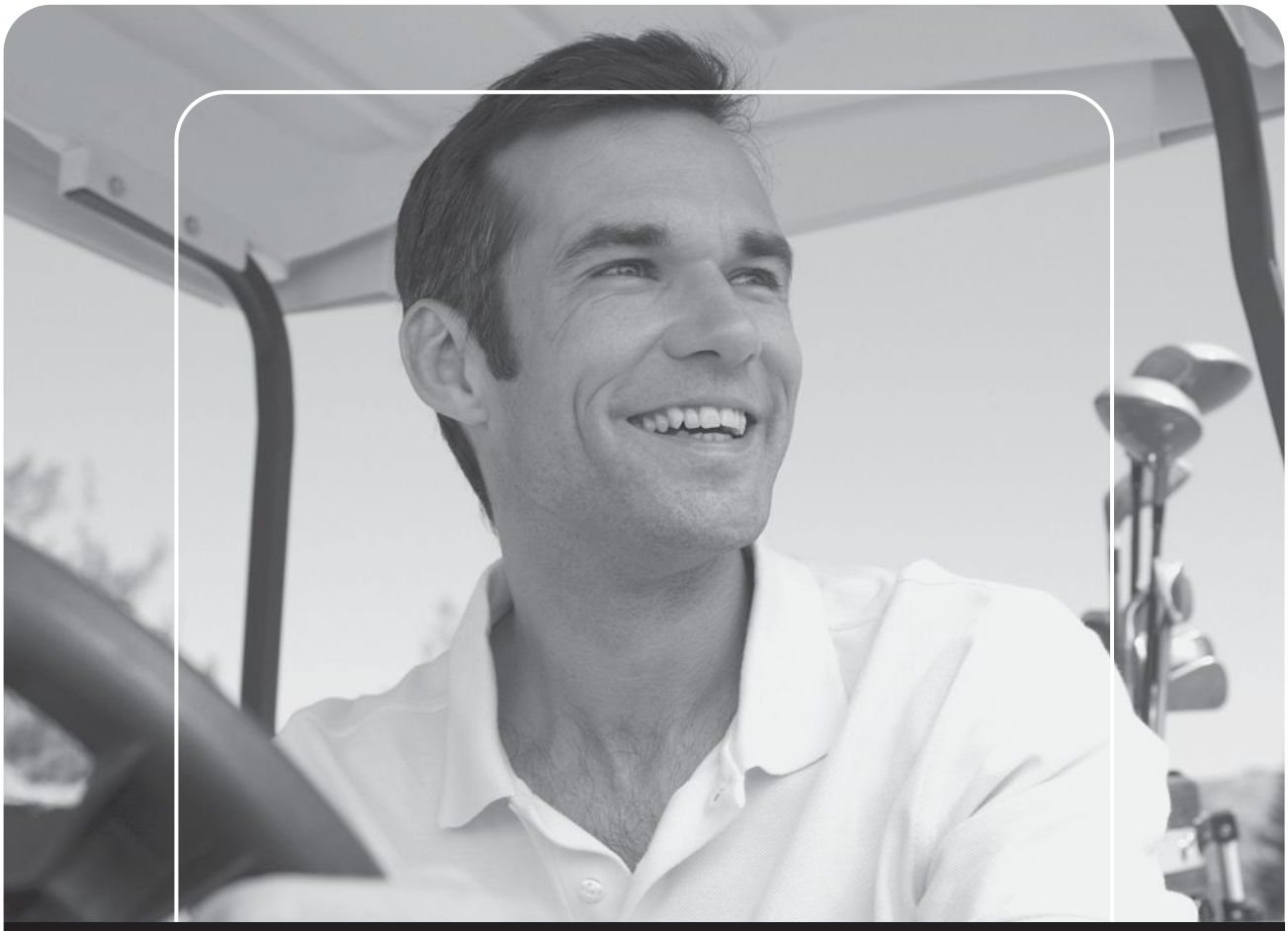
That is easier said than done. A representative from the American College of Physicians stated that doctors are seeing so many patients with chronic conditions that they simply do not have enough time to investigate their symptoms adequately. Oftentimes it's easier just to treat them. A Canadian occupational medicine expert states that family doctors "trust their patients and rely on the histories they take to make a diagnosis. They often see themselves as an advocate. If a patient is saying "I can't do this job' the tendency is to side with the patient."

There is no simple solution to the disability fiscal cliff. Like other U.S. social entitlements it is clearly unsustainable (See Figure 3). Weeding out fraudulent disability applications by physicians or administrative law judges appears to be an impossible task. I suspect that when the money runs out, the only solution will be to limit and reduce disability benefits.

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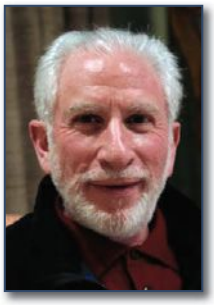
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The Tragedy of Mental Health Law

by Lloyd I. Sederer, MD

Patient protections have become rigid rules excluding families from patient care and exceeding common sense.



Lloyd I. Sederer, MD, the medical director of the New York State Office of Mental Health and an adjunct professor at Columbia University's Mailman School of Public Health, is author of "The Family Guide to Mental Health Care," from W.W. Norton.
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Reprinted with permission from Wall Street Journal

After Newtown, there is widespread concern that laws regarding mental health services need reform. Two places to start are the laws governing involuntary hospitalization, and the restrictions placed on communication with a patient's family.

Across the U.S. today, federal and state laws give people with mental illness the right to decide when, where, how, and if they will receive care. Yet some serious mental illnesses (such as schizophrenia or mania) can make it difficult for those affected to assess the reality of their own experiences or their need for treatment.

An individual with a mental illness that interferes with his judgment, self-interest, self-preservation and safety represents a profound challenge for families and clinicians. Doctors have remarked that when patient rights exceed truly necessary protections, individuals with mental illness can "die with their rights on." Sometimes they may harm others along the way.

Many mental health laws are prohibitive in nature—they describe what cannot be done in certain situations. This is important but comes at a cost. The 1996 federal law known as HIPPA (the Health Insurance Portability and Accountability Act) is meant to protect the medical information of individuals, but it has also come to limit what a doctor can say to a patient's family (with the exception of unemancipated minors).

State laws vary, but all set strict controls regarding involuntary hospitalization, limiting it to circumstances when a person is an imminent danger to himself or others, or likely to become so. State laws also limit involuntary hospital stays to a few days, unless a court orders otherwise based on continued evidence of imminent danger to self or others. Another court order is necessary for doctors to treat hospitalized patients against their will. In other words, we may be able to drag a horse to water but we cannot make him drink unless a judge says so.

Consider the young man in his 20s brought to an emergency room by the police after harassing a bus driver and initially acting aggressively with the officers who arrived on the scene. The young man had never been to this particular ER, so there was no record of any previous treatment he may have received or any medical or mental conditions he may have had. In the presence of the police and hospital security, he appeared quiet and cooperative, even saying he regretted losing his temper.

But his disheveled and fearful look prompted a nurse to call for a psychiatric consult. The consultation revealed that while he lived with his parents, he didn't want the hospital to contact them. He said he'd never had any such outbursts before, and that he had never received mental health care. The psychiatrist continued to request permission to call his family, but he continued to refuse adamantly.

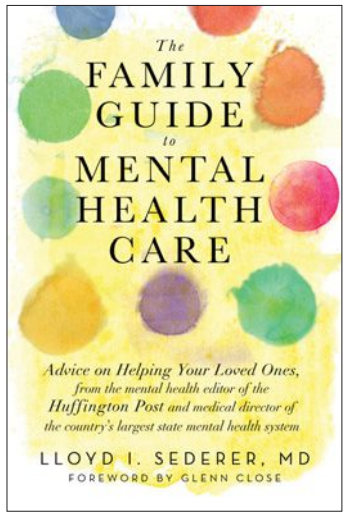
Had the call been made, the young man's parents would have volunteered that this was their son's

THE FAMILY GUIDE TO MENTAL HEALTH CARE

Timely and expert advice from the medical director of the country's largest state mental health program

Lloyd I. Sederer, MD, with a Foreward by Glenn Close

Mental disorders left untreated can devastate our families and communities, as recent tragic events at Sandy Hook Elementary School and in Aurora, Colorado have only too painfully shown us. The families and friends of the more than fifty million people a year who are diagnosed with a mental illness have nowhere to turn for authoritative advice about what to do.



The Family Guide to Mental Health Care is the first comprehensive resource for families struggling with a loved one's mental illness. In it, families can find the answers they need about understanding a variety of disorders, assessing whether doctors are really helping them, and getting the right treatment. From depression to schizophrenia, from Ativan to Zoloft, from the first signs of a problem to successful help, this book walks readers through everything they need to know, and do, to help their loved ones. In these pages, a psychiatrist who knows the mental health system inside and out will help family members who come into doctors' offices every day, asking, "What should I do?"

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third emergency room visit in four weeks, and that he had been involuntarily hospitalized six months earlier after hitting a stranger in a supermarket during an acute episode of psychotic illness.

In another instance, a middle-aged woman with a serious mental illness was involuntarily hospitalized after a very high-risk suicide attempt was accidentally discovered in time. She was diagnosed with a major depression and offered medication and therapy, which she refused.

She could not leave the hospital (for days initially, then for a few weeks after a court order), but she had the right to refuse treatment. In response, the treating psychiatrist had to go to court to obtain a judge's order for "treatment over objection." This resulted in several weeks of delay, but after the order came down the patient agreed to accept treatment the next day.

The law arguably plays a more prominent role in psychiatry than in any other field of medicine. Issues of personal and public safety, civil rights, accountability, privacy, confidentiality and competency are woven throughout the practice of psychiatry. But today's laws were mostly written decades ago, in response to an era when doctors and hospitals had almost unbridled control over patients and their treatments.

What began as patient protections have in many instances become rigid rules and procedures that seem to exceed patient needs and even common sense. Good intentions spawned these laws, but in practice they can interfere with or delay the delivery of necessary care and crucial communication between caregivers and families—as families of people with serious mental illnesses can attest in often heartbreaking detail.

Families are—or can be—our early-warning system: They see the fuse burning months before the bomb goes off. Yet when mental illness produces troubled behavior, families are too frequently sidelined by the refusal of their ill relative to involve them in the considerations about treatment.

No one thing can completely eliminate the risk of tragic events such as those we have witnessed in Newtown, Aurora, Columbine and elsewhere, or the risk of the suicides and violent acts that occur by the tens of thousands nationwide each year. But we can reduce risk through early identification and intervention if families are equipped to highlight problems and mental health professionals are permitted to do the tough work of responding to those whose serious mental disorders have them refuse help that can be lifesaving.

Many successful industries employ "user-driven design," and laws are made to serve the people. Let's ask the families of people with serious mental illnesses what changes in law and clinical practices could better help their family members. MM



Glacial Pace of Approval is Killing Us!

Part I
by the Manhattan Institute for Policy Research

Off-Label, Not Off-Limits: The FDA Needs To Create a Safe Harbor For Off-Label Drug Use

by Paul Howard & James Copland

This three-article perspective series is drawn from the Manhattan Institute, the *Wall Street Journal*, and *Cataract & Refractive Surgery Today.*
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Executive Summary

On December 3, 2012, the U.S. Court of Appeals for the Second Circuit issued a landmark ruling in United States v. Caronia,[1] which, if confirmed on a near-certain appeal to the Supreme Court, will have a profound impact on pharmaceutical promotion in the United States. In its decision, the Second Circuit overturned the federal prosecution of a pharmaceutical sales representative who had communicated truthful information about a drug used in a manner not formally reviewed by the Food and Drug Administration (FDA)—i.e., "off label." The court ruled that "criminalizing the truthful off-label promotion of FDA-approved prescription drugs" was an unconstitutional limitation on free speech in violation of the First Amendment.[2]

The Caronia case highlights two major emerging trends in medicine and law: the widespread prescription of FDA-approved medications for off-label uses; and the increasing application of federal criminal law to regulate pharmaceutical promotion. However the Supreme Court ultimately decides the First Amendment question in Caronia, the FDA needs to rethink its off-label speech regulations, which have become overly broad and unnecessarily opaque. This paper looks briefly at the incidence of off-label drug prescription and at federal application of criminal law to enforce rules on pharmaceutical promotion and proposes that the FDA should adopt a "safe harbor" to allow drug companies to communicate truthful information about off-label drug use to physicians. Our preferred approach is not about helping drug companies but rather to improve medical research and public health by increasing learning about what happens after drugs are licensed and making the best use of pharmaceuticals on the market.



Off-Label Drug Prescriptions: An Overview

Pharmaceuticals that are available for use and marketing under FDA regulations are also commonly prescribed for uses and indications beyond those listed on the drug's FDA-approved label. Some of these off-label uses include treatments for diseases or symptoms not formally reviewed by the FDA, some involve dosages or delivery mechanisms not reviewed by the agency, and some involve patient populations (e.g., pediatric or geriatric) not tested in clinical trials submitted for agency approval. Such uses, while supported by publications in peer-reviewed medical journals, typically do not offer sufficient economic payback to warrant full review under the FDA's 50-year-old system for testing and approving new medicines—a system that requires large, cumbersome, and expensive randomized clinical trials, typically controlled with a placebo or standard of care. Nevertheless, prescribing physicians often find such uses invaluable in treating their patient populations.

How common is off-label drug prescription? A 2006 study in the Archives of Internal Medicine estimates that 21 percent of commonly used drugs are prescribed for off-label uses.[3] Doctors find off-label drugs particularly valuable in life-threatening emergencies: 36 percent of all drugs used in intensive-care units are for off-label indications, according to a 2011 study in the Journal of Critical Care.[4]

In narrow population groups, the share of drugs used off-label rises. Notwithstanding Congress's effort to create incentives for pharmaceutical testing of drugs used on children in the FDA Modernization Act of 1997,[5] a 2007 study in the Archives of Pediatrics & Adolescent Medicine found that almost 79 percent of children in pediatric hospitals received one or more off-label drugs while admitted.[6] Because patients with psychiatric disorders are often excluded from clinical trials and often display significant crossover in symptoms, off-label drug use is also particularly common in psychiatric practice. Off-label prescriptions of antipsychotic drugs alone cost an estimated $6 billion in 2008.[7]

Off-label drug uses are often widely accepted, and private insurance companies as well as Medicare and Medicaid will reimburse for these off-label uses because the medical community or medical compendiums on effective treatment consider them "standard of care." In cancer treatment, for instance, many patients are routinely treated with one or more drugs for an off-label indication. Tricyclic antidepressants have largely been supplanted by more focused drugs to treat depression, but their off-label use to treat neuropathic pains associated with strokes, spinal-cord injuries, or cerebral palsy is a common and preferred medical treatment.[8] Selective serotonin reuptake inhibitors (SSRIs) such as citalopram (Celexa) are commonly prescribed for alcoholism and other addictive disorders, obsessive-compulsive disorder, fibromyalgia, and stuttering.[9] Morphine is commonly used off-label to treat pain in children,[10] magnesium sulfate to treat premature labor,[11] and azathioprine to treat atopic dermatitis and psoriasis.[12] Even the use of aspirin as a preventive measure for patients at high risk of coronary disease—a commonly accepted guideline—is an off-label use.[13]

The FDA's Speech Regime On Off-Label Drug Promotion

The big problem, from a public health perspective, is that doctors often lack adequate information about off-label drug use because those best-positioned to inform them about the benefits and risks associated with such uses—the drug manufacturers themselves—are effectively precluded from doing so by the FDA. Under the 1938 Food, Drug, and Cosmetic Act,[14] the FDA has authority to regulate promotional materials for pharmaceutical products. The FDA not only requires approval for product labeling but also prohibits drug "misbranding," including for off-label uses.[15]

In principle, the FDA is all for a robust exchange of scientific information between a drug or device company and the research and patient community, and the agency recognizes that companies often have the most up-to-date information on a drug's risks and benefits. But the FDA's official line is that companies can share only "scientific" information, not "promotional" information. That line is awfully blurry and ignores the fact that much information about a product's potential uses (both from a safety and an efficacy perspective) evolves when patients and physicians experiment with FDA-approved medicines outside of the constructs of clinical trials and science journals.

For instance, companies must tell patients and doctors about safety issues related to off-label uses when it learns about them. But the FDA won't let companies talk about the efficacy of off-label drug use because that would be "promotional." In one case, the FDA wouldn't let Allergan warn doctors that a commonly used dose of its cosmetic drug Botox, used off-label for juvenile cerebral palsy, was likely too high for that patient class, because it would



have implied that the lower dose was safe and effective—a judgment that the FDA didn't want to endorse.[16] Instead, the FDA would allow only a much more generalized—and potentially less effective—warning regarding all juvenile uses.

Under the 1997 FDA Modernization Act, as interpreted by the FDA's labyrinthine rules, companies can, in theory, communicate scientific information on their medicines by distributing independent articles from medical journals.[17] But since companies sponsor the lion's share of all drug research, much of the relevant literature will be disqualified by the FDA's rules. Even those articles that make the cut may be months or years behind the latest research and may touch only a small fraction of what a company may know about the off-label uses of its products.

Assume that you're at a scientific conference and that you have a deadly disease. You ask a company's researcher about a particular product in a room full of researchers and patients who are all interested in the same subject. The company researcher can't answer—even when the answer would interest everyone in the room. The researcher will tell you to wait for a sidebar and then convey the information to you one-on-one. Why? If the researcher communicates to the broader audience, the government might deem that "promotional."

Ironically, patients, doctors, insurers, and government researchers are free to say whatever they want about off-label uses—even to the point of saying that generic X is a better off-label treatment than branded drug Y—but the company isn't allowed to enter into that debate or dialogue. In practice, companies face a minefield without a map. Companies such as Par Pharmaceuticals are even worried about talking to doctors about on-label indications, such as AIDS-associated wasting for one of their drugs, because so many doctors use the drug off-label for cancer. Just explaining the drug's ability to stimulate appetite to a doctor who also treated cancer patients might, in itself, be evidence of the company's "intent" to misbrand the drug and set the company up for government civil or criminal action.

The Federal Criminal Law Enforcement of Off-Label Drug Promotion

Companies' fear of federal criminal action to enforce off-label drug promotion is not merely hypothetical. Claims of illicit off-label drug promotion have been among the most commonly asserted Medicaid-fraud allegations in federal enforcement actions.[18] Manufacturers cannot afford to fight a criminal investigation because the potential repercussions for a company convicted of a crime include "debarment" from federal contracting—precluding the company from being reimbursed by Medicare or Medicaid,[19] effectively a corporate death sentence for a pharmaceutical manufacturer.

Rather than bet the company on a criminal trial over off-label drug promotion, pharmaceutical companies are increasingly entering into "non-prosecution agreements" (NPAs) with the Department of Justice and U.S. Attorneys' Offices and "corporate integrity agreements" (CIAs) with the Department of Health and Human Services to avoid prosecution. Such agreements involve significant fines (sometimes in the billions of dollars), significantly modified business practices (sometimes overseen by "corporate monitors" who report to a federal prosecutor), and even the removal of top executives.[20]

In 2012, GlaxoSmithKline paid a record $3 billion fine after entering into an NPA and a CIA to resolve allegations of off-label promotion of a pair of antidepressants: paroxetine (Paxil) for use by children; and bupropion (Wellbutrin) as a weight-loss aid.[21] (A partial list of this and other recent federal NPAs involving alleged "drug misbranding" is shown above.) Also in 2012, Abbott Laboratories paid a $1.6 billion fine and pleaded guilty to a criminal misdemeanor for the off-label promotion of the anticonvulsant epilepsy drug valproic acid (Depakote) for schizophrenia, bipolar disorder, and migraines[22]—notwithstanding that such uses are well-established standards of care in the medical community, approved for reimbursement by the federal government and private insurers. In 2009, Eli Lilly and Pfizer paid $1.4 billion and $2.3 billion, respectively, for alleged promotion of drugs for off-label uses.[23]

The cost of the burgeoning application of criminal law to enforce the FDA's off-label speech code goes far beyond the criminal fines imposed. As coauthor James Copland discussed in more detail in a 2012 Legal Policy Report on the subject, the process whereby federal prosecutors and regulators enter into NPAs and CIAs lacks transparency and judicial oversight, and the broad sweep of these arrangements imposes a little-appreciated regulatory burden with real economic impact.[24]

Our Proposal: A Safe Harbor For Truthful Speech

By far the most serious consequence of the FDA's



Selected Recent Drug-Misbranding Non-Prosecution Agreements in the Pharmaceutical Industry				
Company	Jurisdiction	Fine/Settlement	Corporate Monitor	Term of NPA
Merck & Co., Inc.	U.S. Attorney, District of Massachusetts	$950,000,000	No	60 months
GlaxoSmith Kline plc	U.S. Attorney, District of Massachusetts; DOJ Civil Division	$3,000,000,000	Yes	60 months
Forest Laboratories, Inc.	U.S. Attorney, District of Massachusetts	$313,158,058	No	60 months
Elan Corporation Plc	U.S. Attorney, District of Massachusetts	$203,540,783	No	60 months
Ortho-McNeil-Janssen Pharmaceuticals, Inc.	U.S. Attorney, District of Massachusetts	$81,513,407	No	60 months

onerous limitations on off-label drug promotion, amplified by the heavy hand of federal criminal law, is the regime's adverse impact on public health. Simply put, limiting companies' ability to communicate with doctors about new advances in medicine serves patients poorly. The American Medical Association (AMA) has called for streamlining the process for adding new indications to a drug's FDA-approved label, [25] which would ameliorate the economic calculus that leads companies to forgo the multiyear, exceptionally expensive "supplemental new drug application" process for gaining a new label indication under current FDA guidelines.

But given that the FDA is unlikely to streamline its procedures anytime soon, it should at least work to facilitate the communication of the best science available to doctors and other learned intermediaries. Scientific knowledge could be captured and disseminated much better by a "safe harbor" on off-label drug use and promotion that recognizes that patients and physicians are collaborators in developing information on when a drug works (or doesn't work), and for whom.

Under such a safe harbor, the FDA would give companies the ability to communicate truthful science-based off-label information about their products to the physician community. However, companies should also be required to share comprehensive data on safety and efficacy for off-label uses with researchers, regulators, and insurers, who can then mine the information to rapidly validate emerging uses for established therapies. Indeed, we should view these uses less as "off-label uses" and more as "emerging uses."

The physician community is highly trained and sophisticated, and a supplemental warning accompanying such information—emphasizing that the use in question is not FDA-approved and that safety and efficacy information is still emerging from additional research—should enable physicians to evaluate the information with due skepticism.

Ideally, the FDA would couple the safe harbor with a streamlined FDA system for adding (or removing) new label indications, including information for specific subpopulations of patients. This would provide a valuable tool for researchers and patients looking for objective information on new treatments as well as repurpose older medicines for new uses.

At a minimum, the FDA needs to allow those with the greatest knowledge of—and greatest incentive to disseminate information about—medical advances to communicate with prescribing physicians. Americans should be concerned that they may not get the medicines they need because their physicians are unaware of new medical applications that may help them, due to the heavy hand of federal criminal law discouraging truthful speech. We shouldn't be telling companies to shut up when what they have to say can save lives—a message that Congress and the FDA should embrace and one that the Supreme Court should heed when it takes up the Caronia case for review.

References

References available from Managing Editor Liz Fleenor: lfleenor@msma.org



Part II
by the *Wall Street Journal*

FDA Approvals Are a Matter of Life and Death

by Andrew Von Eschenbach & Ralph Hall

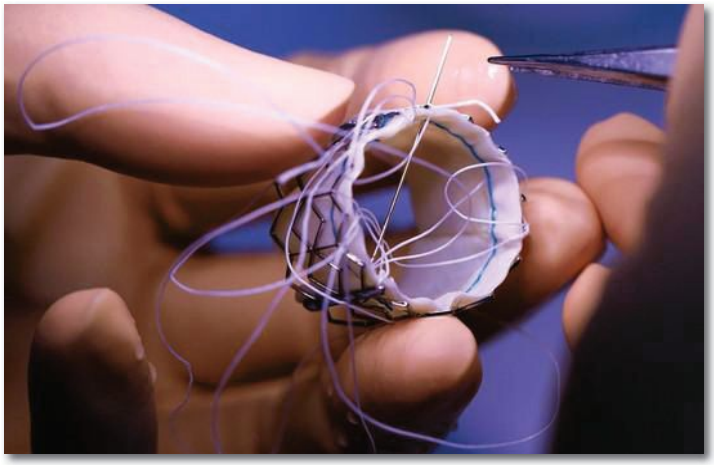
Today the medical-device industry flourishes overseas, even as it struggles under unnecessary regulatory burdens in the U.S.

In November, the U.S. Food and Drug Administration (FDA) approved an innovative product called the Sapien Transcatheter Heart Valve, for the treatment of severe aortic valve stenosis. The Sapien valve can be implanted endoscopically, making it a boon for patients who are too sick to endure open-heart surgery. Clinical trials found that almost 70% of patients receiving Sapien valves were alive one year after treatment, while only 50% of those receiving alternative treatments survived that long.

This would be a great story for American patients, but for one frustrating detail: The Sapien valve has been available in Europe since 2007, saving lives there but not here.

Unfortunately, this delay was not exceptional. American patients used to be the first to benefit from their country's enormous investments in basic medical research. Today, Americans wait as much as 60% longer than they did in 2005 for new lifesaving and life-enhancing medical devices—such as stents that keep arteries open and defibrillators—to reach the market, according to a recent Government Accountability Office report. During that wait, many remain sick or disabled. Some die.

A Sapien transcatheter heart valve.



One significant cause of this delay is the FDA and a decades-old regulatory process that is outmoded and needlessly long. Advances in science and new technologies offer opportunities to update FDA regulations in need of reform. If the agency modernized its premarket approval process, for instance, it could grant health-care professionals faster access to many medical devices with proven benefits and acceptable safety profiles, and then monitor the performance of those devices once they are in use.

This process could start with a better determination of which benefit-and-risk questions can be answered best by faster and lower-cost nonhuman studies—and which require human testing. The FDA can also provide faster reviews of clinical-trial protocols that focus on ensuring patient choice. There is a compelling argument for letting patients and their doctors decide what risks to take. Given the tremendous gains in quality of life and life expectancy associated with medical innovation, it's easy to predict what many patients would choose.

Yet these approaches won't work until the FDA's premarket approval process is modernized in three areas:

- Developing alternatives to clinical trials. Clinical trials have been a traditional part of medical-product regulation, but they are of less value for evaluating medical devices than they are for drugs. The mechanical, electrical or physical properties of devices can often be more robustly tested in the lab than on people.



A small number of recent, high-profile recalls of medical devices have garnered tremendous media attention and led to calls for stricter FDA regulations. But a close analysis of the data demonstrates that serious device problems are rare. According to a six-year study by Ralph Hall, more than 99.5% of medium-risk and high-risk devices—such as heart valves and orthopedic implants—are never subject to Class I recalls, which involve the highest risk of injury or death. Of the very few Class I recalls that do occur, fewer than 9% are for problems that more clinical testing could have discovered.

In the future, instead of implementing more clinical trials—with their long time frames, high cost and human risk—the FDA should enhance its "quality system" regulation process, and make more use of bench testing and computer modeling to identify potential clinical problems. The FDA should also expand its recently-announced Innovation Pathway 2.0, which seeks to develop a faster approval process for breakthrough devices—for kidney-failure patients, for instance—by encouraging collaboration between product developers and FDA experts throughout the development process.

- More and better postmarket surveillance. When devices are recalled, it's usually because of problems in the quality system, such as manufacturing or labeling errors, or long-term product-performance issues. Yet the FDA's system for tracking these failures is currently largely passive, based on reports the FDA receives from manufacturers, which in turn received them from providers and patients.

With advances in wireless communications, sophisticated information-sharing systems, and electronic medical databases, the FDA can create a proactive system of surveillance—in real time in some cases—that would greatly enhance safety by identifying patients who benefit the most from the device, detect early signs of device failure, and allow rapid mitigation of potential harm to patients.

- Collaboration. Finally, both before and after approval, the FDA, industry and other stakeholders need to work together more. The reauthorization of the Medical Device User Fee and Modernization Act—which will provide better and more transparent metrics for evaluating the FDA's performance, and some limited reforms to premarket review—is only a start. We need a public-private partnership in which regulators, researchers and industry experts can learn from each other and develop patient-centered regulatory standards, focus on the most-serious safety challenges, and identify the greatest opportunities for medical-device innovation.

The consequences of not doing so are clear. Today the medical-device industry flourishes overseas, even as it struggles under unnecessary regulatory burdens in the U.S. A 2010 study found that European patients gain access to "new U.S.-created medical technologies" more than two years earlier, on average, than American patients. Not surprisingly, the device industry is leaving. According to a summer 2011 survey by the National Venture Capital Association, in the next three years, 85% of venture-backed health-care companies expect to seek regulatory approval for their new products outside the U.S. first.

With assets like the National Institutes of Health, cutting-edge academic medical centers, vibrant venture-capital networks, and a vast industrial infrastructure, the U.S. has no excuse not to lead the world in providing new medical devices. American workers should be employed in this vital industry; American investors should profit from it; and most of all, American patients should benefit from it, in the form of better health and longer life. But that won't happen if we saddle the industry with regulations that are slow, costly and ineffective.

The medical-device industry is valuable. If the U.S. doesn't want it, someone else will. For patients, meanwhile, the only alternative to improving the regulatory process is the current system of withholding products, when delay can mean death, disability or "just" a diminished quality of life.

About the Authors

Dr. von Eschenbach (left) is the chairman of the Manhattan Institute's Project FDA. He is a former director of the National Cancer Institute and was commissioner of the U.S. Food and Drug Administration (2005-2009). Mr. Hall (right) teaches at the University of Minnesota Law School and is of counsel to Faegre Baker Daniels. He also is CEO of MR3 Medical LLC, a start-up medical device company.







Part III
by *Cataract & Refractive Surgery Today*

All Hat No Cattle

by Stephen G. Slade, MD

Americans wait as much as 60% longer than they did in 2005 for new lifesaving and lifeenhancing medical devices.

I attended the 25th International Congress of German Ophthalmic Surgeons Meeting in Nürnberg, Germany, from June 14 to 16, 2012. The DOC, as the meeting is known, is one of my all-time favorites and is masterfully led by Armin Scharrer, MD. The congress represents the largest meeting in Europe, after the ESCRS, with some 5,000 attendees. The lectures are superb, I love to see my overseas friends, and I especially enjoy learning about the very latest lenses, lasers, and technology—all state of the art. Most of it, US surgeons do not have.

I used to see a lot of patients from abroad, but now, they go to Germany, including family members of some of the patients I once treated. The last few times an international patient called to make an appointment with me, I felt a bit self-conscious. Can they get the best possible care in this country? I believe US physicians are world-class, despite the claims of too many health care economists, but no new ophthalmic devices at all were approved from January 2011 to the time of this writing in June 2012. According to Andrew Von Eschenbach, FDA chief from 2005 to 2009, "Today, Americans wait as much as 60% longer than they did in 2005 for new lifesaving and lifeenhancing medical devices."[1]

There are three alternative pathways by which US physicians and their patients can access new technology: 510(k) clearance, off-label use, and clinical trials. For example, surgeons and their patients can thank the FDA for the 510(k) clearance of laser cataract surgery, a far faster process than the typical full premarket approval that most lasers should complete. Off-label uses are common among physicians and, in ophthalmology, include PRK, all retreatments in refractive surgery, and the pre- and postoperative use of most drugs (eg, antibiotics and steroids). Clinical trials help a small number of patients, as in the case of corneal collagen cross-linking.

Sadly, all of these pathways are under attack. The 510(k) has been criticized in favor of a slower process. In May, Abbott paid a $1.6 billion fine for detailing off-label uses of valproic acid (Depakote).[2] A major FDA trial of corneal collagen cross-linking was halted in mid-June, 70 patients short of completion, largely due to the cost of the FDA process, according to the company. The latest laser's maker, Schwind Eye-tech-solutions GmbH & Co.KG, has no plans to seek U..S approval due to the cost and duration of a clinical trial. Venture capital firms, which fund nearly all technological startups and clinical trials in this country, now question whether health care is the wisest place for their money.

At minimum, U.S. surgeons must defend 510(k)s, off-label usage, and access to clinical trials. In addition, however, they should encourage the government to adopt a more European approval process based on safety and to allow the market to determine efficacy. Otherwise, how will ophthalmologists reply the next time an overseas patient calls, willing to make the trip here and saying, "Everyone knows American medicine is the best"?



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About the Editor Stephen G. Slade, MD, is Chief Medical Editor of *Cataract & Refractive Surgery Today.* Dr. Slade practices Ophthalmology in Houston, Texas.

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Drivers of Health Care Costs

A Physicians Foundation White Paper - Second of a Three-Part Series

For many years and in countless articles, physicians have been the scapegoat for rising health care costs in the United States. In fact, they have been blamed by many critics for the United States leading the world in health care expenditures.

In the January/February 2013 issue of Missouri Medicine, we saw a close examination of the data that indicates that this blame is misplaced – that delving into key components in health care spending reveals something else. While there is general disagreement among the so-called experts as to the degree of impact of each component, almost everyone seems to agree that new technology – not physicians – is number one on the list of contributors to rising health care costs.

In this issue of Missouri Medicine, the Physicians Foundation examined data on the leading key components and found that chronic disease conditions, life style – including obesity and addictions, administrative expenses, hospitals, pharmaceuticals, mandated insurance benefits, aging, end-of-life care, defensive medicine and health disparities have all had anywhere from a moderate to significant impact on rising overall health care costs.

In the final section, entitled "Interesting Statistics about U.S. Health Care System", we examine why infant mortality rates can be a poor indicator of the success or failure of a health care system. The same applies for life expectancy statistics. Issues such as medical innovation need also to be considered in the general discussion of a health care system's success or failure.

THE PHYSICIANS FOUNDATION
Empowering Physicians
Improving Healthcare

Following a settlement of a class action lawsuit brought by physicians against the managed care industry, The Physicians Foundation (PF) was created in late 2003. It is a nonprofit 501(c)(3) organization that seeks to advance the work of practicing physicians and help facilitate the delivery of quality health care to all Americans. It pursues its mission through a variety of activities, including grant-making, white papers, research, and policy impact studies. The PF focuses on the following core areas: health system reform, physician leadership programs, workforce needs and pilot projects. As the health care system in America continues to evolve, The Physicians Foundation is steadfast in its determination to foster the physician/ patient relationship and assist physicians in sustaining their practices during these challenging and turbulent times.

To this end, The PF commissioned comprehensive national physician surveys in 2008, 2010 and 2012 which revealed a deep sense of frustration, stress and anxiety. Navigating an increasingly hostile practice environment was causing widespread dissatisfaction and low morale. In the wake of burgeoning insurance and regulatory red tape, little or no negotiating power with insurers, increasing office operating costs with low margins, declining reimbursements and the ever present threat of a malpractice action--physicians were having serious problems in sustaining their medical practices.

And then along came The Affordable Care Act (ACA), passed by Congress on March 23, 2010. With its myriad of provisions affecting physician practices--not to mention its length and sheer comprehensiveness--physician angst only multiplied. And it doesn't appear that the recent action of the U.S. Supreme Court on June 28, 2012, has lessened that anguish.

Among the publications appearing on The PF website (www.physiciansfoundation.org) are several "Roadmaps" examining the provisions of the ACA and how they will impact physician practices. One of the goals of The Physicians Foundation is to bring these issues to the attention of the public, business, state legislators, members of Congress and policy-makers so they can better understand how these practice impediments are adversely affecting physicians in their efforts to deliver the best possible care to all Americans. The PF intends to continue its mission to remain in the forefront of those activities and projects to help physicians to better navigate through all of the practice uncertainties ahead.



Timothy B. Norbeck is the Chief Executive Officer of The Physicians Foundation and has over 45 years of experience in the health care field.
Contact: www.physiciansfoundation.org
Part one of a three-part series. Reprinted with permission from The Physicians Foundation.



Technology

According to a report from the Robert Wood Johnson Foundation (RWJF), its authors agree that technological change is the most important driver of health care spending increases over time. A technical review panel convened to advise CMS on future health care costs trends concluded that about half of real health expenditure growth is attributable to medical technology, "where new options for diagnosis and treatment often replace older technologies when none existed before." The RWJF goes on to say that advancing technology may have a particularly large impact on spending in the United States because of "few requirements that effectiveness be demonstrated before technologies are used broadly and concern that their application tends to go beyond those patients likely to benefit the most from them."[28]

In late September 2012, an article in the *Journal of the American Medical Association (JAMA)* indicated that total knee replacement surgeries have soared 161.5% among Medicare participants in the past 20 years, and will continue to grow as the USA's 77 million baby-boomers age. In 2010, people aged 65 and older underwent 243,802 operations to replace damaged knees or to "revise" previous replacements – up from 93,230 in 1991. At about $15,000 each, the total knee replacement tab for patients at every age is now about $9 billion.[29]

By comparison, and according to the Kaiser Family Foundation, Medicare spending for 2011 was estimated at $550 billion. The good news as pointed out by *USA Today* is that such procedures have eased the pain and improves quality of life especially for a rapidly aging population. The bad news is that it "can be viewed as another stress on government, individuals and businesses struggling with current growth in health care costs."[30]

Just another example of new technology is robotic surgery which is now performed in more than 36% of hospitals across the USA, according to PWC's Health Record Institute. According to an August 19, 2010 article in the *New England Journal of Medicine*, the cost of robotic surgery was estimated to be $2.5 billion and growing.[31]

Defining new technology as encompassing the use of any new procedure, drugs or devices, the Congressional Budget Office estimated in 2008 that technology so defined, accounts for anywhere between 38% to more than 65% of new health care spending.

Administrative Expenses

Princeton medical writer and economist, Uwe Reinhardt, suggests that the U.S. health care administrative overhead load is huge by international standards. "The McKinsey Global Institute estimated that excess spending on health administration and insurance accounted for as much as 21% of the estimated total excess spending ($477 billion in 2003). Brought forward, that 21% of excess spending on administration would amount to about $120 billion in 2006 and about $150 billion in 2008."[32]

The McKinsey team estimated that about 85% of this excess administrative overhead can be attributed to the highly complex private health insurance system in the United States. "Product design, underwriting and marketing account for about two-thirds of that total. The remaining 15% was attributed to public payers that are not saddled with the high cost of product design, medical underwriting and marketing, and that therefore spend a far smaller fraction of their total spending on administration."[33]

The Institute of Medicine and the Centers for Medicare and Medicaid (CMS) estimate that administrative costs in the U.S. health care system consume an estimated $361 billion annually, 14% of all health cost expenditures in the nation. Administrative costs are defined as "including spending by public and private health insurers other than actual payments to providers and costs incurred by other system participants, including providers, employees, and consumers, in dealing with insurers."

In the Robert Wood Johnson Foundation (RWJF) report entitled: *High and Rising Health Care Costs,* "Administrative costs were noted as a key reason why spending in the United States exceeds that of other advanced countries."[34]

According to a National Academy of Social Insurance report for the RWJF, overall administrative costs for physicians are in the range of 25-30% of practice revenues. One study cited in the report found costs related to claims and utilization management amounting to 10% of practice revenues. Still another study, which estimated insurance-related costs in most cost centers and included an estimate of physicians' time spent on insurance matters, estimated costs for a primary care office of 15% of revenues.

A U.S. Congress Office of Technology Assessment report on administrative costs in health care, cited an (American Medical Association) AMA 1988 socio-economic survey which indicated that, way back then, the value of physicians' time spent on insurance issues were: $17.4 billion on non-physician salaries, $ 6.64 billion in physician time spent on administration, and $19.54 billion in other administrative costs, for a total of $43.58 billion in 1991.



Of course, the number of physicians has greatly expanded since 1991 along with increased administrative time spent on more regulation, not to mention a plethora of new ones included in the Patient Protection and Affordable Care Act – therefore rendering the $43.58 billion number far lower than today.

Pharmaceutical Costs

According to the 2010 Kaiser study, while spending on prescription drugs ($259.1 million) accounts for only 10% of total health care expenditures, its rapid growth has received considerable attention (a 114% increase since 2000, compared to 88% for both hospital and physician/clinical services combined). However, the 2010 average annual spending growth from 2009 was lower for prescription drugs (1.2%) than for hospitals (4.9%) or physician /clinical services (2.5%). A large part of these rising costs is reflected in the trend away from chemical agents to biological agents which are significantly more expensive to manufacture and to administer.

Mandated Insurance Benefits

According to the Council for Affordable Health Insurance report (CAHI): Health Insurance Mandates in the States 2011, a health insurance "mandate" is a command from a governing body, such as a state legislature, to the insurance industry or health plans to include coverage for (or less frequently, offer coverage for) a particular health care provider, benefit and/or patient population. Some examples are:

- Providers such as chiropractors, podiatrists, social workers and message therapists;
- Benefits such as mammograms, well-child care, drug and alcohol abuse treatment;
- Populations such as non-custodial children and grandchildren.

The total mandate count in 2011 is 2,262, up from 2,156 in 2010. "Today the majority of states have more than 40 mandates each – some have more than 60 - and the accumulated impact of those dozens of increases has made health insurance unaffordable for many Americans." Rhode Island and Virginia (70) have the most mandated benefits with Maryland (67), Minnesota (65) and Connecticut (63) close behind. Idaho (13) has the least mandated benefits, followed by Alabama (19), Michigan (23), Hawaii (24) and Utah (26).

(Note: Mandates in Signatory Society States of The Physicians Foundation are: AK(37), CA (56), CO (58), CT (63), FL (49), GA (45), HI (24), LA (51), NC (55), NE (47), NH (46), NJ (47), NY (61), SC (30), TN (41), TX (62), VA (70), VT (46), and WA (58).)[35]

Strangely enough, the report does not give overall cost estimates of the mandates. But it does say, unequivocally, that "one of the biggest cost drivers in our health care system is the steady proliferation of federal and state-based coverage mandates." According to the CAHI research and annual analysis, "mandated benefits currently increase the cost of basic health insurance from slightly less than 10% to more than 50%." The CAHI concludes that "government interference in the health care system is steadily increasing. So too is the cost of (health) insurance."

Lifestyle

Some 47% - 50% of Americans account for zero percent of all health care spending. A positive lifestyle had much to do with it.

Chronic diseases are the most common and costly of all health problems, but they are also the most preventable. According to the CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), our common, health-damaging but modifiable behaviors – tobacco use, insufficient physical activity, poor eating habits, and excessive alcohol use–are responsible for much of the illness, disability, and premature death related to chronic disease.[36]

- More than 43 million (about one in five) U.S. adults smoke.
- One in five U.S. high school students are current smokers.
- More than one-third of all U.S. adults fail to meet minimum recommendations for aerobic physical activity based on the 2008 Physical Activity Guidelines for Americans. As reported in *The Week* (August 17, 2012), a global study found that the U.S. ranked among the most physically lazy countries in the world, with 40% of Americans engaging in little or no physical activity. Greece was found to be the most active country in the Western world with just 15% inactive.[37]
- Only one in three U.S. high school students participated in daily physical education classes.
- More than 60% of U.S. children and adolescents eat more than the recommended daily amounts of saturated fat.

- Only 24% of U.S. adults and 20% of U.S. high school students eat five or more servings of fruits and vegetables per day.

Obviously, one important way of encouraging prevention is to begin with obesity. A recent article in the *JAMA* pointed out that in 2010, more than 35% of adults and 16% of children aged 2-19 years were obese.[38]

A recent *Wall Street Journal* article tracks the overall U.S. obesity rate as being 17% in 1997, 22% in 2002 and 28% in 2011. The maximum load or weight limit for a CAT scanner to accommodate an obese patient was 300 pounds in 1997, 490 in 2002 and 660 in 2011. New machines are being built for heavier patients, and hospitals and physicians will have to pay as much as 40% more for the larger sized scanner which now costs up to $650,000.[39]

Chronic Diseases/Conditions

According to federal data, the costliest 1% of patients account for 20% of all health care spending in the United States. Ten percent of the population consumes 63% of the total health care dollars in the country. People with three or more chronic disease conditions generally fall into that 1% category, according to Linda Dunbar, RN, PhD, and Vice President of Care Management at Johns Hopkins Healthcare.[40]

Experts seem to all agree that more than 75% of health care costs are due to chronic conditions such as heart disease, cancer, stroke, diabetes and arthritis. The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) says that chronic diseases cause seven in ten deaths each year in the U.S. and that, alarmingly, the percentage of U.S. children and adolescents with a chronic health condition have increased from 1.8% in the 1960s to more than 7% in 2004. Although chronic diseases are obviously more common among older adults, (nearly one in two adults live with at least one chronic illness, and 88% of Americans over 65 have at least one chronic health condition) they affect people of all ages and are now recognized as a "leading health concern of the nation."

The NCCPDHP points out the following about key chronic diseases:

- Heart disease and stroke are the first and third leading causes of death, accounting for more than 30% of all U.S. deaths each year.
- Cancer, the second leading cause of death, claims more than half a million lives each year.
- Diabetes is the leading cause of kidney failure, non-traumatic lower extremity amputations, and new cases of blindness each year among U.S. adults aged 20-74 years.
- Arthritis, the most common cause of disability, limits activity for 19 million U.S. adults.
- Obesity has become a major health concern for people of all ages. One in every three adults and nearly one in every five young people aged 6-19 are obese.[41]

Chronic diseases are the most common and costly of all health problems, but they are also the most preventable. Four common, health-damaging, but modifiable behaviors – tobacco use, insufficient physical activity, poor eating habits, and excessive alcohol use – are responsible for much of the illness, disability, and premature death related to chronic diseases.

All experts agree that in order to get a better handle on rising health care costs, we must better address the costliest 10% which account for 63% of health care costs.

Aging

The previously mentioned authors of the RWJF Report entitled *"High and Rising Health Care Costs: Demystifying U.S. Health Care Spending"* agree that technological change is the most important driver of health spending increases over time and that population aging plays only a minor role.[42] Just as in examining all of the components driving health care costs, there is room for much disagreement.

For example, the Social Security Advisory Board's report entitled *"The Unsustainable Cost of Health Care"*, reiterates that "most research on the effect of aging on health care spending has found relatively small effects." Mentioned in the report is a CBO review of the literature which estimates that from 1940 to 1990 population aging only accounted for about 2% of overall health care cost growth.[43]

But the aging of the baby boomer generation over the next 25 years or so is expected to play a large role in the increased cost of Medicare and Medicaid. "According to the CBO's most recent Long-Term Budget Outlook projections, aging will account for about 44% of growth in the two programs through 2035."

End of Life Care

WNET, N.Y. Channel 13 reported recently on the Health Care Financing Administration (HCFA) end-of-life spending trends study of 1993 which looked at data for 1975, 1980, 1985, and 1988. Although somewhat dated, it remains one of the most extensive studies in the field.

"Their findings belie perceptions that a larger percentage of



medical expenses are accounted for by terminally-ill persons whose lives were prolonged by expensive technology. Gerald Riley, a HCFA actuary, conducted the analysis with colleague James Lubitz and published in the 1993 New England Journal of Medicine. They found no evidence that elderly persons in the last year of life account for a larger share of Medicare expenditures today than before the onslaught of technology. In fact, Medicare paid the exact same percentage for patients in the last two months of life in 1976 as in 1988. This implies that heroic efforts to preserve life in the last months did not have a disproportionate effect on increasing the proportion of Medicare outlays. Riley says that if life-preserving efforts had become more frequent, there would have been an increase in the percentage of dollars spent in the last couple of months of life."

More data on end-of-life care included:

- 27 to 30% of Medicare payments cover the cost of care for people in the last year of life.
- 12% of Medicare spending covers people who are in the last two months.
- 10% of Medicare beneficiaries account for 70% of program spending. [44]

Reuters Health reported in October 2010 that *"health care costs at the end of life show no signs of leveling off, according to new research from the United States and Canada published in the Archives of Internal Medicine. But other trends over the past decade, including a sharp increase in use of hospice services, could point the way toward bringing these costs down while improving patient care," Dr. Jonathan Bergman of the University of California at Los Angeles, author of one of the studies, told Reuters Health.*

"We end up spending about a third of our overall health care resources in the last year of life," Bergman said. "It represents a huge avenue for improvement."

"Bergman and his team did find that hospice patients were about 20% less likely to receive high-intensity care, for example admission to the intensive care unit, two or more emergency department visits, or cardiopulmonary resuscitation. They also received fewer imaging tests, which are costly and are known to have no benefit for dying prostate cancer patients. Evidence suggests that hospice care can cut health care costs, especially for cancer patients, Berman and his team note, although they did not look at cost in their study.[45]

According to a *Wall Street Journal* analysis of Medicare data reported in July 2012, a "sliver of the sickest patients account for the majority of health care spending. In 2009, the top 10% of Medicare beneficiaries who received hospital care accounted for 64% of the program's hospital spending. Medicare patients rack up disproportionate costs in the final year of life. In 2009, 6.6% of the people who received hospital care died. Those 1.6 million people accounted for 22.3% of total hospital expenditures."[46]

Health Disparities

The U.S. Department of Health and Human Services' Centers for Disease Control and Prevention, issued a Health Disparities and Inequalities Report for the United States in 2011. It states that the existence and persistence of substantial disparities in mortality, morbidity, risk behaviors, and hazardous environmental exposures between and among segments of the U.S. populations have been well-documented. The socioeconomic circumstances of persons and the places where they live and work strongly influences their health. Educational attainment and family or household incomes are two indicators used commonly to assess the influence of socioeconomic circumstances on health. A substantial proportion of the child and adult population is vulnerable to health problems because of insufficient resources.[47]

Richard Cooper, MD, argues that it is economic disparity that drives health care utilization and therefore health care spending.

He goes on to say that "Poorer people are demonstratively sicker and cost more to treat than do economically stable people by a large margin. Therefore, the key to lowering health care costs is to reduce poverty and increase wealth." A poll commissioned by the Canadian Medical Association which was reported in an editorial of the *Globe and Mail* in August of 2012, substantiates Dr. Cooper's claims by suggesting that low-income Canadians are in significantly worse health than those with higher income and more education. The survey, carried out by Ipsos Reid, found that just 39% of those who earn less than $30,000 believe their health is excellent or good, compared with 68% of those who earn $60,000 or more. Those in the latter group also reported that they smoke less, sleep and exercise more and eat more vegetables.[48]

Another article in the *Globe and Mail* went on to say that: "One in four Canadians earning less than $30,000 annually have delayed or stopped taking prescription drugs because they did not have money to pay for the treatment. By contrast, fewer than one in 30 citizens earning more than $60,000 a year has had trouble paying for necessary medication, according to the survey commissioned by the Canadian Medical Association. "What is particularly worrisome for Canada's doctors is that in a nation as prosperous as Canada, the gap between the haves and have-nots appears to be widening."[49]



That gap is widening in the United States as well. A report in the *New York Times* magazine on August 19, 2012, describes its impact. The Census Bureau tracks a category that the government calls "deep poverty"; families are said to be in deep poverty if they earn less than 50% of the poverty line – which means around $11,000 a year for a family of four, not including food stamps or other noncash support. The number of families in deep poverty grew sharply during the recent recession and its aftermath, and in 2010, the share of Americans whose families made less than half of the poverty line hit a record: 6.7% of the population, or one in fiftenne Americans. The numbers are even higher for children, disturbingly so. In 2010, one in every ten American children lived in deep poverty."[50]

These numbers are sobering and lead to tragic consequences, including poorer health. The poor health also leads to higher health care costs and poorer outcomes.

Between 2003 and 2006 the Joint Center for Political and Economic Studies estimated the total direct and indirect costs of health inequities affecting racial and ethnic minority populations, including lost wages and productivity – exceeded $1.2 trillion.

The Urban Institute says that among African Americans and Hispanics, the health care cost burden of three preventable conditions – high blood pressure, diabetes and stroke – was about $23.9 billion in 2009.[51]

Conclusions

According to a Henry J. Kaiser Family Foundation Study in May 2012 entitled: *Health Care Costs – A Primer – Key Information on Health Care Costs and their Impact*, the U.S. spent $2.6 trillion on health care in 2010.

Half of health care spending is used to treat just 5% of the population. "A recent study (David Squires: Explaining High Health Care Spending in the U.S., May 2012) found that U.S. health care spending is higher than that of other countries most likely because of higher prices and perhaps more readily accessible technology; and greater obesity, rather than higher income, an older population, or a greater supply of utilization of hospitals and doctors.[52]

As mentioned in the Kaiser study, "another factor which may help explain rising health spending is the falling share of health care expenditures that Americans pay out-of-pocket. Between 1970 and 2010, the share of personal health expenditures paid directly out-of-pocket by consumers fell from 40% to 14%. Although consumers face rising health insurance premiums over the period which affected their budgets, lower cost sharing at the point of service likely enabled consumers to use more health care, leading to expenditure growth."

Clearly, to achieve cost savings in our health care system, experts must look at those factors that are driving health care costs above the gross domestic product (GDP), population growth and inflation.

Nearly one-third of all health care spending goes to paper work and administration; *(Newsweek*: The Cost of Hope, June 4 and 11, 2012)[53]

- Technology, which most experts agree accounts for the greatest rise in health care costs;
- Chronic conditions, which account for up to 75% of all health care costs;
- Obesity, which often leads to diabetes which begets peripheral vascular disease and coronary disease which begets congestive heart failure;
- Life style behavior including addiction
- Inefficient medical liability system
- End of life costs
- Legislative mandates – especially health insurance mandates
- Half of all health care expenditures are used to treat just 5% of the population. (It would seem that this represents the most fertile area for cost savings.)

The literature and data simply do not point to physicians as a primary or even secondary cause of rising health care costs. Physicians have been a favorite target of critics for years for cost increases, but the facts indicate otherwise.

For those who truly want to reduce the growth of health care costs in America, further examination of chronic disease conditions/ lifestyle choices, medical technology and a closer look at the 5 % of patients who account for half of all health care expenditures would be of real value. Pointing the finger at physicians for these things is fruitless, incorrect and misleading and will only serve to divert researchers from delving into the real causes.

Part three of this white paper will appear in a future issue of *Missouri Medicine.* References can be found at www.physiciansfoundation.com.

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1 Picture = 1,000 Words

SO YOU THINK TORT REFORM DOESN'T MATTER?

These graph, from the Missouri Department of Insurance, show the number of malpractice lawsuits pending at the end of every year since 1990. Follow the lines up and up and up until 2005, the year MSMA won enactment of a pivotal tort reform bill in the Missouri legislature. Then follow the lines down and down and down to today, when the number of lawsuits pending is at a historical low.

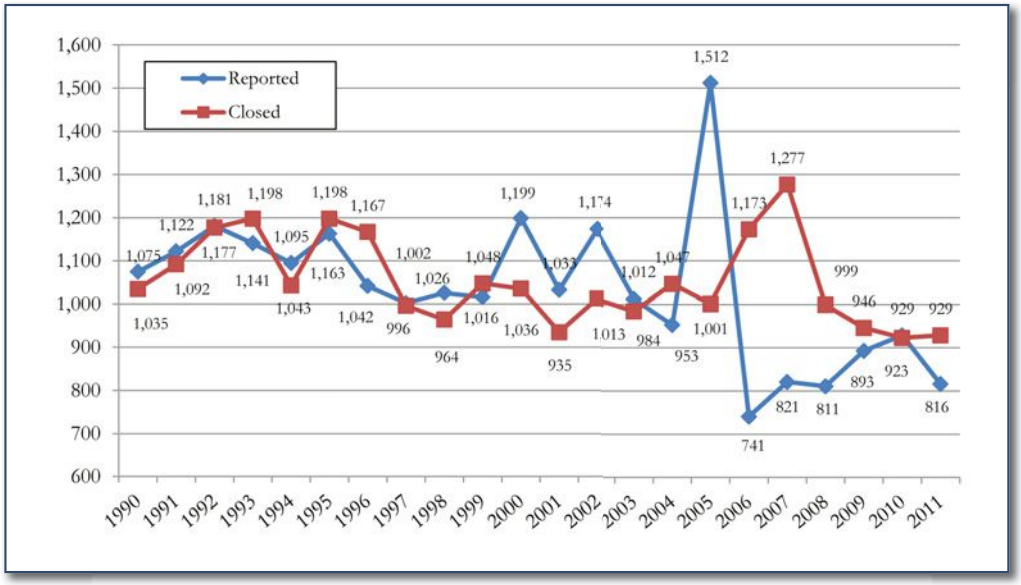
THE FACTS SPEAK FOR THEMSELVES: TORT REFORM WORKS.

Now, however, the courts have thrown out the cap on non-economic damages, the very linchpin of our 2005 tort reform law. And so MSMA is busy trying to restore them, before history repeats itself and the number of lawsuits go up and up and up again.

Source: 2011 Missouri Medical Malpractice Insurance Report Statistics Section November 2012

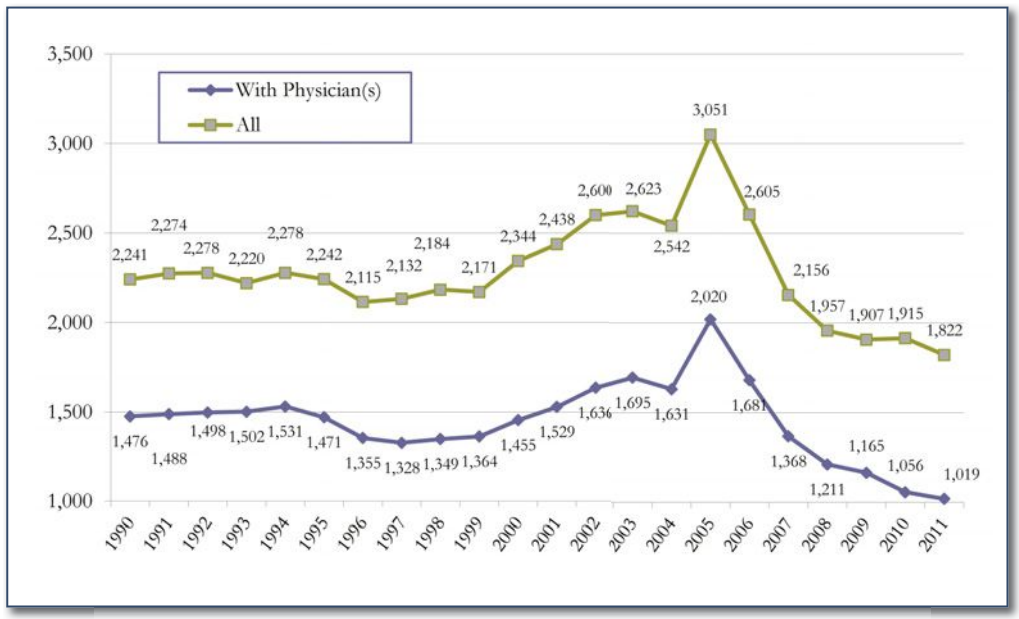
New Incidents Reported and Closed

After new claims spiked sharply in 2005, newly-opened claims declined substantially in subsequent years. Aside from the anomalous 2005 spike in new claims, the number of claims reported has declined substantially in recent years. New actions declined rapidly after 2005, and by 2011 stood at 816.



Number of Claimants with Actions Pending at Year-End

The number of claimants with pending actions at the end of a year has declined substantially after 2005, and in 2011 reached a historic low.





Should Ophthalmologists Test Hearing & Sell Hearing Aids?



Our series in the January/February issue of Missouri Medicine by Steven M. Silverstein, MD, Martin E. Anderson, MD, Anthony A. Mikulec, MD and Charles M. Lederer, MD drew the attention of members who wrote in for comment.

There are many reasons for physicians to think creatively about revenue streams for medical practices. Mostly they relate to fiscal cliffs, Medicare cuts, reinstated payroll taxes, escalating overhead and insurance costs for employees. Because my younger sister is completing her training in audiology now, I may be an ophthalmologist with a unique perspective. From my sister, I have learned that hearing aid sales are quite profitable. I imagine this is why Wal-Mart and Costco now offer them in addition to their contact lens services. Hearing aid providers are also lightly regulated. Providers range from licensed audiologists accountable to the Missouri Board of Health and Healing Arts and the ENTs they practice under to independent providers with little, if any, formal training. Ultimately, as a physician providing health care services, liability would be the most significant deterrent to my adopting these services. Physicians who sign off on services are accountable for the actions, inactions and outcomes of every service provider caring for patients in my name. Because I concentrated on the eye in my studies and barely remember the malleus, incus and stapes, I'm going to sit this one out.

Melissa Toyos, MD, Ophthalmology
Kansas City, Missouri
MSMA Member Since 1999

The decision to add hearing services (selling hearing aids) to the practice of the author of the "PRO-Selling Hearing Aids in an Ophthalmology" is profit-driven and precisely demonstrates the major problem in that industry: a basic lack of understanding of hearing loss, possible etiologies, and who needs specialty referral. The majority of hearing losses are not conductive, as the doctor boldly claims. While some may benefit from amplification, these are precisely the patients most likely to benefit from medical care and possible surgery. Patients with neuro-sensory loss are the primary beneficiaries of amplification, but these patients are also well served by specialty consultation to identify probable etiology, associated disease, and direct appropriate treatment that may well include amplification. Selling hearing aids can be a profitable business as attested to by the ads in the daily paper and my junk mail. Unfortunately, the buyer need beware. The seller often does not have the patient's interest at heart but the cash generated in the sale.

John J. Bonacorsi, MD, FACS, Otolaryngology
Bridgeton, Missouri
MSMA Member Since 1977

I found myself scratching my head while reading the recent article touting the benefits of ophthalmic practices expanding into audiologic/hearing aid services. Am I missing something here? Do ophthalmology residencies now include audiologic training? I don't think so. I sincerely hope that this type of practice expansion does not become a trend. Our specialty frequently finds itself under attack from lesser trained individuals who would like to perform ophthalmic surgical procedures. That in itself should be the reminder we need to just stick to doing what we are actually trained to do.

James G. Luetkemeyer, MD, Ophthalmology
Past-President, Missouri Society of Eye Physicians and Surgeons
Jefferson City, Missouri
MSMA Member Since 1994

Ophthalmologists testing hearing and selling hearing aids seems, in my opinion, motivated by pure economics versus medical ethics and the tenets of the Hippocratic

oath. Anyone holding a medical license can responsibly control or abuse their delivery of medical services. If delivery of those services extend beyond their area of expertise and knowledgeable oversight, then those purveyors tread precariously an extremely fine line between charlatanism and medical incompetency. The current times of reduced reimbursement for physicians' services creates tempting economic pressures to expand the breath of services delivered. In commercial parlance, "develop alternate income streams." The guiding principal incumbent on any medical professional expanding their practice is competency in these "add on" services. In 1896 the American Academy of Ophthalmology & Otolaryngology was formed. In 1979 that august society deemed the body of "Eye, Ear, Nose and Throat" knowledge so diverse that ophthalmologists and otolaryngologists sundered their organization into separate Academies. I believe that otolaryngologists and most ophthalmologists would look in askance at creating an income stream for ill trained ophthalmologists selling hearing aids and recognize the specious justification as a "service' to their patients.

Warren E. Hagan, MD, Otolaryngology, Plastic Surgery
Fellow, American Society of Plastic Surgery
St. Joseph, Missouri
MSMA Member Since 2003

Editor's Note

The PRO author will publish his comments in the May/June issue of *Missouri Medicine*.

Mary Jane Still Dulls the Pain

Our paper entitled "Legalization, Decriminalization & Medicinal Use of Cannabis: A Scientific and Public Health Perspective" by Svrakic DM, Lustman PJ, Mallya A, Taylor AL, Finney R & Svrakic NM, published in the March/April 2012 issue of *Missouri Medicine* cites the study by Stokes et al (2010) as demonstrating "decreased levels of cortical dopamine after THC challenge" (p. 94). In fact, Stokes et al (2010) show significant decreases in frontal and temporal [11C]-raclopride binding after THC challenge, thus demonstrating increased dopamine release after THC challenge. Note however that this miscitation of Stokes et al (2010) does not undermine the argument that cannabis causes cognitive dulling and impairments. Following an inverse "U" shape pattern, prefrontal cortex function is optimal at intermediate levels of dopamine (Winterer & Weinberger, 2004) and is impaired in states of dopaminergic hypofunction (e.g., patients with Parkinson's disease) and hyperfunction (e.g., in amphetamine-induced psychosis). THC clearly alters prefrontal and temporal dopamine release, and this shift could be one of the mechanisms underlying well documented cognitive impairments in cannabis users.

Literature:

- Stokes, P.R.A., Egerton, A.,Watson, B. et al. Significant decreases in frontal and temporal [11C]-raclopride binding after THC challenge. NeuroImage 2010; 52: 1521–1527
- Winterer G, Weinberger D. Genes, dopamine and cortical signal-to-noise ratio in schizophrenia. Trends in Neurosciences 2004; 27(11) 683-690 2004

Dragan M Svrakic, MD, PhD
St. Louis, Missouri

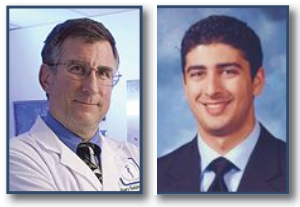
Useful Issue All Around

While Missouri Medicine is always outstanding, I'm very impressed with the quality and quantity of information in the November/December 2012 issue. It was interesting, informative, and I will be able to use the information from multiple articles in my practice and for my personal use. Well done.

Dan Sullivan, MD, Diagnostic Radiology
Springfield, Missouri
Chair of the Greene County Medical Society
Retired Physicians Group
MSMA Member Since 1977

ERRATA

The academic degrees were not included in the submission of the November/December 2012 article, "Study of Secondhand Smoke Exposure in St. Louis City and County Suggests Need for Comprehensive Smoke-free Missouri Law Adoption." Academic degrees are Sarah Moreland-Russell, PhD, Julianne Cyr, MPH, Peter Benson, PhD, Graham Colditz, MD, DrPH, Deren Pulley and Joaquin Barnoya, MD.



The photographs of the authors of Gary Salzman, MD, and Michael Amini, MD, were incorrectly identified in the January/February 2013 issue for the article, "Infectious Spondylodiscitis." See photo of Dr. Salzman on left and Dr. Amini on right.

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Good News from MSMA Members

Vincenzo Galati, MD, MSMA member since 2011, urologist at Saint Francis Medical Center in Cape Girardeau, received certification in the MD Anderson Cancer Center Network. This certification will allow Galati to use the Anderson Center's resources in treating local cancer patients.

Richard Hellman, MD, MSMA member since 1976, has been elected as Vice-Chair of the Executive Committee of the Physician Consortium for Performance Improvement (PCPI), the premier physician-led quality measurement organization in the United States. His election has been confirmed by the Board of Trustees of the American Medical Association (the convener of the Consortium), by the Council of Medical Subspecialties, and by the 190 members of the PCPI, which includes nearly all medical specialty organizations, many state medical societies, and many of the certifying boards of the specialties.

Scott D. Kirkley, MD, MSMA member since 2007, was appointed to the Parkland Health Center Board of Directors in Farmington, Mo.

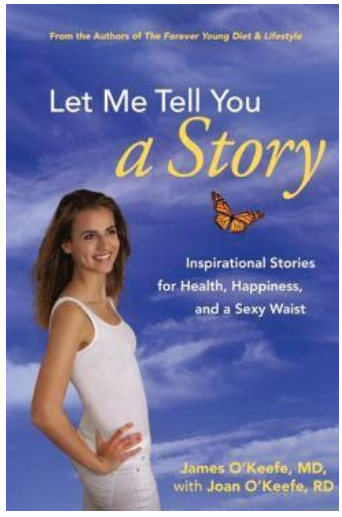
William Marshall, MD, MSMA member since 1977, was announced as the Glasgow Citizen of the Year Award. Dr. Marshall has practices in that area for more than 50 years.

Ozarks Medical Center Rehabilitation Services in West Plains, Mo., has partnered with local physicians and the West Plains School District to provide athletes with the services they need to keep them on the field and in the game. Physicians working with the students include **Clara Applegate, MD**, MSMA member since 2008, **Richard Bowles, MD**, MSMA member since 2012, **Douglas Green, MD**, MSMA member since 2003, **Jay Jones, MD**, MSMA member since 2011, **Vikas Kumar, MD**, MSMA member since 2011, and **John McCormack, MD**, MSMA member since 1991.

Missouri Medicine announces the **The Arthur Gale Freedom of Expression Award** to be presented annually to the author of the best commentary article published in *Missouri Medicine*, in honor of **Arthur Gale, MD**, one of the Journal's Contributing Editors and MSMA member since 1976.

This prestigious and monetary award is offered to encourage MSMA physicians to submit personal perspective essays on issues that are topical and provocative. All MSMA members shall be eligible to submit articles, and a special, independent MSMA committee shall be appointed in December of every year to judge the submissions published during that calendar year. Visit www.msma.org/missourimedicine for more information.

Book Review



Based on their experiences, the husband and wife team of *Missouri Medicine* Preventive Medicine Editorial Board cardiologist James O'Keefe, MD, MSMA member 2003, since and dietitian Joan O'Keefe bring real-life, inspirational stories of everyday people who have achieved healthy lifestyles to help increase their health, happiness, and longevity.

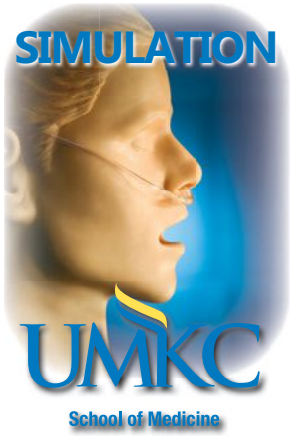
In *Let Me Tell You a Story,* Dr. James O'Keefe and his dietitian wife Joan O'Keefe, co-authors of the best-selling *The Forever Young Diet & Lifestyle*, present stories of real-life people and how they found their way to living a happy, healthy, and joyful existence. The authors firmly believe that the human brain best learns new concepts and internalizes information that can change one's perspective and alter behavior through story-telling.

Endorsements for *Let Me Tell You a Story*:

"True to its title, in Let Me Tell You a Story, the O'Keefes weave a wonderful collection of stories that provide the starting place for conveying lessons in health. This clever storytelling tool makes each story real, immediate, and relevant to the reader. The lessons they convey cover just about every facet of human existence, from mental and emotional health and constructive ways to manage stress, to heart health and how to reduce risk maximally and naturally, to why sexual health is important to a healthy and rich life. From start to finish, the O'Keefes create a heartfelt message that is certain to captivate, entertain, and educate."

—William Davis, MD: author of New York Times Bestseller *Wheat Belly: Lose the Wheat, Lose the Weight and Find Your Path Back to Health*

Paperback: 320 pages Publisher: Andrews McMeel Publishing; Original edition (February 26, 2013) Language: English ISBN-10: 1449407773 ISBN-13: 978-1449407773 Available at Amazon.com MM



The Use of Simulation in Medical and Surgical Education

by Nicole M. Fearing, MD

The power of having a living simulator is priceless and leads to endless possibilities for scenarios to prepare the learner for future encounters with their patients

As I am writing this, I sit in the Washington Dulles airport waiting for a flight to Kansas City. It is amazing that I will soon get on my flight (albeit three hours delayed) and allow a person I don't know to transport me up thousands of feet in the air to catapult me back to Kansas City.

I assume several things about this person I have never met. They are a professional. They are safe. They are well-trained. They have my safety in mind. They have practiced flying airplanes many times before actually doing it. And if, God forbid, trouble occurs with the plane, they know how to handle just about any emergency, because they have practiced it in a simulator prior to ever getting into a real cockpit. I'm afraid of flying, and if I was not sure these assumptions were true, I never would step onto a plane.

Shouldn't patients have the same expectations of physicians, nurses, pharmacists, dentists, paramedics and all medical professionals? By choice or by tragedy, these people meet us and put their lives in our hands. They expect us to be well trained, safe, professional, empathetic to their needs, and that when something unexpected happens, we should have the knowledge to handle it even if it is our first time really experiencing it. Somehow, we are supposed to know the right thing to say when someone dies or finds out they have cancer, despite the fact it can be a horribly uncomfortable conversation to have.

How do we practice suturing a laceration first, before actually performing it on a screaming four-year-old in an emergency room? How do we learn how to recognize and treat malignant hyperthermia when the likelihood of seeing it in our career is minimal? How do medical professionals get comfortable with their own discomfort?

The answer is simulation by in a wide variety of settings. First, however, it is important to know what the types of simulation are. Simulators are classified as low- or high-fidelity. Many of you are familiar with ResusciAnnie. We used to use her to practice CPR, but now we have a more advanced version of her to do high-fidelity simulations. These high-fidelity mannequins can be still be used for CPR, but can do so much more. Some have the ability to monitor chest compressions (are they effective, hard enough, fast enough?) They can tell you when you need to change what you are doing to be more effective. They can and respond to medication administration. They can speak, they can be hooked to monitors, be defibrillated. And some even can deliver a high-fidelity neonate that cries, turns blue, responds to oxygen and other treatments.

These high-fidelity mannequins aren't human, but sometimes participants can forget that in the midst of a simulated crisis. There are also high-fidelity simulators on which candidates can practice various surgeries, prior even touching an actual human being. These simulators can monitor the movements of each hand, and help learners to become more efficient in space and time before transitioning later to the operating room.



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The Youngblood Medical Skills Lab at the University of Missouri Kansas City School of Medicine opened in 2007. It was named in honor of Dr. James Youngblood, a former chair of the Department of Obstetrics and Gynecology.

There are a huge number of low-fidelity simulators. These models break out lower-level tasks that can be practiced repeatedly, to get the proper steps and technique down. They include skills as simple as placing as IV to more complex procedures like placing a central line. The learner can become familiar with equipment used to perform techniques, and they can practice over and over until they get it right on the task trainer. The comfort factor increases for the learner and later leads to increases in patient confidence and satisfaction in the real-world setting.

One of the most popular types of simulation is the use of standardized patients. These are actors trained to play the role of the patient, family member, support staff, etc. The power of having a living simulator is priceless and leads to endless possibilities for scenarios to prepare the learner for future encounters with their patients. This is the fastest-growing portion of our program at the University of Missouri Kansas City School of Medicine.

Standardized patients are an effective tool to work on delivering bad news. We can do the same encounter and have the patient react differently each time: Anger, grief, tears, denial, and silence. The learner gains practice in how to handle each scenario in a way that shows empathy and good communication. Our ability to communicate effectively with our patients is what physicians and medical providers are really judged on.

Standardized patients are used throughout the medical school curriculum in almost every year and in numerous residency programs. They are a core component of our year 2, 3, and 5 patient-based assessments and are essential to preparing for the Clinical Skills Exam. The standardized patients are also an excellent tool to provide feedback evaluation to the learner about their verbal and nonverbal communication.

The final key component of simulation is the debriefing of the task or the simulation. Sitting down and reflecting on their actions allows the learners to apply clinical concepts to their actions. This can be done with the use of videos, group or individual discussion and evaluation. This is where the learning really takes place and concepts are solidified.

At UMKC School of Medicine, we are doing all those facets of simulation, and the practice is growing by leaps and bounds. In this *Missouri Medicine* theme issue you will learn about simulation in its various forms in medical/surgical specialties.

There are other ways to also learn about the growing field of medical simulation. Each year, Johnson County Community College has a simulation conference in September where simulation leaders from the community and the nation give talks and seminars on simulation. Visit www.jccc.edu/healthcaresimulation for more information. The Society for Simulation in Healthcare is a national organization that has a national meeting in January yearly. Their website is www.ssih.org. The Association for Standardized Patient Educators has a national conference in June. Visit www.aspeducators.org.

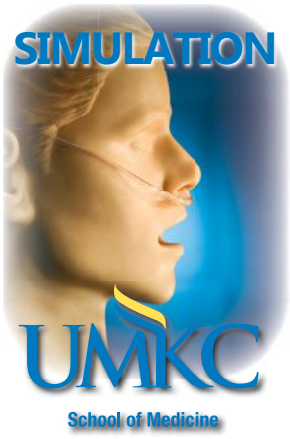
Acknowledgments

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Disclosure

Some images provided with permission by Gaumard Scientific.

MM



Task Training and Simulation in the Pre-Hospital Environment

by Paul E. Ganss, MS & Courtney McCain, BS

Simulations are case-based and may either focus on the individual skill, or may involve the assimilation of multiple skills to help develop critical thinking.





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Abstract

The increasing popularity of standardized patients is helping Emergency Medical Services (EMS) educators to develop (and reinforce) good professional behaviors among EMS students before they hit the streets to serve our communities.

Introduction

The paramedic team was met on scene by their patient's husband, who escorted them to her side. The patient, who was pregnant with her first child, had come home from work complaining of a severe headache and visual disturbances. Her concerned husband had called 911. As the paramedics began assessing their patient, she had a seizure. Within several minutes, the EMS team had an airway established in their still-unresponsive patient. One paramedic ventilated the patient while the other worked to obtain IV access.

The patient in this case was not real, but a Noelle® high-fidelity simulator (See Figure 1). Her husband was a standardized patient, or an actor trained to portray the patient's spouse. The rescue team included paramedic students from the EMS Education program at the UMKC School of Medicine, and the case was a simulation to reinforce their didactic lessons.

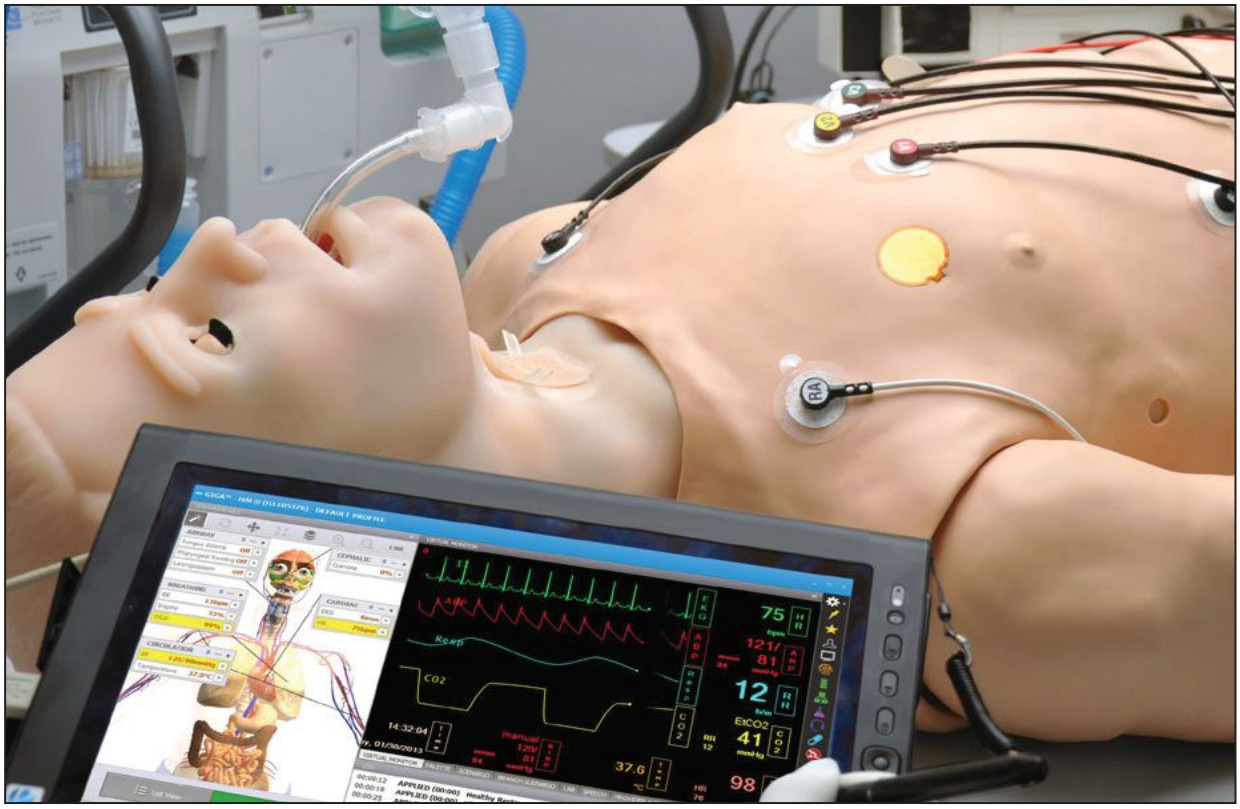
Early Simulation in Emergency Medicine and Pre-hospital Care

Simulation in pre-hospital care education can be traced back more than 50 years ago, when an anesthesiologist by the name of Dr. Peter Safar conducted research into the life-saving technique that became mouth-to-mouth resuscitation. Safar used a paralytic to stop the breathing of volunteers, and then demonstrated that the expired air of a rescuer could maintain adequate oxygenation. Safar later collaborated with Norwegian toymaker Asmund Laerdal, and the Resusci-Anne (arguably the first, human patient simulator) was born. Today, such simulations as repetitive task training, standardized patient and high-fidelity simulation are commonplace in educating pre-hospital responders. Those simulations extend to large-scale regional and national-level exercises.

Levels of Pre-Hospital Care in the United States

In the United States, there are four, general levels of pre-hospital care provider, although the actual titles differ from state-to-state. Emergency medical responder (EMR) renders very basic pre-hospital care such as non-invasive airway management, ventilation, bleeding control, and fracture stabilization. Many EMR personnel often work primarily as law enforcement officers, in some fire departments and in the industrial environment (pre-hospital care is their secondary responsibility). The EMR should not be confused with the term "first responders" which

Figure 1
HAL® S3201 Tetherless Patient simulator with automatic or Instructor control.



collectively describes all responders — fire, police, EMS and emergency management — to large-scale events.

Emergency medical technician (EMT) is considered entry level for a career in pre-hospital care. The EMT is a basic life support provider who provides the care of an EMR with expanded capabilities for medical emergency and trauma management, and safe transportation of the sick and injured.

Higher-acuity levels of pre-hospital care include advanced EMT (AEMT) and paramedic designations. The AEMT has the capability to administer limited medications and establish IV therapy. The paramedic provides advanced airway management such as endotracheal intubation, medication administration, cardiac monitoring and 12-lead interpretation, defibrillation, and pacing. In addition to intensive skill training required by all levels of pre-hospital care, it also is essential to combining those technical abilities with critical thinking. This is where simulation becomes a vital part of training the pre-hospital provider.

Task Training and Simulation

Task training and simulation have uses in the initial and continuing education of pre-hospital providers. Simulated local, regional, and national level exercises are important to emergency managers to test response plans, and evaluate the effectiveness of first responders should a large-scale event occur.

Typically, a pre-hospital initial education program will introduce learners to various required tasks through didactic lecture and instructor demonstration. Those demonstrations of techniques may take place on a task trainer, manikin or human model (depending upon the skill, and the degree of invasiveness). As training progresses, learners utilize formative skill sheets or scripts to perform the skill while being evaluated by a peer. After a pre-determined number of repetitions (which require learners to have a specific number of consecutive successes), instructors will perform final evaluation of the level of competence for each skill. Once learners meet desired level of competence at this level, they practice those skills in simulation environment before advancing to a real patient.

Simulations are case-based and may either focus on the individual skill, or may involve the assimilation of multiple skills to help develop critical thinking. For example, the learner may be given a scenario in which a non-breathing patient still has a pulse. The expectation for this scenario

would be for the learner to assess the patient's airway and ventilatory status, secure the airway, and provide ventilations. In a more complex case, the learner may be given a scenario that requires a physical examination, airway management skills, vascular access, and administration of a medication. In those simulations, the learner will be required to gather information, come to a conclusion regarding the presenting problem, then select and prioritize treatments.

In the early stages of pre-hospital care initial education, task training and simulation will focus on the cognitive and psychomotor aspects of the educational program. However, there is a third domain (affective) which plays a critical role in the formation of a competent EMT or paramedic. Education and evaluation in the affective domain involves the attitudes and professional behaviors that each provider takes into the field. Mastery of this level is important, as poor professionalism can impact communication, often resulting in a negative effect on patient safety and outcome. The affective domain has long been considered to be difficult for educators to address, but higher levels of simulation can be an effective tool for teaching and evaluating how students react behaviorally to different circumstances.

Creating simulations that are of high-fidelity, and allow the learner to suspend disbelief, allows the pre-hospital educator to evaluate how students are likely to behave when are faced with real patients. This observation allows corrective actions to be taken before the learner enters a field internship and displays adverse behaviors in real-life situations. Human patient simulators and standardized patients are used in the UMKC program (among others) to craft realistic scenarios which allow instructors to observe patient communication, team communication, and clinical decision-making.

Uses for simulation in Continuing Education and Quality Improvement

The UMKC EMS Education Program utilizes skills trainers and simulation in providing initial and continuing education, as well as specialty pre-hospital education courses such as Advanced Cardiovascular Life Support (ACLS), Pediatric Advanced Life Support (PALS), and International Trauma Life Support (ITLS). The use of such technology in these offerings allows the program to keep these courses fresh and interesting, which increases learner interest and knowledge transfer.

Standardized patients have long been utilized by medical schools to prepare students for clinical encounters and board examinations, and now are becoming more commonplace as pre-hospital trainers. They are people of various ages who are trained to perform the same cases identically, and then evaluate student performance from the patient's perspective. Standardized patients (or SPs) most often are used in communication-based scenarios, such as mental health cases, breaking bad news or addressing the needs of family members while rendering patient care. Increasingly, they are being used in the ITLS curriculum to add a more interactive element to trauma care simulations. UMKC Standardized Patient Program has expanded to include cases geared specifically toward pre-hospital care.

Simulation and standardized patient scenarios can be written also to demonstrate the correct process for addressing issues that were identified in the quality improvement process. Agencies and programs can also conduct forensic analysis using simulation, designed to identify interpersonal issues with providers, and remedy those difficulties in lieu of discipline or discharge.

Simulation in the Emergency Management Environment

Large-scale situations (weather-related disasters, earthquakes, mass shootings, terrorism, hazardous materials releases) often result in a convergence of multiple local, state and federal agencies to address the event and mitigate further damage and loss to the community. Collectively, these "boots on the ground" workers are often referred to as first responders, but should not be confused with EMS first response. The unpredictable and infrequent nature of these events poses a problem for emergency management officials in that these are low-frequency, high-risk events where even the best detailed play books will not have all of the answers.

The majority of EMS, fire, and law enforcement personnel will respond to one of these events once in a career—if at all. For this reason, emergency managers take an "all-hazards" approach to planning for these events, using the National Incident Management System (NIMS), the Incident Command System (ICS) which is embedded in NIMS, and a uniformly accepted approach to triage, treatment, and transportation of patients such as the Simple Triage and Rapid Transport (START) triage system. The emphasis moves from managing the actual

Resusci Anne: The Mother of All Simulators



Resusci Anne, also known as Rescue Anne, is a training mannequin used for teaching cardiopulmonary resuscitation (CPR) to both emergency workers and members of the general public. Resusci Anne was developed by Norwegian toy maker Åsmund Laerdal, based on the research of Peter Safar and James Elam, and was first introduced in 1960. The mannequin is designed to accurately simulate the human respiratory system and external body landmarks in order to facilitate training.

The distinctive face of Resusci Anne was based on L'Inconnue de la Seine, the death mask of an unidentified young woman reputedly drowned in the Seine River around the late 1880s.

Source: Wikipedia.com

problem to managing the aftermath. This planning occurs at the institutional level (i.e. schools, hospitals, factories), as well as the local, state, and federal levels.

After a plan has been written, issues still remain: Who are the players and what are their roles? How is the plan disseminated to the players, and how will they learn how to perform their roles? Will the plan work? What limitations might impact the plan?

Simulation will effectively address these issues and is used at all levels of the planning process. In fact, such emergency response simulation is required for accreditation at many levels. Local ordinances, state and federal regulations may address the frequency and level of simulations that are required to evaluate emergency response plans. These simulations can include table-top drills where paper assets and "patients" are moved around in a walk-through of the plan. Simulations then may expand to test individual facets of the response plan (such as walking patient data through an institution to test the process flow).

Multiple agencies can participate in drills that test the emergency response, inter-agency communication, and flow of patients or transport and hospital capacity. At the local level, annual, disaster drills are commonplace. In recent history, state and federal governments have held real-time, large scale drills to test community response and identify issues in response and patient movement. Such drills can be regional and national in scope, and involve dozens of agencies and hundreds of responders.

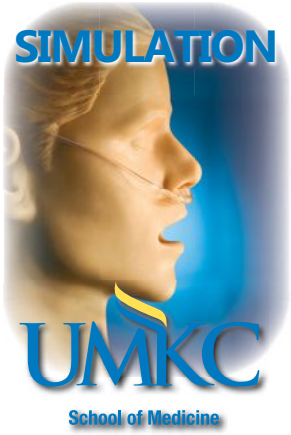
Summary

The education of pre-hospital responders has grown in complexity from the days of the early Resusci-Anne, and the first teams of EMTs and paramedics. Rudimentary task trainers have grown in complexity and realism. High-fidelity simulation mannequins can bring realism to higher level skills training while maintaining a safe environment for both formative learning and summative evaluation. The increasing popularity of standardized patients is helping EMS educators to develop (and reinforce) good professional behaviors among EMS students before they hit the streets to serve our communities.

Disclosure

None reported.

MM



Simulation in Internal Medicine Training

by Ashraf Gohar, MD & Eyad Al-hihi, MD

Simulation helps learners use mistakes to learn from rather than to harm patients, practice working in teams, and standardize curriculum and competency skill evaluation.



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Abstract

Simulation is a growing safe format to train learners on different skills and procedures in the field of Internal Medicine. This article will provide an overview of Simulation in Internal Medicine training as well as a description of different procedures and competencies. The goal of this review is to provide clinician educators and learners specific information on how they can implement simulation training in their clinical setting.

Introduction

Simulation-based medical education has revolutionized training in both undergraduate and graduate medical education. Simulation-based medical education has been used and studied by the specialties to provide clinical training, reduce medical errors, and improve patient safety. [1] Simulation improves resident confidence in performing procedures in addition to improving skill level in a safe environment.[2] The American Board of Internal Medicine identifies a set of procedures and skills and different levels of required competency levels with a focus in patient safety and adequate training (Review ABIM procedure requirements at: http://www.abim.org/certification/policies/imss/im.aspx#procedures). ABIM strongly recommends that procedural training be conducted initially through simulations.[3] There is growing emphasis on importance of simulation to the educational mission of Internal Medicine.[4]

Internal Medicine physicians need many skills in MICU setting. A randomized study at Northwestern University in Chicago showed that simulation-based education significantly improved resident knowledge and skill in the MICU and that knowledge acquired in the simulated environment was transferred to improved bedside skills caring for MICU patients.[5] A study from Mount Sinai School of Medicine reviewed the evidence regarding simulation use and found that residents trained on simulators were more likely to adhere to the advanced cardiac life support protocol than those who received standard training for cardiac arrest patients.[6]

Simulation activity at the University of Missouri-Kansas City is robust and increasing daily. It encompasses everyone from medical students to attendings and fellows.

Procedure based simulation

UMKC School of Medicine department of Internal Medicine does yearly critical care/pulmonary fellows' orientation courses that help to prepare our new fellows for fellowship. This course started in July 2011 and is for ten hours in the first week of fellowship and five of the ten hours are procedures simulation in skills lab and bronchoscopy.

Orientation procedures for new pulmonary /CC fellows include

Figure 1

Simulation in Internal Medicine training	
Potential simulation area	Clinical application
ACLS & Airway management	
1- Airway management	Endotracheal intubation
2- CPR & defibrillation	Cardiac arrest, Ventricual Fibrillation
3- Chest tube	Pneumothorax
Internal Medicine procedures	
1- Central venous catheter insertion	Venous access
2- Arterial line insertion	ABGs, arterial line access
3- Lumbar puncture	Meningitis, diagnostic & theraputic LP
4- Thoracocentesis	Pleural effusion
5- Venipuncture	Blood draws
6- Shoulder injection	Acromial bursitis
7- hand & wrist injection	Trigger finger, carpal tunnel, DeQuervain's
8- Knee injection & aspiration	Osteoarthritis, septic joint, gout, knee injection
9- Hip injection	Greater trochanteric bursitis
Physical exam skills	
1- Auscultation	murmurs, abnormal heart sounds, pericarditis, valve disorders
Bedside management & clinical reasoning	
1- Bedside simulation scenarios	Bedside management of acute decompensation, syncope, hyperkalemia

procedures that they usually do not get enough exposure in residency such as chest tube placement, intubation/ airway management, intra-osseous line placement and bronchoscopy (See Figures 1 and 2). It also involves a refresher of difficult airway management and procedures that they should be certified in such as ultrasound guided thoracentesis/paracentesis/ and central line placement as well as arterial line placement. We have ultrasound guided central line model in our skills lab. Central line placement is one of the most common procedures in ICU setting (See Figure 3). The use of ultrasound in central line placement is the standard of care now as it decreases complications by allowing vein visualization and confirming vein patency. It also decreases the times of attempts to get into the vein that decreases mechanical complications.[7]

Some of the fellows come from other programs that do not use ultrasound in procedures. It is important to teach them about ultrasound use especially we have ultrasound in our ICU available all time. We have even provided an ultrasound course to our fellows and staff to be able to practice with the ultrasound machine itself and improve technique in its use. We also concentrate in each procedure on reviewing proper sterile technique, patient time out, obtaining consent, and documentation of the procedure.

We have monthly procedure morning report for residents and students rotating in TMC. Every month we teach different procedure such as ultrasound guided central line placement (See Figure 2), thoracentesis, paracentesis, arterial line placement and intra-osseous line placement on task trainers and mannequins and stress the sterile technique and check list for procedure, introduce the kit and procedure steps, discuss pitfalls and how to avoid and detect complications. Each resident practices the procedure on model under the supervision of an expert.

At the end of the internship there are two full days of a critical care refresher course for interns to prepare them to become supervisor residents. In that course, 4 hours of simulation that include two hours of procedural simulation for 3 procedures (US guided central line, arterial line and IO) and three simulation sessions for scenarios for ventilator management (ARDS and COPD) , BIPAP (COPD) and shock (septic and cardiac). 23 interns usually attend this course every year. We started this course in June 2011 and continued every year since.

Half day teaching course for residents began in January 2012. Within those courses there is protected time for procedural simulation. The residents are split into 3 groups, each group gets half day protected education time monthly. We teach one procedure each month in the skills lab to increase the exposure to procedures and improve the skills. We teach procedures as arthrocentesis, intra osseous line and lumbar puncture that residents have little exposure to or common procedures as central line, arterial line, thoracentesis or paracentesis. This is very well received by residents and the goal is to improve residents' skills and patient care, this also overcomes the busy schedule and the

Figure 2
Orientation procedures for new pulmonary /CC fellows include procedures that they usually do not get enough exposure in residency such as chest tube placement, intubation/airway management, intra-osseous line placement and bronchoscopy.



reduced work hours where opportunities for doing these procedures may be less available.

Started in June 2012 a course for 6th year medical students was developed by Dr. Gohar for procedural simulation. The course includes 4 sessions, 2 hours each, during the internal medicine rotation (average 12-15 students). It includes 5 procedures simulations (Ultrasound guided central line placement, arterial line placement, Ultrasound guided thoracentesis, US guided paracentesis and IO). Session include didactics, procedural indications, contraindications and complications, how to perform a consent as well as proper sterility and documentation. Students learn the set-up of the kit for procedure and eventually do the procedure on a mannequin under the tutelage of an expert attending who signs off on the student.

Small group sessions are used to review difficult patient scenarios such as shock, ARDS and COPD exacerbation with residents. Shock is one of the most common causes of ICU admission especially septic shock in MICU and cardiogenic shock in CCU. We wanted to train our residents about shock management by creating 2 shock scenarios one for pneumonia/septic shock and the second for acute MI complicated with cardiogenic shock. The scenarios include clinical history and examination that suggest type of shock and available investigations as CXR and EKG. Residents then suggest management plan and based on the plan we move few hours in time and give them patient progress and they modify management plan based on new data. So it simulates what happens in reality and we discuss different opinions and stress on mistakes to be avoided and proper plan to be followed.

Similarly, ARDS is one of the most difficult diseases to manage in ICU as sometimes it is associated with refractory hypoxemia. Management of hypoxemia on ventilator is a very good discussion for teaching small groups as options are wide and suggestions open many tracks for discussion. We use ARDS scenario to discuss management of hypoxemia on ventilator. Respiratory therapists and critical care physicians use ventilators connected to model in this scenario discussion and they create changes on ventilator suggested by the group and are able to create improvement or complications that may happen from these changes in reality on the model.

Finally, COPD exacerbation with acute on chronic respiratory failure is also very rich subject and one of the common situations that is very liable to mistakes as physicians in training like to normalize values in ABG and this may push them to use large tidal volume or rapid respiratory rate so numbers look better, not realizing that this is harmful to patients as this may cause auto-peep and pneumothorax. Also correction of CO2 in chronic CO2 retaining COPD patient push the kidney to get rid of compensatory bicarbonate retention to correct PH and this creates a problem after extubation and may cause reintubation. Learning the concept of permissive hypercapnia and goal of acceptable numbers instead of normal numbers is the goal of this scenario for COPD Ventilator management. Respiratory therapist and critical care physician use ventilator connected to model in this scenario too.

Moving away from use of the simulators, the Department of Internal Medicine at UMKC uses standardized patients to help the learners with imparting bad news and having end of life discussions. Informing a patient or his or her family about sad news, such as death or cancer, is one of the most difficult situations a physician may face in his or her practice. Many times this is done in a way that may upset the family due to physician discomfort in talking

about the situation. Learning this art from experienced physician in a simulation setting allows the learner to get the practice and get the words right. We currently have an ongoing study of breaking the news of a death after a code situation and then asking the patient's family for an autopsy. In doing so we teach the resident about how to talk with the family, answers to common questions on autopsy and really who should be the person to ask for the autopsy itself. Surveys of the residents involved in the study show they are more comfortable talking with the family about the death and then asking for an autopsy.

Figure 3
Central line placement is one of the most common procedures in ICU setting.



Brain death evaluation and properly informing the family about the death of their loved one is a sad but common scenario in the ICU. If not done properly it may lead to increased grief and confusion. We are also working with critical care fellows in simulation to improve their comfort in evaluation for brain death of a patient and what is the proper way to involve an organ donation team without compromising the care team's involvement.

Occasionally we, as physicians, see patients with end stage diseases such as very severe COPD, or advanced cancer where no one has discussed with them what they want to do if the condition worsened and they are unable to tell us their wishes. A common scenario is, patient comes very ill to emergency department and gets intubated and this creates a big family burden to decide for their loved one whether to keep them intubated or not in a situation that may be futile care. This situation may be avoided if we create discussion with patient in clinic about his or her wishes regarding code status, intubation and other situations as dialysis. So we have created opportunities for the residents to practice these types of scenarios in a controlled environment. Here the standardized patients can be scripted to be angry, tearful, silent or in denial. The residents are critiqued by their standardized patients and do a self-evaluation. The residents will often have the opportunity to watch the videos of their encounters and see how they interact with their patients or their families. Afterwards a debrief occurs where group discussion is done on the scenarios and how events were handled giving the learner a chance to reflect on their actions and possibly change what they would say or do to improve the situation for the patient or their family.

Summary

Simulation-based education has many applications in Internal Medicine training that foster skill competencies in a controlled safe environment. Simulation should be an integral part of any Internal Medicine training or education. Simulation helps learners use mistakes to learn from rather than to harm patients, practice working in teams, and standardize curriculum and competency skill evaluation. The table below summarizes some areas of simulation use in Internal Medicine training and clinical applications:

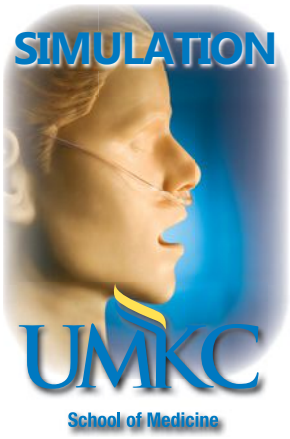
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Disclosure

None reported.

MM



No Longer Waiting for an Accident to Happen
Simulation in Emergency Medicine

by Stefanie Ellison, MD, Christine Sullivan, MD & Robert McCullough, MD

Simulation in Emergency Medicine fosters a safe environment to develop medical decision-making skills, diagnosis and management skills, and essential procedural skills in graduate and undergraduate medical education.







Stefanie Ellison, MD, MSMA member since 2012, (top) is an Associate Professor and Emergency Medicine Clerkship Director, and Christine Sullivan, MD, MSMA member since 1983, (left) is an Associate Professor and Emergency Medicine Residency Program Director. Both are in Department of Emergency Medicine at Truman Medical Center. Robert McCullough, MD, (right) is a PGY-2 Emergency Medicine Resident at Truman Medical Center.
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Abstract

The practice of emergency medicine (EM) requires proficient and expert skills in multiple high risk procedures. The emergency physician in-training needs a safe and realistic environment in which to practice and perfect the skills necessary to care for patients ranging from the critically ill to the patient with difficult intravenous access. Undergraduate medical education overall has a need for training that enables students to develop the knowledge, skills and attitudes to practice in a variety of specialties. This article provides an overview of simulation in a three-year emergency medicine residency at Truman Medical Center, in a required final year clerkship for all medical students at the University of Missouri-Kansas City, and discusses national trends for the use of simulation in emergency medicine.

Introduction

Simulation is the artificial structuring of a situation, environment, or experience for the purpose of learning, evaluation, or skills training.[1] This can include high-fidelity mannequins, task trainers, standardized patients or professionals, or a combination of these tools to meet the teaching and assessment needs of the experience. The practice of emergency medicine is ideally suited to this form of training to teach and assess the merging of decision-making and procedural skills because the specialty frequently requires recognition and action of life-saving skills such as, an open thoracotomy or the intubation of a patient in respiratory distress. Simulation education is well established in EM residency training and is expanding in scope and practice in undergraduate medical education, especially in EM student clerkships.[2]

In the past, residents in emergency medicine were trained in an apprenticeship model where they learned about procedures through didactic lectures and reading and then practiced their skills by treating patients under supervision and performing procedures when necessary but often in high risk environments.[1, 3] Skills training and judgment occurred on real patients and in a high stress environment. For more than a decade, residency programs and training facilities have focused more on efficiently training residents and the need to integrate an ever growing body of knowledge to practice in the field.

Simulation also suits the growing need to provide more active learning for knowledge acquisition, medical decision-making and skills development. Additionally, the Council of Residency Directors have recognized the need for alternative and clinically oriented teaching tools for assessment in the Accreditation Council for Graduate Medical Education (ACGME) competencies.[4]

Residents and medical students report increased confidence and satisfaction with the use of simulation in their training.[5, 6] For residents, realistic patient experiences can provide relevance and context to learning, including improving retention of the material.[7] An undergraduate medical education program is ideally suited for simulation to function as a teaching tool for evaluating and training students, especially as medical education is evolving to more clinically oriented case-based scenarios and small-group didactic sessions. Studies have demonstrated the effectiveness of simulation in teaching basic science, clinical knowledge, communication skills, procedural skills, and team-based care.[2]

Simulation activity for training of medical students and residents in emergency medicine is growing and is essential at the University of Missouri-Kansas City (UMKC) School of Medicine and at the Truman Medical Center emergency medicine residency training program.

UMKC-Truman Medical Center Emergency Residency Program

The emergency medicine residency training program utilizes simulation to teach and assess residents in acquiring the knowledge, medical decision-making skills, and to practice skills to prepare them in the care of patients. The residency curriculum is broken down into the following categories:

Simulation Experiences

Advanced Cardiac Life Support (ACLS) training utilizes computerized simulation and task trainers to provide training and certification to all learners. Each year, post graduate year one (PGY-1) emergency medicine residents obtain ACLS provider and instructor certification during their residency orientation month. The UMKC Youngblood Medical Skills Laboratory (YMSL) is the site for ACLS certification for senior medical students and all specialty residents. Emergency Medicine residents serve as ACLS instructors for these courses throughout their three-year training program. This model promotes residents as teachers which also facilitates the maintenance of these skills by our residents. As instructors, residents use basic airway Laerdal® Airway Management Trainer (Laerdal Wappingers Falls, NY) and CPR models along with high-fidelity computer-integrated mannequins (METIman® mannequin simulator, Medical Education Technologies, Inc, METI, Sarasota, FL and Laerdal SimMan®, Laerdal, Wappingers Falls, NY) to teach and assess basic and advanced resuscitative techniques. This expertise is carried further as EM residents are looked to for guidance not only in the emergency department, but when they respond to medical codes throughout the hospital. Advanced Trauma Life Support, Pediatric Life Support, and Basic Life Support certification also utilize simulation and are required certifications for all EM residents.

An Emergency Medical Services curriculum has also been adapted and implemented for the 2012-2013 academic year as a three-year longitudinal experience for residents. Throughout training, EM residents will teach and learn alongside Emergency Medical Technician (EMT) and Paramedic students in their training program at the School of Medicine. This is an inter-professional component of the residency curriculum that allows these learners to develop skills in simulated patients utilizing the programmed Laerdal SimMan® and METIman® cases that further reinforces their roles and responsibilities and the teamwork of their future practice. As residents progress in their skill level, they will have an increasing role in teaching the EMT and paramedic students. This curriculum includes objectives based on post-graduate level and assessment in-line with the ACGME competencies.

There are many additional simulation experiences in the course of the academic year. Some examples include advanced airway skills and adjuncts, procedural sedation, central line placement, and lumbar puncture. Quarterly, residents work with pediatric emergency medicine faculty using high-fidelity mannequins to manage critical pediatric cases, maternal and neonatal resuscitation, as well as essential procedures on size appropriate models. Ultrasound education focuses on interpreting images and enhancing techniques, and allows for practice both on procedural models as well as resident peers. Future simulation experiences include the evaluation of residents' skills in hand-over communication (transition in patient care) using standardized health care team members.

Cadaver Laboratory

Despite advances in simulation technology, the residency program leadership realizes that cadavers provide a more authentic, anatomically detailed simulation experience for certain procedural skills. A three-week annual cadaver lab for high acuity, low frequency procedures is provided to all residents. The curriculum endeavors to assess procedural competency, namely knowledge, skills and attitudes of learners. Procedures practiced in the curriculum include: retrograde wire intubation, open and percutaneous technique for cricothyrotomy, chest tube thoracostomy, thoractomy, peridcaridocentesis, diagnostic peritoneal lavage, and intraosseous access. An introductory session prior to the laboratory emphasizes each procedure's indication, contraindications, key anatomy, equipment, and methods to confirm success. Residents are encouraged to do further reading on each procedure and must successfully pass a knowledge test to participate in the lab. Residents receive one-on-one faculty observation during all procedures with immediate verbal as well as written checklist feedback. Residents can practice each skill multiple times and incorporate faculty feedback as they repeat the skills. The cadaver lab supports the patient care, medical knowledge, and practice-based learning and improvement competencies.

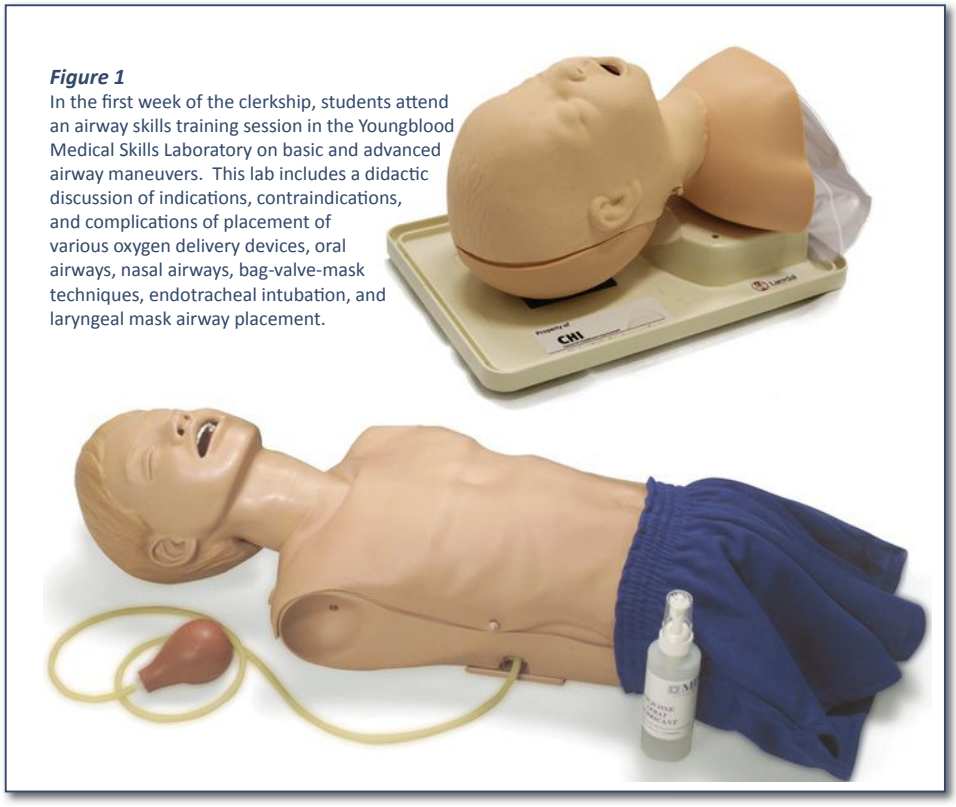


Figure 1
In the first week of the clerkship, students attend an airway skills training session in the Youngblood Medical Skills Laboratory on basic and advanced airway maneuvers. This lab includes a didactic discussion of indications, contraindications, and complications of placement of various oxygen delivery devices, oral airways, nasal airways, bag-valve-mask techniques, endotracheal intubation, and laryngeal mask airway placement.

Emergency Medicine Required Clerkship

All medical students at the University of Missouri-Kansas City School of Medicine are required to complete a one-month emergency medicine clerkship in the last eighteen months of medical school, and have done so for greater than 30 years. As a final year clerkship, it is essential to enable the student to evaluate the undifferentiated patient, learn critical patient management principles, and learn the skills necessary to perform procedures such as endotracheal intubation, lumbar puncture, central line placement, and intraosseous line placement, all germane to the practice of emergency medicine.

Experiential Learning

During orientation, students are introduced to a systems-based approach to the undifferentiated and sometimes critical patient. Students are provided an approach to identify problems with "airway, breathing, and circulation" and an interactive discussion of management principles occurs. The objective of this session is to teach students skills on how to recognize and manage the technical aspects of critical illness. This activity also stresses techniques on how to communicate with the critically ill patient, the patient's family, consultants, and the health care team -- skills they will need as resident physicians,

regardless of specialty. Students are then asked to manage eight "paper" cases as a team where they are provided the chief complaint and vital signs and then discuss the differential diagnosis, physical examination, diagnostic tests and procedures for each patient. Students are also instructed on critical communication skills to ensure that they safely and efficiently care for these patients. This approach has been detailed in a previous manuscript. [8] Following this activity, students are required to observe a critical patient encounter during the month and document on a worksheet the airway, breathing and circulatory status of the patient, interventions of the healthcare team, and list the tests and procedures that lead to all decision-making until that patient is stable or admitted. This exercise guides the experiential learning of the student and reinforces the management principles taught throughout the month.

Simulation Experiences

In the first week of the clerkship, students attend an airway skills training session in the Youngblood Medical Skills Laboratory on basic and advanced airway maneuvers. This lab includes a didactic discussion of indications, contraindications, and complications of placement of various oxygen delivery devices, oral airways, nasal airways, bag-valve-mask techniques, endotracheal intubation, and laryngeal mask airway placement (See Figure 1). Students practice each of these skills and complete this lab early in the clerkship so that they learn and practice essential skills prior to observing them during critical encounters in the ED. The Laerdal® Airway Management Trainer and the METIman® mannequin simulators are used during this simulation.

Students also attend a 90-minute simulation skills session with faculty where students manage two critical cases that are programmed into the Laerdal SimMan® (Laerdal, Wappingers Falls, NY) to reinforce concepts learned in the classroom and during patient care. Students individually are asked to manage the patient scenario using the systematic approach learned in the classroom. Students make clinical decisions about airway, breathing and circulation management, establish intravenous access, and practice ACLS treatment protocols while their classmates observe. They can ask faculty and their peers for assistance. The simulation is designed to provide experiential learning in order to reinforce the medical decision-making, deliberate practice, and management principles from the didactic and interactive lectures for the month.

Procedural Curriculum

In 2008-2011, two faculty developed and implemented a multi-session, interactive procedural curriculum to teach two procedures, internal jugular central line and lumbar puncture, during the emergency medicine clerkship. This curriculum was funded internally by the UMKC School of Medicine dean's fund. Our goal was to teach task training along with decision-making so that students have deliberate practice to achieve competence in the performance of high-risk procedures. The first session consisted of a pre-test, a one-hour interactive PowerPoint presentation about each procedure, and introduction of a checklist for each procedure. The session ended with a step-by-step demonstration by the faculty using the Blue Phantom Internal Jugular Central Line® (Blue Phantom, Redmond, WA) and the Kyoto Kagaku lumbar puncture simulator II® (Kyoto Kagaku Co., Ltd Head Office, Japan 612-8388) low-fidelity simulators. Each student then practiced and performed the procedure and observed other students while faculty provided instruction and feedback. In the second week, students were given a case-based, online tutorial outlining procedural complications, video instruction of the procedure, and a review of the checklist. In the third week, students worked through two interactive computerized cases requiring management decisions and recognition of indications for each procedure. As a capstone experience, in the final week students managed one of two critical patients programmed into a high-fidelity simulator. In the course of management, the student would decide that one of the procedures was clinically indicated, perform that procedure and be evaluated by faculty based on the skills checklist. Students then took a post-test and evaluated the curriculum. Ninety-two students completed all elements of the curriculum and the results showed that students demonstrated improvements in both cognitive and mechanical aspects of these procedures. Student evaluations showed a high level of satisfaction with the content and skills they learned in participating in the curriculum. This curriculum is ideally suited for the final year medical student and can be adapted to a



Figure 2
The Laerdal® SimMan™ patient simulator is used for clinical skills teaching including airway, breathing, cardiac and circulation management, and wound assessment / care. It features heart, bowel, respiratory and vocal sounds, and trauma modules can also be used with this simulator.

residency program, but it takes faculty time for adequate teaching and assessment during a one-month clerkship.

Students with an interest in emergency medicine at the UMKC School of Medicine have assembled a student SIMWARS team for the current academic year. Simulation teams have convened on the regional and national level in conferences of The Society for Academic Emergency Medicine and this year at the national meeting marks the 8th annual SIMWARS competition between residents. Residents and faculty in emergency medicine have designed a simulation training track at UMKC and are continuing to train the student team. This training has utilized cases programmed in Laerdal SimMan® as the simulated patient and incorporates the use of standardized professionals, as well as the use of task trainers to practice and demonstrate procedural airway skills (Laerdal® Airway Management Trainer and SimMan®), central line placement (Blue Phantom Internal Jugular Central Line®), and lumbar puncture (Kyoto Kagaku lumbar puncture simulator II®). Training has also included EMS students to highlight a collaborative team approach to patient care. The four-student team represented the UMKC SOM and lost in the final round to the champions in the Great Plains regional SAEM conference in September 2012. Residents and students are planning the upcoming training schedule and plan to compete again this year. This is a great opportunity for students and residents to learn and practice the team-based approach to care.

National Simulation Applications

In 2008, greater than 90% of emergency medicine programs in the United States reported the use of simulation to train their residents while 85% reported specifically using mannequin-simulators.[9] (See Figure 2.) Most residency programs have added simulation to a well-designed curriculum with a focus on medical decision-making and procedural skills training. A comprehensive medical simulation education curriculum for emergency medicine residents was introduced by Brigham and Women's Hospital in 2005 and reported it in 2007.[2] Their model involved a complete curriculum redesign to create a fully integrated medical simulation model that included adult learning principles, medical simulation learning theory, and standardized curriculum requirements to create a set of simulation-based modules. They utilize computer simulation, an advanced skills laboratory, human patient simulation, and classroom techniques to integrate simulation across the continuum of residency education.

The 2011 Model of the Clinical Practice of Emergency medicine was released in July of this year and represents the fifth review of the EM Model.[10] This model cites a listing of medical knowledge, patient care and procedural skills essential to the fundamental treatment for patients that present to emergency departments and is based on data collected by the National Center for Health Statistics at the Centers for Disease Control and Prevention. It is representative of the core knowledge and skills that are required of the emergency medicine physician to provide safe and effective patient care. The section on procedural skills is comprehensive, containing 67 procedures in all and including airway techniques, resuscitation skills, anesthesia and pain management, diagnostic and therapeutic procedures by system, and other procedures including ultrasound. As many of the model's listed procedures are infrequently performed, the need to maintain procedural competency through simulation is of increasing importance.

The ACGME will implement The Next Accreditation System (NAS) in July 2013. A key component will be the reporting of individual resident educational milestones.[11] Previous work has demonstrated that there is considerable variation between residents'

exposure to clinical patient care encounters relevant to the practice of emergency medicine.[12] Simulation may have an increasing role to ensure that resident learners experience all types of patient care scenarios in appropriate frequency as well as to document competency of educational milestones.

For undergraduate medical education, graduate medical education and across professional schools, simulation provides an ideal interprofessional education (IPE) opportunity. The World Health Organization recently described IPE and collaborative practice to mean: "Interprofessional education occurs when students from two or more professions learn about, from, and with each other to enable effective collaboration and improve health outcomes. IPE is a necessary step in preparing a 'collaborative practice-ready' health workforce that is better prepared to respond to local health needs."[13] Simulation also supports enhanced teamwork and encourages patient safety between professionals through deliberate practice of communication skills, including the opportunity to learn and practice the roles and responsibilities inherent to professionals as they contribute to the team-based care of a patient. As the focus has shifted to patient-centered care and team-based care, health professionals will need to learn with, from and about one another in real-life settings in order to facilitate teamwork and collaboration.[14] Providing this IPE is an essential next step for all professional schools and simulation of patient care scenarios that combine these learners in realistic scenarios will reinforce experiential learning in the same context of how the learners will practice. We predict that simulation will be an important and innovative tool to provide IPE in the areas of patient safety, communication, and improved health care delivery.

Summary

Simulation-based education is fundamental to an emergency medicine residency program and the emergency medicine clerkship. It fosters a safe environment to develop medical decision-making skills, diagnosis and management skills, and essential procedural skills in graduate and undergraduate medical education. Future directions will be to develop simulations as educational milestones measures in residency training and possibly for medical student promotions in a medical education program. Ideally simulations will be added as experiential learning activities in courses and clerkships across the medical education program since there is a growing emphasis on active learning for the adult learner in residency training and in medical school curricula. Simulation is an ideal activity to assist learners with integration of basic science knowledge and clinical medicine, with motor skill development of clinical skills and procedures, and it can also provide the learner with the context to better understand systems-based physiology and pathophysiology in developing a diagnostic and treatment plan for patient care.

Simulation is also an opportunity to provide interprofessional education and training in the areas of patient safety, communication, and team-based care.

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Disclosure

None reported.

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Simulation in Anesthesiology: A Key Element in the New Recertification Process

by Ben Newell, MD, Eugune Fibuch, MD & Michael McCartney, MD

This type of training environment is designed to ensure that the residents have not only the academic and technical skills, but also the behavioral, judgment, and communication skills that will make them a safe and successful anesthesiologist.







Ben Newell, MD, (top), MSMA member since 2012, is Assistant Professor and Director of Anesthesiology Simulation. Eugene Fibuch, MD, CPE, CHCQM, FAIHC, (bottom left), MSMA member since 1978, is Professor, Chairman, and Program Director. Michael McCartney, MD, (bottom right), is Assistant Professor and Associate Program Director, Department of Anesthesiology. All are at the University of Missouri – Kansas City School of Medicine.
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Abstract

The training of anesthesiologists has long utilized simulation based on the need to achieve maximum patient safety. The value of this type of training is that it can provide a real life experience and instruction in the complex dynamic environment of the operating room or intensive care unit through the use of didactic sessions, group or team-based exercises, and computer or servo-mechanical simulator training with post-simulation debriefings. This type of training is becoming more important in the formal training of anesthesiologists and will become part of the ongoing evaluation and certification of providers in the future.

Introduction

The specialty of anesthesiology has long utilized simulation in the training of anesthesiologists. A driving force behind the use of simulation was based on the need to achieve maximum patient safety. There has been a long recognized fact that what anesthesiologists do in the operating room, in terms of crisis management, is very similar to what pilots do in the cockpit of airplane. The airline industry has utilized Crew Resource Management (CRM) for the last 30 years to train its pilots in team-based activity and how to deal with a crisis during flight.[1] Orasanu and Connolly have described the environment in the operating room as a "complex dynamic world" consisting of patient care problems that are ill-structured, full of uncertainty, and time pressured.[2] These elements are difficult to teach in a real life experiential training environment. The value of CRM is that it can provide this complex dynamic environment through the use of didactic sessions, group or team-based exercises, and simulator training with post-simulation debriefings. Today, in the training of future anesthesiologists, residency programs are using a variety of methods that would fall into the overarching umbrella of CRM. This would include case-based scenarios, team-based interactive and communication training, computer simulation programs and servo-mechanical mannequin-based patient simulator experiences.

A Successful Simulation Experience

The factors that are required for successful simulation experiences are: 1) a plausible environment, 2) plausible responses, 3) plausible interactions, 4) familiar equipment, and 5) realistic simulation tools and mannequins.[3] Seropian suggests that there are seven practical aspects for the implementation of full-scale high-fidelity simulation. These include: 1) presence of a team leader; 2) trained actors (could be patients or providers); 3) high-fidelity mannequin(s); 4) realistic environments; 5) audiovisual

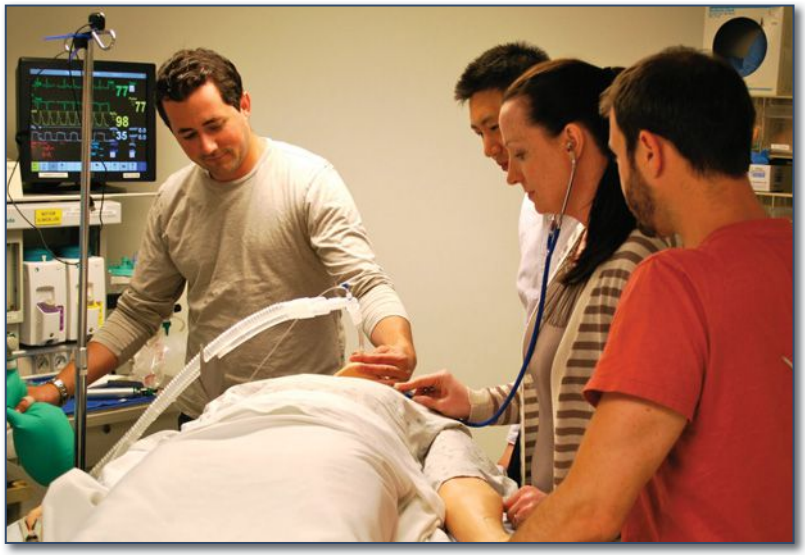
equipment (to provide feedback); 6) participants; and 7) trained facilitators (de-briefers). In addition, predetermined computer generated simulation scenarios need to be created, such as how to diagnosis and manage an intra-operative myocardial infarction. Therefore, providing satisfactory simulation training requires adequate resources and trained instructors, in addition to significant pre-planning and preparation.

The first month of clinical anesthesia training (PGY 2 year) is probably the most unsettling period of anesthesia residency training, since it involves, on the part of the resident, a clear lack of knowledge, skills, and problem recognition. Resident confidence is generally low and response time to problems is long. Using a prospectively designed simulation study during the first month of anesthesiology residency training, Lee, et al. studied 23 trainees who completed simulation scenarios involving routine intra-operative problems such as hypoxemia, hypotension, or hypertension. The residents received instruction in these events utilizing the SimMan mannequin. Following completion of the training there was a significant increase in confidence ($p<0.001$) in the 23 residents as measured by a pre and post course survey tool. The outcome from Lee, et al., is similar to outcomes reported from other specialties.[5, 6, 7] Thus, one can conclude that simulation training is becoming a vital and important tool in the primary training of anesthesiologists.[8] Furthermore, Schwid, et al., reported on a 10 institution mannequin-base simulation study that utilized 99 anesthesia residents.[9] They noted that numerous management errors occurred, even in senior (CA-3) residents, despite four years of training. The implications of this study is that high-fidelity mannequin-based simulation has the potential to further identify and potentially correct patient management deficiencies, even in very experienced individuals.

It is evident that simulation training and performance evaluation is an important tool in the primary education of anesthesiologists (and probably other physicians as well).

Figures 1 & 2
In the Figures below, residents ideally experience the patient care circumstance before they actually experience the issue clinically.





The question that might be raised at this point is, why the American Board of Anesthesiology (ABA) included the requirement for simulation training in the re-certification process (Maintenance of Certification in Anesthesiology – MOCA) for all anesthesiologists who have achieved their primary board certification after year 2000. The majority of the literature suggests that there is a difference in outcome data between individuals who have achieved primary board certification and those individuals who have not achieved board certification.[10,11]

There is less available data that would suggest that simulation in the MOCA process can achieve additional benefit in patient outcomes for those physicians who have undergone a high-fidelity simulation experience compared

to their colleagues who have not had the simulation experience. Furthermore, Haddad suggests that there is little data to support the notion that physicians who have participated in continuing medical education programs (CME) have better outcomes than their counterparts who have not participated in CME.[12] The issue than is why are the certifying boards moving to simulation as another tool to evaluate physicians' ongoing competency? Clearly, there is growing evidence of the importance and value of high-fidelity simulation in the primary training process of physicians and other providers. The airline industry has demonstrated over the last 30 years that the use of simulation is an important method to achieve and maintain competency. Savoldelli, et al., has provided data concerning performance based on written examination, oral examination and evaluation of performance using simulation.[13] The results from their study suggests that examinees differed in performance based on how their skills were assessed. The written and oral examination process appears to evaluate the "knows how" while the simulation experience appears to evaluate the "shows how". In other words, some individuals understand and can articulate the scientific and patient care information, but have difficulty in putting that information into clinical practice.

Finally, the question might be asked: Which is better-computer-based or mannequin-based simulation? Nyssen, et al., concluded that computer-based simulation is useful in teaching the technical aspects of patient care management, but mechano-servo simulation is better in teaching the behavioral aspects of communication and leadership.[14] Thus, high-fidelity simulation appears to have the potential to become an important adjunct to the written and oral examination process of the ABA. It makes logical sense, therefore, that the use of simulation will be of benefit in helping to evaluate the competency of anesthesiologists during their MOCA.

Innovation at UMKC Anesthesia Department

What are we presently doing in our Department at the University of Missouri-Kansas City School of Medicine to train the next generation of anesthesiologists? We are using a curriculum that is designed to provide our residents with a broad-based clinical experience linked to an extensive didactic program. The fundamental training tool used by the faculty is the use of Socratic teaching methods, such that we are continually challenging the residents by questioning their knowledge, judgment and decision making. This process is linked to the use of case-based conferences which discuss clinical decision making and judgment, requiring the residents to verbalize and make acute decisions. In other words, we want the residents to ideally experience the patient care circumstance before they actually experience the issue clinically. (See Figures 1 and 2.) In addition, we augment this training environment with frequent mock oral examinations using prospectively designed guided case environments, computer-based simulation scenarios and routine mechano-servo simulation sessions throughout the training program.

Additionally, we are spending increasing amounts of time in our formal didactic and case-based conferences instructing the residents on the behavioral, team-based, and communication issues that they will face when they eventually graduate and start practicing on their own. This type of training environment is designed to ensure that the residents have not only the academic and technical skills, but also the behavioral, judgment, and communication skills that will make them a safe and successful anesthesiologist.

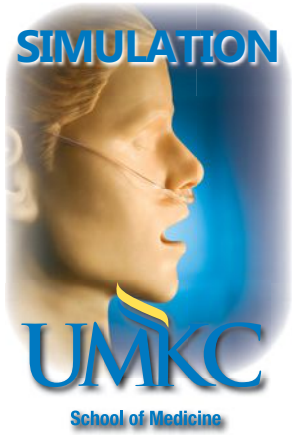
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Disclosure

None reported.

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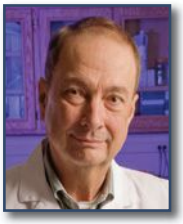


Simulation in Surgery

by Nicole Fearing, MD, Charles W. Van Way, III, MD & Glenn Talboy, MD

You can find everything from simulated skin and organs to virtual reality trainers that measure your every hand movement while practicing a whole case such as a laparoscopic appendectomy.







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Practice makes perfect. However, does practicing on patients until your skills are perfect make sense? Obviously not, but for years that is how skills were honed in the apprenticeship model of surgery. Surgical education has changed greatly in the 108 years since William Halsted established a graduate training program for surgeons at Johns Hopkins Hospital. Surgical simulation has been a growing part of that change. This has been due in part to the rise of laparoscopic surgery, the limits on resident work hours, the fast changing pace of surgical technology, and the change in the types of cases the residents are exposed to.

Surgical training is guided by the ACGME, the Accreditation Council for Graduate Medical Education. This organization establishes a rigid set of program requirements for each type of residency. For general surgery, the program requirements contain the following:

Section II.D. The institution and the program must jointly ensure the availability of adequate resources for resident education, as defined in the specialty program requirements.

Section II.D.2. Resources should include simulation and skills laboratories.

This is pretty non-specific. Nothing in the program requirements tells the program how the residents should actually use the simulation and skills laboratories. Nonetheless, there is a strong implication that the ACGME expects them to be a part of resident education.

The program requirements imply a difference between simulation and skills laboratories. Skills laboratories are focused on particular techniques. Familiar examples are the "knot box," in which junior residents learn to tie knots in a deep hole, or the very basic laparoscopic simulators in which residents learn to manipulate instruments while watching through a television screen. Simulation implies an effort to mimic some part of patient care, and not just technical skills. It may include, for example, management of resuscitation and critical care emergencies, as well as the use of simulators to teach Advanced Trauma Life Support and Advanced Cardiac Life Support. In practice, skills and simulation facilities are almost always combined.

Notice that the ACGME's program requirements don't mandate any particular courses, or even type of training. For example, while the Fundamentals of Laparoscopic Surgery course is widely used in surgical training, there's nothing in the program requirements. There are good reasons for this. For one thing, the ACGME maintains strict objectivity, and will not endorse particular courses. More fundamentally, the ACGME sets out the requirements, but feels that each program should have the freedom to decide how to meet them in its own way and with its own resources.

This has led to a wide variety of curriculums around the country for surgical simulation. At a minimum to become boarded in surgery all residents must complete ACLS, ATLS, and Fundamentals of Laparoscopic Surgery. However past this point, many residencies and surgical clerkships for medical students struggle on how to incorporate further training for their learners. In response to this the

American College of Surgeons, along with the Association of Program Directors in Surgery, created a national residency curriculum that is not mandatory at this time. Their curriculum has three phases: Phase 1- covers basic skills such as basic knot tying, suturing, and basic laparoscopy; Phase 2 - includes common procedures such as laparoscopic cholecystectomy and more advanced procedures such as thyroidectomy and gastric resection; Phase 3 - involves team bases skills such as traumas, handoffs, and pulmonary embolus. Each module has its own goals and objectives with written with expectations and metrics for those. Each module uses simulation to help teach these things whether it is a case scenario or utilizes a task trainer.

At the UMKC School of Medicine in the Department of Surgery, the ACLS, ATLS and FLS curriculum are already incorporated into the curriculum. The surgical interns now attend an orientation where they are introduced to Fundamentals of Laparoscopic Surgery (see Figure 1). They have instruction on basic suturing techniques and are introduced to the surgical instruments they will spend a lifetime using. Upcoming sessions using surgical simulators include basic and advanced laparoscopy, vascular surgery, central line insertion, and trauma triage, to name a few. Sessions are guided by attending surgeons who are experts in the topic covered with fourth or fifth year residents helping to teach each session. A study by Seymour et al. showed that adding in simulation in surgical training showed transference to the operating room improving operative performance.[1]

Surgical simulators themselves are a hot industry. Today you can find everything from simulated skin and organs to virtual reality trainers that measure your every hand movement while practicing a whole case such as a laparoscopic appendectomy. (See Figure 2.) Simulators are not just for general surgery. There are vascular simulators that allow the practice of techniques for heart catheterization, neurological embolization of bleeding aneurysms, and peripheral vascular surgery. Often they have multiple scenarios built into them that allow for practice of the technique itself and also for complications a physician may encounter as well. There are breast simulators that allow for learning of ultrasound of breast lesions and the practice of core needle biopsies of these lesions. There are amazing urological trainers that one can practice removing a kidney laparoscopically or removing a renal stone. The cost of many of the simulators are limiting to surgical programs building their simulation labs. There is great controversy as well as to whether it makes a difference when using the high-fidelity simulators vs. something made from a local hardware store.

Figure 1
Surgical resident working on Fundamentals of Laparoscopic Surgery.

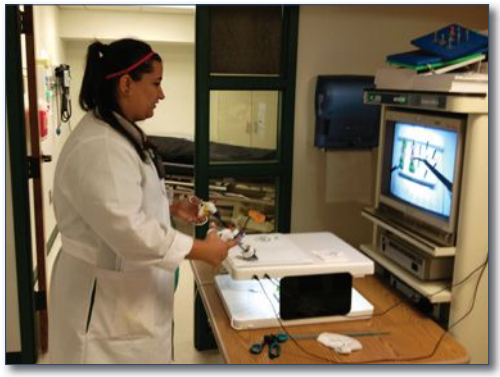
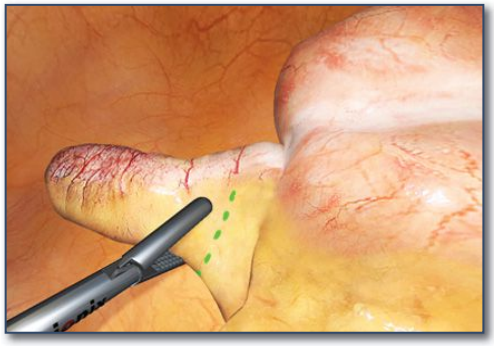


Figure 2
Simbionix Laparoscopic Appendectomy Module
Reprinted with permission from Simbionix, USA Corp., Cleveland, OH



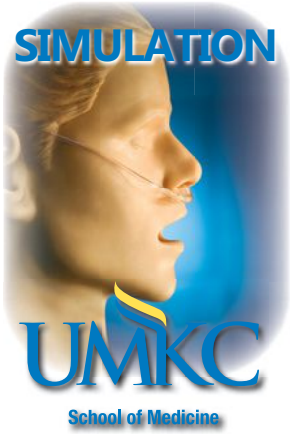
In addition to task-orientated skills training, we are incorporating the ACGME core competencies into resident simulation training. Using standardized patients we can work with the learners on professionalism, empathy in difficult situations, and improve their communication skills with patients and with other team members they work with. This can be done simulating a basic clinic session evaluating their communication and clinical decision skills or something more difficult such as a mass casualty triage setting where they have to communicate with a team to provide care to a large group of injured patients and actually triage those patients by level of injury.

Finally and most importantly, simulation is an adjunct to patient-centered training. The program requirements for surgery include a minimum case number for residents completing a program. Even with the growth of simulation, that requirement has gone from 500 to 750 over the last five years. This reflects the growing complexity of general surgery. Simulation can be a great aid to surgical education. It allows practice away from the bedside and outside of the operating room in a controlled setting where they can make mistakes and learn from them prior to treating a live patient. These budding young surgeons still must manage resuscitations, handle emergencies, and do operations, all in a real patient care environment. Simulation can help make those encounters a better experience for the surgeon, staff and the patient.

Disclosures

None reported.

MM



Simulation in Obstetrics & Gynecology

by Gerard J. Malnar, MD

Gynecologic simulations help improve resident confidence in actual patient procedures.



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Introduction

The simulation program for the University of Missouri - Kansas City Obstetrics & Gynecology residency program currently employs a number of low- and high-fidelity activities at the Youngblood Skills Lab. The benefits of simulation are self-evident. The varied activities allow residents and faculty to practice skills in a safe, non-judgmental environment. The care providers report a very favorable experience with the simulation activities at our institution.

Residency Training

As part of resident orientation, the incoming first-year residents participate in a standardized patient office simulation that incorporates EMR (Electronic Medical Record). Clerical and nursing staff also participate in this exercise. The primary objective of this activity is to instruct on efficient integration of EMR in an office encounter. Participants preview a video of an office encounter with EMR prior to the simulation. The video also illustrates the creation of a level 5 history and exam (HPI-4 elements, ROS-10 systems, PE-8 elements). Video recording the simulation provides feedback on EMR integration and level 5 document creation. Video review also affords allied staff an opportunity to review clinic efficiency from check in to check out. In addition to this exercise, first-year residents participate in sensitive female exams on standardized patients that are proctored by faculty. Performance feedback is provided by the standardized patients and the faculty.

Resident physicians perform a number of low-fidelity exercises twice monthly during their gynecology rotation. The sessions focus on common gynecologic procedures. For example, the laparoscopy skills menu aims to develop the basics of laparoscopic surgery. In addition to understanding correct use and troubleshooting of laparoscopic equipment, the activities test eye-hand coordination, traction/counter traction, plane dissection, precision cutting, suturing, and knot tying. Loop Electrosurgical Excision Procedure (LEEP) and cone biopsy is also simulated using a sausage in an

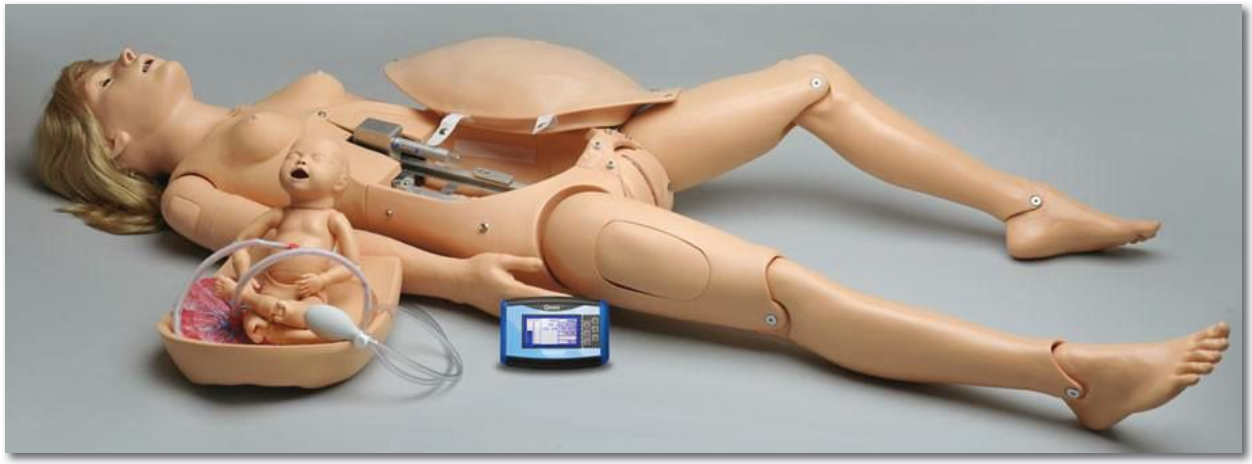


Figure 1
NOELLE is perfect for competency based programs since each delivery can be precisely controlled while devices track student actions. The fetus may be manipulated to resolve a delivery dilemma. See instant feedback of force and torque on the fetus as well as its head position. This data is graphed and synchronized with our fetal monitor for debriefing and evaluation. The fetus is released on command after the instructor has observed and logged required competencies.
Source: www.gaumard.com

empty toilet paper roll. Finally, diagnostic hysteroscopy is simulated with a plastic and foam model uterus. This activity focuses on hysteroscopy fundamentals including navigation, targeted biopsy, intrauterine device (IUD) retrieval, equipment assembly, and troubleshooting. (See Schedule next page.)

Teaching a Smooth Delivery

The obstetrical teams participate in a number of group simulations on the Noelle® Advanced Simulator from Gaumard Scientific (Miami, FL) (See Figure 1). Residents are taught correct forceps application and delivery before they are performed on live patients. Breech vaginal delivery, shoulder dystocia, and eclampsia, infrequent yet critical clinical scenarios, are simulated. Residents also participate in a simulation on delivering bad news, which is highly relevant in obstetrical care. A debriefing after these simulations provides helpful feedback regarding performance. All supervising physicians at Truman Medical Center are currently required to perform the Noelle® breech vaginal delivery simulation for maintenance of hospital privileges.

The Noelle® Advanced Simulator is also employed by the faculty and staff at the recently opened Elizabeth J. Ferrell Fetal Health Center at Children's Mercy Hospital in Kansas City. Noelle® helps the staff practice various scenarios that have never previously presented to this pediatric hospital. For example, a recent simulation was performed in the emergency department involving a precipitous vaginal delivery. At the debriefing, constructive feedback was provided by observers and participants regarding personnel and equipment issues.

Simulation training provides practical learning for care givers of any stripe. Gynecologic simulations help improve resident confidence in actual patient procedures. The high-fidelity obstetrical simulations have facilitated team building and have provided opportunities to practice a coordinated response to infrequent scenarios that invariably arise on every L&D suite.

In our pediatric hospital, simulation is helping establish interdisciplinary coordination on a new service line. We anticipate expanding our menu of simulation to facilitate effective provider learning and to maintain clinical competence.

UMKC Obstetrics-Gynecology Resident Simulation Exercises

Junior Gynecology Resident Low-fidelity Simulation Exercises

1) Loop electrosurgical excision procedure
2) Cone biopsy
3) Contraceptive subdermal implant procedure
4) Laparoscopy skills
   a. Eye-hand coordination
      i. Bead transfer from one container to another
      ii. Grasping a bead and placing it over a post
   b. Traction/ Counter traction
      i. Unwrap a wrapped candy
      ii. Remove individual sections of a Twizzler® Pull and Peel
   c. Precision cutting of a drawn figure on a gauze pad
   d. Plane dissection
      i. Peel the leaves off a Brussels sprout
      ii. Divide the scrubber layer from the sponge layer of a kitchen sponge

Senior Gynecology Resident Low-fidelity Simulation Exercises

1) Hysteroscopic resection of polyp or myoma
2) Laparoscopy skills
   a. Eye-hand coordination
      i. Stretching a rubber band over two posts
      ii. Applying a clip over a rubber band stretched over two posts
   b. Ligation and transection
      i. Loop suture ligation of exam glove finger and transaction
      ii. Clip ligation of exam glove finger with transection
   c. Plane dissection
      i. Incise and peel the skin of a grape
      ii. Divide the scrubber layer from the sponge layer of a kitchen sponge
   d. Inspecting small bowel: systematic inspection of a shoestring
   e. Suturing with knot tying
      i. Extracorporeal knot tying
      ii. Intracorporeal knot tying

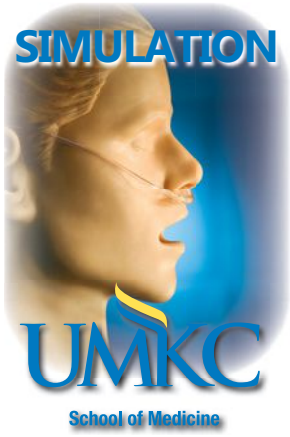
Obstetrical Team Simulations

1) High-fidelity simulation on Noelle® Advanced Simulator – Gaumard Scientific
   a. Forceps delivery
   b. Breech vaginal delivery
   c. Shoulder dystocia
   d. Eclampsia
2) Low-fidelity – Delivering bad news

Quarterly Low-fidelity Simulation Sessions (Friday afternoon)

1) 4th degree perineal laceration repair
2) Principles of Laser Therapy
3) Principles of Electrosurgery
4) Amniocentesis
5) Vaginal colpocleisis
6) Open surgery general skills (e.g. suture placement, knot tying)
7) Diagnostic hysteroscopy
8) Intrauterine contraceptive device insertion and removal

MM



Simulation in Pediatrics

by Jotishna Sharma, MD, Douglas Myers, MD & Chitra Dinakar, MD

Simulation in forms of low-fidelity, high-fidelity and standardized patients (actors) has now become part of residency training, especially in intensive care medicine.







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Introduction

Simulation is a generic term used to describe an artificial representation of a real world process to achieve educational goals through experiential learning.[1] Medical simulation has its origins from the aviation crew resource management (CRM) training based on D. L. Kirkpatrick's framework for evaluating training: these include reactions, learning, behavior, and organizational impact.[2] A review of 58 published researches on CRM training showed this type of training produced positive reactions, enhanced learning, and promoted desired behavioral changes.[3]

Medical simulation can have several purposes which include medical education in bridging classroom theory to real world practical "experience" in developing individual skills for novice learners, developing teamwork and team cohesion, and maintaining one's procedural skills.

Simulation Training in Pediatrics at UMKC

With the residency training duty hour restrictions, residents are less likely to have opportunities for exposure to certain procedural skills necessary for their future practice, and also have decreased exposure to a variety of clinical situations. Therefore, simulation in forms of low-fidelity, high-fidelity and standardized patients (actors) has now become part of residency training, especially in intensive care medicine.

Both low- and high-fidelity simulations are mannequin-based, and the level of fidelity depends on how closely the simulation mimics real-life clinical situations. Low-fidelity simulations using simple mannequins are useful for certain procedural skills, including bag-mask ventilation and placement of umbilical lines, while high-fidelity simulation using computerized technology enables virtual feedback in response to clinical decision-making. High-fidelity simulator mannequins such as SimNewB® (Laerdal, Wappingers Falls New York), and Newborn HAL® S3010 (Gaumard, Miami, FL) can also simulate heart tones and provide other vital clinical signs, providing real-time information.

Neonatal Training

The neonatal training for the pediatric residents involves learning procedural skills and attendance at high-risk deliveries. Part of the first year resident curriculum at Children's Mercy Hospital, involves a monthly, high-fidelity simulation of neonatal procedural skills stations, which includes setting up for a high-risk delivery, airway management (bag/mask ventilation), chest compression, endotracheal intubation, umbilical line placement, and resuscitation medication dosing and administration. (See Figure 1.) The other aspect of the simulation curriculum involves case-based delivery simulations where residents are part of a team in high-risk delivery resuscitation. The team usually completes 15-20

Figure 1
A neonatal simulator helps the pediatric residents learn procedural skills at high-risk deliveries.



minute resuscitation under supervision of a team leader. (See Figure 2.) The team leader during the simulation is usually a third-year resident or a neonatal fellow, allowing for more advanced learners to develop leadership skills. Team-leaders can also be "blind-folded" having to rely completely on their team members to provide information for decision-making, which encourages teamwork.

Debriefing: The Most Important Component of Simulation

Debriefing, which is considered the most important component of the simulation process, follows the case scenarios. Debriefing focuses on the cognitive process involved in decision making and behavioral responses to the critical situation. Debriefing is conducted by the facilitator (faculty) and is meant to occur in a collegial atmosphere with team members reflecting on how they performed during the simulation process and what they would do differently when encountering a similar situation in future. Debriefing allows for active learning.

Simulation Helps the Challenges of Present-Future Medical Education

Patient care has become multidisciplinary in the twenty-first century. With advancing medical care, increasing workload, emphasis on patient safety, prevention of medical errors, and realization that teamwork improves patient outcomes, there has been a transformation in inter-professional collaboration in health care. Simulation can be used to enhance this inter-professional collaboration and teamwork. Case-based scenario simulation activities at Children's Mercy Hospital that involve working on collaboration and teamwork include mock codes, fetal health center high-risk delivery simulation and extracorporeal membrane oxygenation (ECMO) medical team simulation. These case-based scenario simulations allow participants to develop interpersonal communication, teamwork, leadership skills, and task prioritizing skills.

In an effort to further develop the Accreditation Council for Graduate Medical Education (ACGME) core competencies of professionalism and communication in resident education, physicians and staff at Children's Mercy Hospital developed a novel curriculum. Evaluation of a seminar conducted by pediatric hematology/oncology staff focusing on reflection as a method to learn improved communication skills with families experiencing crisis or a tragedy, situations not infrequently occurring on the hematology/oncology service, revealed the need for additional training. The resident physicians expressed an interest in receiving training in the skill set required to deliver bad news to patients and families regardless of their future specialty or practice as physicians. This stated need was viewed as an opportunity to develop a curriculum, with a component utilizing simulation to teach professional communication and providing family centered care.

Preparation for Simulation Experience

In preparation for initiating the simulation experiences, case scenarios, pre- and post-simulation experience surveys, and training modules for simulated patients (SPs) were developed and implemented. Second- and third-year pediatric and med/peds residents, while on their hematology/oncology rotation and after experiencing the seminar described above, were taken to the University of Missouri-Kansas City School of Medicine simulation laboratory for approximately 1.5 – 2 hours. After signing confidentiality statements they took a pre-simulation experience survey (five multiple choice questions). A case scenario, designed specifically to avoid history-taking or physical examination, was then delivered to each resident, along with a reminder to gather their thoughts and anticipate potential responses of families prior to entering the room. The scenarios required the delivery of bad news to a family with whom they had no prior relationship. The simulation scenarios included delivery of the diagnosis of

Figure 2
A neonatal simulation in progress with the neonatal resuscitation team.



leukemia in the general pediatric office setting or emergency department, or the report of the death of a child to the parents after an accident. The scenario had no minimum time requirement but was not allowed to continue for more than 10 minutes. Immediately thereafter, residents watched a video taping of their performance and performed self-evaluation. A debriefing with staff and SPs was then performed for the remainder of the time. Evaluation forms were then placed in the resident's folder in the Graduate Medical Education office.

Interestingly, of the first twenty-seven second and third year pediatric residents who experienced the simulation, 26% (7/27) reported never having given the news of death of a child or diagnosis of a serious disease to a patient or their family. Additionally, 67% (18/27) had done so only a few times (1-5 times). While often reported as "painful," residents reported that watching their videotaped simulation experience provided useful information. One resident was struck by her viewing, stating, "I can't believe I was smiling while I told the family their child had leukemia!" Debriefings focused on delivering constructive criticism and utilizing Socratic methods to promote reflection on the SP experience and prior experiences. Attending physicians and fellows on the hematology/oncology rotation discussed their observations on the difference in evaluating the performance of others delivering bad news versus being the physician across from the recipient of the bad news. Attending physicians during the debriefing also provided additional information on positive and negative experiences that had shaped their methods for delivering bad news.

Summary

Although simulation allows for learning in a more controlled environment and preparation for real life situation, it should always be an adjunct to, and not intended to replace, clinical learning.

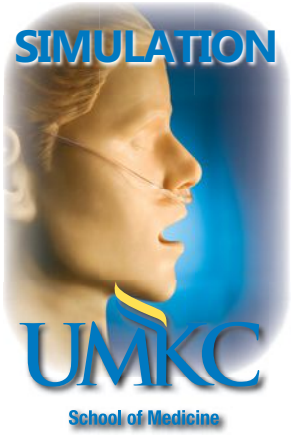
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Disclosure

None reported.

MM



Simulation in Orthopaedics

by Nigel Price, MD & Michael Boin, BA

Surgical simulation provides resident surgeons an opportunity to learn basic surgical skills in a risk-free environment.

Surgical training is not what it used to be. With the newly implemented work hour restrictions and the development of technically difficult procedures, surgeons are forced to master a multifaceted surgical skill set in a limited amount of time. Surgical simulation has been proven to be successful in stepping up to this challenge.

Surgical simulation provides resident surgeons an opportunity to learn basic surgical skills in a risk-free environment. Residents, with their lack of experience, take more time in the OR as opposed to proficient attendings. This leads to greater costs for the hospital and can put the patients in increased risk of harm. The use of simulation can help blunt the learning curve, making residents more competent early in training.

Orthopedic simulation has been existent for hundreds of years through the use of cadaver models. Although cadavers have been effective in training residents, their use has its shortcomings. Synthetic bone models offer a more reproducible and cost-effective way for residents to practice procedures.[1] (See Figure 1.)

An area of growing interest is simulation for arthroscopic surgeries. Because of new technologies and their minimally invasive nature, arthroscopic surgeries are an increasingly popular procedure. Knee arthroscopies constitute 16% of all ambulatory orthopedic procedures.[2] There have been concerns expressed about resident proficiency in arthroscopic surgery upon graduation.[1] Computer simulators exist that mimic an arthroscopic surgery providing active and passive feedback to the surgeon. A study of arthroscopic simulation by Gomoll et al.[3] showed that:

"Subjects significantly improved their performance on simulator retesting three years after initial evaluation. Additionally, across independent groups with equivalent surgical experience, similar performance can be expected on simulator parameters; thus it may eventually be possible to establish simulator benchmarks to indicate likely arthroscopic skill."[3] (See Figure 2.)

Using computers, CT images, and virtual reality residents can also practice their preoperative planning. By seeing fractures in detail on a computer screen, residents can plan their procedure as if it were an actual patient with a risk-free trial and error system. With these programs residents can work their way through many cases, further preparing themselves for real life scenarios.

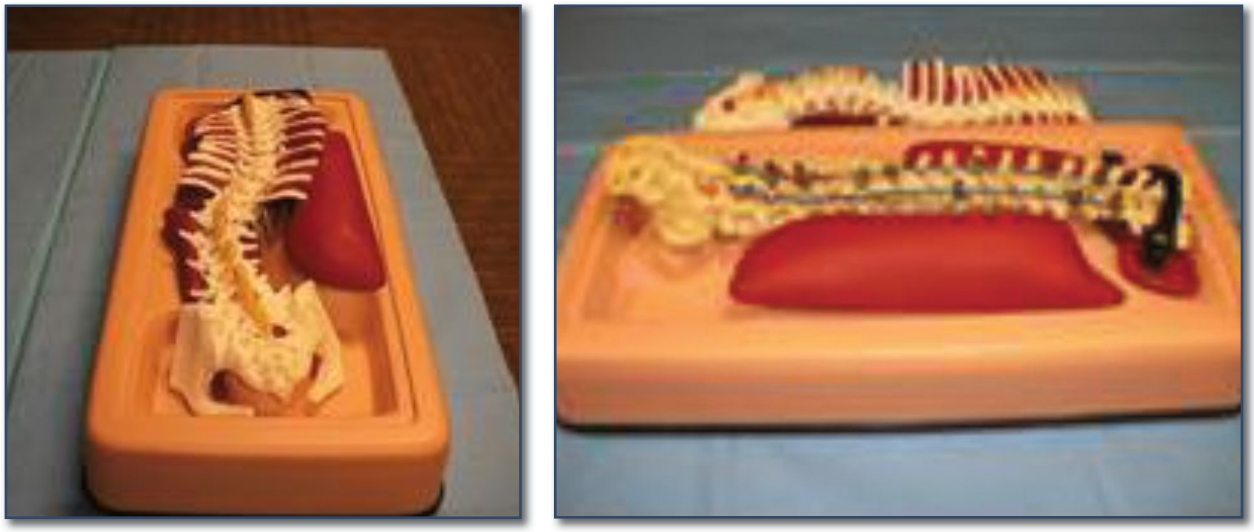
The real question behind simulator training is, does it actually help? A study by Sonnadara et al.[4] showed that intense training with a simulation program in orthopedics is superior to training with solely





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Figure 1
Synthetic Bone Model
(Photo courtesy of Medtronic, Minneapolis, MN)

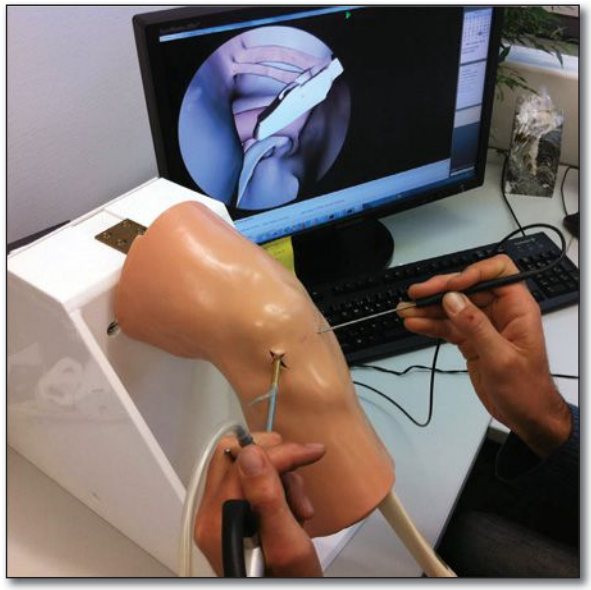


clinical duties. This study compared two groups of residents, one group that received simulator training and a group who did not. The study concluded:

"The intensive skills course used in this study was highly effective at teaching and developing targeted surgical skills in first-year orthopedic residents. We predict that allowing residents to acquire key technical skills at the start of their training will enhance learning opportunities at later stages of training."[4]

It is clear that simulation labs are beneficial to orthopedics residency programs, but the challenge is how to get simulation integrated into curriculum. Many orthopedics programs have no form of simulation lab for their residents to train with. In these programs the residents are trained through live surgery on actual patients. Perhaps the next step is for a nationalized objective score for proficiency on orthopedics simulations. This could be required of all orthopedics residency programs. Residents would be required to achieve a passing score on the simulation before they could attempt the procedure on a patient. One thing is for certain, orthopedic training will have to change as this dynamic field of medicine changes.

Figure 2
A training simulator for knee arthroscopy.



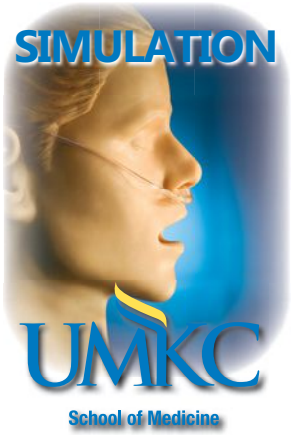
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Disclosure

None reported.

MM



Simulation in Ophthalmology

by Billi S. Wallace, MD & Nelson R. Sabates, MD

Given the mounting evidence of construct validity and efficacy of ophthalmic surgery simulators, future surgical training is likely to incorporate this technology into formal surgical curricula.



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Cataract extraction is one of the most common surgical procedures performed nationwide, accounting for nearly 9% of all ambulatory surgeries.[1] Understandably, ophthalmology residents dedicate a majority of their surgical training to learning cataract surgery.

In 2007, Randleman et al. published their review of 680 resident-performed phacoemulsification cases at the Atlanta Veterans Affairs Medical Center and outlined nicely the phacoemulsification learning curve of residents.[2] They concluded that rates of posterior capsular tear and vitreous loss, two common surgical complications, were more than double in a resident's first 80 cases when compared to their last 80 cases and appeared to plateau after 160 cases. Additionally, they found that surgical efficiency as measured by adjusted phacoemulsification time decreased throughout residency and continued beyond the first 200 cases.

In 2007, the Accreditation Council for Graduate Medical Education increased minimum requirements from 45 to 86 phacoemulsification cases for residents as primary surgeon. From 2007 to 2011, average phacoemulsification cases ophthalmology residents had completed at graduation increased from 126 to 148 (most recent range 43-380).[3] Obviously, the need exists to shorten the resident learning curve and improve surgeon competency by graduation in the setting of significant advances in medical and surgical technologies. Enter virtual simulator training.

Presently, there are two commercially available ophthalmic surgical simulators. One is the PhacoVision (Melerit Medical, Linkoping, Sweden) and the other the Eyesi (VRmagic, Mannheim, Germany). The first system focuses exclusively on the capsulorhexis and phacoemulsification aspects of cataract surgery. The second system was originally designed as a vitreo-retinal surgical training device, though an anterior segment module was subsequently developed. The Eyesi anterior and posterior segment platforms were obtained and implemented at the University of Missouri-Kansas City Department of Ophthalmology Residency and Retina Fellowship programs as part of organized surgical training curricula in 2008.

The Eyesi simulator consists of a mannequin head with a mechanical eye, various probes which mimic different intraocular instruments, a virtual operating microscope with functioning foot pedal, and a separate instrument foot pedal. The surgeon is shown stereoscopic images of the eye and instruments through the microscope while an observer is able to monitor from a separate viewing screen (See Figure 1 used with permission of VRmagic).[4]

The anterior segment platform includes training modules for anti-tremor, forceps, capsulorhexis, and phacoemulsification practice with adjustable difficulty levels, (See Figures 2, 3, 4 used with permission of VRmagic). The posterior segment platform includes training modules for posterior hyaloid detachment, peripheral vitrectomies, endolaser, and internal limiting membrane peeling.

Various parameters relating to instrument and microscope handling, surgical efficiency, and tissue treatment are recorded by the system to allow objective assessment of a resident's surgical performance and progression over time, including detailed skill evaluation. Construct validity has been shown for the vitreo-retinal as well as anterior segment anti-tremor, forceps, and capsulorhexis modules of the simulator.[5-7]

Recently, Belyea et al. assessed the effect of implementing a surgery simulator during residency training on cataract surgery performance.[8] They retrospectively reviewed 592 resident cataract surgeries that occurred before (the nonsimulator group) or after (the simulator group) utilizing the technology at George Washington University. Residents who trained using the simulator performed phacoemulsification more efficiently, used lower percentage powers, and had fewer intraoperative complications. In the simulator group, phacoemulsification times were decreased by 22%, phacoemulsification powers lowered by 10%, and adjusted phacoemulsification power diminished by 34%.

As the ACGME implements competency-based requirements in addition to the historical volume-based requirements, ophthalmology residency programs will undoubtedly look for alternate means of educating residents surgically. Given the mounting evidence of construct validity and efficacy of ophthalmic surgery simulators, future surgical training is likely to incorporate this technology into formal surgical curricula.

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Disclosures

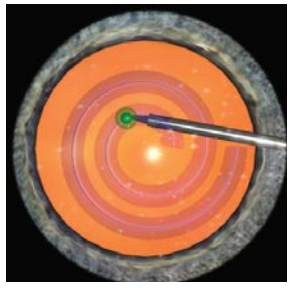
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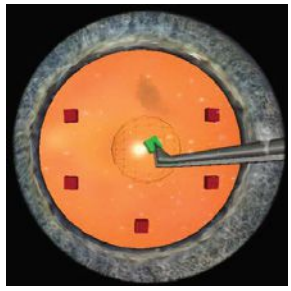
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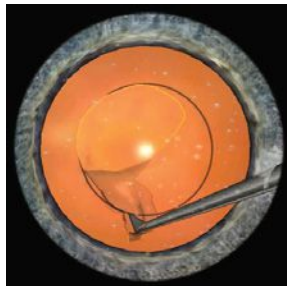
Figure 1
The Eyesi eye operation system consists of a microscope through which surgeons can view simulated operations while guiding medical instruments into a mechanical eye situated in a model of the head.



Figure 2
Eyesi Antitremor Module: trains residents to pivot at incision and control instrument tip to create curvilinear capsulorhexis while keeping eye centered and avoiding tissue injury.

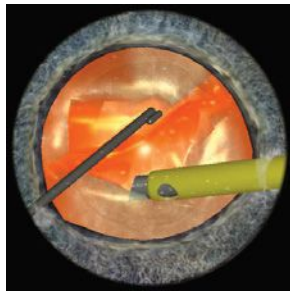






Figures 3A & 3B (above)
Eyesi Forceps and Capsulorhexis Module: trains residents to grab the capsulorhexis flap while keeping eye centered and avoiding tissue injury.

Figure 4
Eyesi Phacoemulsification Module: trains residents to remove lenticular material while keeping eye centered and avoiding tissue injury.



SPECIAL SERIES Preventive Cardiology

Modern Cardiac Rehabilitation: Integrating the Best Measures to Reduce a Second Cardiac Event

by Robert A. Armbruster, MD & Michael J. Lim, MD

The comprehensive and multi-factorial approach used in cardiac rehabilitation has been shown to improve outcomes.





Robert A. Armbruster, MD, (left) is Clinical Instructor in Medicine in the Division of Cardiology. Michael J. Lim, MD, FACC, FSCAI, (right), is the Jack Ford Shelby Endowed Professor of Cardiology and Director of the Division of Cardiology. Both are at Saint Louis University.
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Abstract

Patients with established cardiovascular disease are at high risk for future myocardial infarction, stroke, and death. Interventions that may reduce recurrent cardiovascular events serve a critical role in improving both long-term morbidity and mortality. Cardiac rehabilitation following a cardiac event has been modernized with the integration of coronary risk factor reduction programs in addition to its traditional role of early graded mobilization of the patient and has been shown to significantly benefit men and women with coronary heart disease.

Introduction

Cardiovascular disease is extremely common in the United States. There is a high prevalence of risk factors for the development of atherosclerotic disease with subsequent myocardial infarction, heart failure, stroke, and death. Lifestyle changes and medical therapy have both been proven to decrease cardiovascular events in high risk patients, though these interventions are often underutilized. This article will review the prevalence of coronary heart disease, patient risk factors involved in the development of atherosclerosis, and recommended interventions to lower the risk of future cardiovascular events with a particular focus on cardiac rehabilitation.

A Tremendous Burden

An estimated 80 million Americans have established cardiovascular disease, causing one of every three deaths in the United States with an estimated total cost of $450 billion annually.[1] Specifically, coronary heart disease (CHD) causes nearly one of every six deaths in the United States. Coronary heart disease and stroke are currently the number one and number four causes of mortality, respectively.[2] For persons aged 40 years in the United States, the lifetime risk of developing CHD is 49% in men and 32% in women.

Patients with recognized coronary heart disease have a higher risk of ensuing cardiovascular events, which includes myocardial infarction, stroke, and death from cardiovascular disease.[3] In 2010, approximately 785,000 Americans experienced a new cardiac event, and an estimated 470,000 had a repeat acute myocardial infarction. Men and women with CHD have a risk of myocardial infarction 20 times higher than those without CHD.[4]

Elderly patients are of particular concern. Clinical evidence of CHD is present in 20% of the population by the age of 80 years with a similar prevalence between men and women. Heart failure, most frequently resulting from CHD, is the most common discharge diagnosis for hospitalized Medicare patients.[5] Elderly patients are at higher risk of complications and long-term disability following a cardiovascular event. The aging population continues to grow and is expected to exceed 23 million by 2030.[6]

Table 1
Coronary Heart Disease Equivalents

Coronary Heart Disease Equivalents
Peripheral arterial disease
Carotid artery disease
Abdominal aortic aneurysm
Multiple CAD risk factors with 10 year Framingham risk score >20%
Diabetes mellitus
Chronic kidney disease

Table 2
CAD Risk Factors

Modifiable Coronary Artery Disease Risk Factors
Hypertension
Dyslipidemia
Cigarette smoking
Obesity (BMI>25 kg/m^2)
Diabetes mellitus

For millions of Americans, interventions that may reduce recurrent cardiovascular events, collectively referred to as secondary prevention, play a vital role in improving both long-term morbidity and mortality.

Who Is At Risk?

There are many patients without known CHD that nevertheless have a high risk of future cardiovascular events.[3] Due to this elevated risk, each of the following groups should be managed just as aggressively as patients with prior CHD as recommended by the American College of Cardiology/ American Heart Association (See Table 1).

Patients with non-coronary atherosclerotic arterial disease, including carotid artery disease, peripheral arterial disease (PAD), or abdominal aortic aneurysm, all have a 10 year risk of CHD >20%. In fact, identification of PAD in the setting of claudication confers a 25-30% five-year mortality in those >55 years with 75% of the deaths due to cardiovascular causes. An additional 20% of individuals with intermittent claudication will suffer nonfatal cardiovascular events.[7]

Patients with multiple risk factors for atherosclerotic disease (See Table 2) are at elevated risk of a cardiovascular event. When the combination of these comorbid conditions confer a 10-year risk of CHD >20% as estimated by the Framingham risk score, the patient is considered to have a CHD equivalent.[8]

Patients with diabetes mellitus are considered to have a high risk of future cardiovascular events. This classification was based upon the observation that patients with type 2 diabetes with no prior MI were at the same risk for MI (20 versus 19%) and coronary mortality (15 versus 16%) as patients without diabetes that have had a prior MI.[9]

Patients with chronic kidney disease, defined as a serum creatinine concentration that exceeds 1.5 mg/dL or an estimated glomerular filtration rate that is less than 60 mL/min per 1.73 m,[2] are now considered to have a CHD equivalent as recommend by the National Kidney Foundation (NFK) and ACC/AHA.[10, 11]

Is There Cause For Hope?

After defining the various patient populations that are at high risk for cardiovascular events, the primary focus is on measures to reduce this risk and prevent future events. Fortunately, there are both therapeutic lifestyle changes and adjunctive drug therapies that are of proven benefit. Unfortunately, however, utilization rates for many of these proven measures remain low. The ACC/AHA have updated guidelines for secondary prevention and risk reduction therapy with the goal of reducing cardiovascular morbidity and mortality.[12]

Cardiac Rehabilitation: A Comprehensive Approach

Cardiac rehabilitation programs have been remodeled over the past several decades. Undoubtedly, the prolonged periods of bed rest prescribed in the 1950s are no longer recommended. Extended bed rest has been shown to result in physiologic deconditioning, resting tachycardia, and a significant decrease in aerobic capacity.[13] Contemporary cardiac rehabilitation following a cardiac event has been modernized with the integration of coronary risk factor reduction programs in addition to its traditional role of early graded mobilization of the patient.

Cardiac rehabilitation has been shown to significantly benefit men and women with coronary heart disease. In a meta-analysis of 48 trials, >8,000 patients with CHD were assigned to cardiac rehabilitation or usual care. Cardiac rehabilitation was associated with statistically significant reductions in both all-cause mortality (odds ratio 0.80) and cardiac mortality (odds ratio 0.74).[14]

The AHA/ACC has recommended cardiac rehabilitation in a variety of settings[15]:

- Post-MI
- Following coronary revascularization (PCI or CABG)
- Hevart or heart/lung transplant recipients
- Patients with stable angina or stable chronic heart failure

Table 3
Essential Components of Cardiac Rehabilitation

Essential Components of Cardiac Rehabilitation
Patient assessment
Nutritional Counseling
Exercise Training
Risk Factor Modification
Weight Management
Psychosocial Management

- Peripheral arterial disease with claudication
- Following heart valve repair or replacement

The Centers for Medicare and Medicaid Services (CMS) reimburses for many variants of cardiovascular disease, including acute MI within 12 months, revascularization, stable angina, or heart valve repair or replacement. CMS, however, does not reimburse for cardiac rehabilitation in patients with chronic stable heart failure.

In spite of substantial morbidity and mortality benefits, cardiac rehabilitation services remain greatly underutilized. Only 20% of eligible patients are referred with even lower rates in women and the elderly.[16] Furthermore, patients with comorbidities, less medical insurance coverage, and with geographic limitations to accessibility to program sites were less likely to be referred and to participate.[17]

A significant dose-response relationship between the number of sessions attended and long-term outcomes exists.[18] In an analysis of >30,000 individuals that participated in at least one session, those that attend all 36 sessions were found to have an 18% lower risk of death compared to those attending 24 sessions, a 29% lower risk compared with attending 12 sessions, and a 58% lower risk compared with attending one session. Participation in cardiac rehab has been shown to reduce all-cause mortality by 20% and cardiac mortality by 26% in a meta-analysis of randomized controlled trials.[14]

The essential components of a cardiac rehabilitation program have been outlined by the American Heart Association and American Association of Cardiovascular and Pulmonary Rehabilitation[19] (See Table 3). Outpatient programs typically consist of three sessions weekly for 12 weeks. The goals for these sessions are to develop an exercise prescription, to introduce measures to reduce coronary risk factors, and to identify and manage psychosocial problems that commonly affect cardiac patients.

The Exercise Prescription

Components of an exercise prescription include the frequency, mode, duration, and intensity of exercise.[20] Patients are encouraged to exercise at least five times weekly, which is essential to attaining a significant improvement in functional capacity.

The mode of exercise should certainly be one that is enjoyable for the patient and simple to perform in order to enhance compliance. It should entail the use of large muscle groups and aerobic exercise such as cycling, rowing, walking, jogging, machine stair climbing, and other endurance activities. Low impact activities are suggested as a result of a lesser risk of physical injury.

The duration of exercise should include a 5-10 minute warm-up, which typically consists of the same activity at a lower intensity. The conditioning phase should last for at least 20 minutes and preferably 30-45 minutes. A cool-down phase of 5-10 minutes, again consisting of a low-intensity exercise, is recommended. Exclusion of cool-down can produce a momentary decrease in venous return, dropping coronary blood flow when the heart rate and myocardial oxygen consumption still remain high. Adverse consequences can include hypotension, angina, ischemic ST-T changes, and ventricular arrhythmias.[21]

The intensity of exercise should range from 40-85% of functional capacity (VO2 max), which corresponds to 55-90% of maximal heart rate (estimated as 220 minus the age in years). Many patients, though, take medication that may limit the heart, such as beta-blockers, making the estimated heart rate an inappropriate goal. A second validated method of prescribing exercise intensity involves the use of the Borg scale, or rating of perceived exertion.[22] A level of 12-13 corresponds to 60% of VO2 max while a level of 16 corresponds to 85% VO2 max.

Exercise should begin at lower intensity and progress throughout the rehabilitation period. Patients are supervised by trained medical personnel with appropriate equipment for ECG monitoring and advanced cardiac life support. The risk of cardiac rehabilitation, however, is very low with one cardiac arrest for every 120,000 patient-hours of exercise and one death in every 750,000 patient-hours of exercise.[23]

Along with exercise training, cardiac rehabilitation programs address modifiable risk factors for coronary artery disease, including dyslipidemia, hypertension, diabetes, and tobacco use.

Lipid Modification

There is a curvilinear relationship between serum cholesterol concentration and the risk of subsequent risk of CHD[24] (See Figure 1). Over the past two decades, multiple large randomized trials have demonstrated the benefits of lipid lowering. A meta-analysis of 25 trials using statins for cholesterol lowering in >69,000 patients with CHD found a 16% reduction in the risk of all-cause mortality and 23%

Figure 1
Association of Increasing Plasma Cholesterol and Coronary Risk

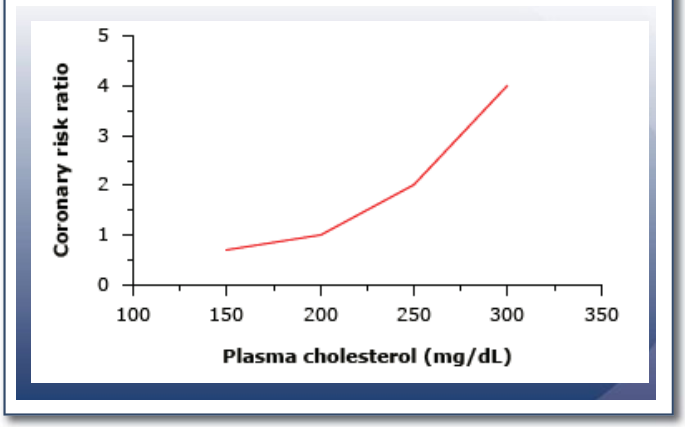


Table 4
Very High Risk Patient

The "Very High Risk Patient"
Presence of cardiovascular disease plus any 1 of the following:
-Multiple major risk factors (especially diabetes)
-Severe and poorly controlled risk factors (especially smoking)
-Multiple risk factors of the metabolic syndrome
-Patients with acute coronary syndrome

decrease in CHD mortality.[25] Further data suggests similar benefits in stroke reduction, too, with a relative risk reduction of approximately 30% .[26]

AHA/ACC guidelines recommend statin therapy to achieve an LDL of <100 mg/dL.[12] If triglycerides are >200 mg/dL, then non-HDL should be <130 mg/dL. Patients deemed to be at "very high risk" (See Table 4) have targets of LDL <70 mg/dL and non-HDL <100, respectively.

Besides statins, other potential lipid-lowering agents include fibrates, niacin, fish oil, or ezetemibe. The available evidence in support of these options, however, is far less robust and less persuasive. To date, none of these agents have been shown to improve clinical cardiovascular disease outcomes beyond that achieved with statin therapy.

Hypertension

The seventh Joint National Committee (JNC 7) report has proposed the following definitions based upon the average of two or more properly measured readings at each of two or more visits[27]:

- Normal blood pressure — systolic <120 mmHg and diastolic <80 mmHg
- Prehypertension — systolic 120-139 mmHg or diastolic 80-89 mmHg
- Hypertension — systolic ≥140 mmHg or diastolic ≥90 mmHg

Hypertension accounts for an estimated 54% of all strokes and 47% of all ischemic heart disease events globally.[28] In a meta-analysis of patients with mild to moderate hypertension, lowering the blood pressure with antihypertensive therapy by 4-5 mmHg reduces the rate of stroke by 40% and CHD by 16%.[29]

Despite evidence in strong support of blood pressure lowering, it has proven to be difficult to achieve goal blood pressure. Less than half (46%) of people with high blood pressure have their condition under control.[30]

AHA/ACC guidelines recommend a goal blood pressure of <140/90.[12] This may be achieved with lifestyle modification, including weight control, increased physical activity, alcohol moderation, and sodium restriction, as well as medications, using β-blockers and/or ACE inhibitors to achieve goal blood pressure. Patients with a prior MI should be treated with β-blocker and ACE inhibitors independent of BP control given the demonstrated benefits in both morbidity and mortality.[31, 32]

Diabetes Mellitus

Diabetic patients have significant cardiovascular risk. The AHA/ACC guidelines do not specify a target HbA1c but rather emphasize the importance of lifestyle modifications and coordinated care with the patient's primary physician and endocrinologist.[12] Of note, diabetics often have concomitant risk factors that require treatment and monitoring. Patients with the constellation of abdominal obesity, hypertension, dyslipidemia, and diabetes are considered to have the metabolic syndrome[3] (See Table 5) and are at increased risk for cardiovascular events.[33] These patients will require an aggressive multifactorial approach to their care. Control of blood pressure and lipids may have even greater benefit than glycemic control in this patient population.[34, 35]

Antiplatelet Agents

Antiplatelet therapy, particularly aspirin, has a well-established role in reducing the risk of subsequent myocardial infarction, stroke, and vascular death among patients with coronary heart disease.[36] Yet, in 2007-08, antiplatelet medications were prescribed at only 46.9% of visits for patients with ischemic vascular disease. General medicine or primary care physicians prescribed antiplatelet medications for this population only 34.8% of the time.[37]

The ACC/AHA recommends aspirin at a dose of 75-162 mg daily in all patients with CHD unless contraindicated.[12] Monotherapy with a platelet P2Y12 receptor blocker improves outcomes in patients with stable coronary artery disease and is beneficial in the approximately 5% of patients who cannot tolerate aspirin[38] (clopidogrel 75 mg daily is the recommended

Table 5
Metabolic Syndrome Definition

Defining the Metabolic Syndrome (≥3 of the following):
Fasting glucose ≥100 mg/dL*
HDL <40 mg/dL for men or 50 mg/dL for women*
Triglycerides ≥150 mg/dL*
Abdominal Obesity with waist circumference ≥102 cm (40 in) for men or ≥88 cm (35 in) for women
Blood pressure ≥130/85 mmHg*

alternative). For patients that have received a bare-metal or drug-eluting stent, clopidogrel 75 mg daily, prasugrel 10 mg daily, or ticagrelor 90 mg twice daily should be given for at least 12 months.[12]

Therapeutic Lifestyle Changes

Therapeutic lifestyle changes have clinically relevant and statistically significant favorable effects on cardiovascular morbidity and mortality and are a vital component of any secondary prevention program.[39]

Smoking cessation provides cardiovascular benefits within months, and event rates reach those of a non-smoker in three to five years.[40] In a meta-analysis of >12,000 smokers with prior MI, CABG, angioplasty, or known CAD, the relative risk for those that quit smoking compared to those that continued was 0.64.[41] The current recommendation is to inquire about tobacco use at every office visit. Every smoker should have an assessment of their readiness to quit and factors that may impede success and be advised to quit. The clinician should assist the patient with counseling and pharmacotherapy, if needed, and arrange for follow-up. All patients should be advised to avoid environmental exposure to tobacco smoke.[12]

The ACC/AHA recommends that body mass index and/or waist circumference be assessed at every visit. The clinician should consistently encourage weight maintenance/reduction through a combination of physical activity and structured exercise and caloric intake to maintain or achieve a body mass index between 18.5 and 24.9 kg/m.^{2} If waist circumference, which is measured horizontally at the iliac crest, exceeds 35 inches (89 cm) in women and 40 inches (102 cm) in men, therapeutic lifestyle interventions should be intensified and focused on weight loss. The initial goal of weight loss therapy should be to decrease body weight by approximately 5% to 10% from baseline.[12]

Individuals with CVD or with multiple coronary risk factors may have increased risks for complications of influenza infection. In two randomized trials with approximately 600 combined patients, those assigned to influenza vaccination had decreased incidence of major cardiovascular events.[42, 43] The ACC/AHA currently recommends that all patients with cardiovascular disease have an annual influenza vaccination.[12]

Psychosocial Management

The final major component of a cardiac rehabilitation program is the recognition and management of the various psychosocial problems that arise as a result of a cardiac event. Depression, anxiety, and denial are common in patients following myocardial infarction, occurring in up to 20% of patients.[44] Depression is associated with more fatigue, lower exercise capacity, and a reduced quality of life. Women, and in particular younger women, are at increased risk for depression.[45]

In a randomized trial of psychosocial interventions in nearly 2,500 patients after MI, patients receiving psychosocial intervention had less depression and better levels of perceived social support, though there was no reduction in mortality.[46] The ACC/AHA states that it is reasonable to screen for depression in patients with recent MI in partnership with their primary care physician and a mental health speciavlist. Though treatment of depression has not been demonstrated to improve cardiovascular disease outcomes, it may be reasonable for other clinical benefits.[12]

Summary

Patients with established coronary heart disease (CHD) have high risks of subsequent cardiovascular events, including myocardial infarction, stroke, and death from cardiovascular disease. In addition, many patients without known CHD have similarly high risks of cardiovascular events. Cardiac rehabilitation consists of a baseline patient assessment, exercise training, coronary risk factor management, nutritional counseling with weight control, and psychosocial management. The comprehensive and multi-factorial approach used in cardiac rehabilitation has been shown to improve outcomes, including a significant reduction in all-cause and cardiac mortality, in patients with cardiovascular disease.

References

References exceed space. Email Managing Editor Liz Fleenor at lfleenor@msma.org for listing.

Disclosure

None reported.

MM

MSMA Annual Financial Reports to Membership
MSMA Balance Sheet 2012

ASSETS		LIABILITIES AND NET ASSETS	
CURRENT ASSETS:		**CURRENT LIABILITIES:**	
Cash and Cash Equivalents	$ 882,442	Accounts Payable and Accrued Expenses	$ 19,455
Certificates of Deposit	461,557	Accrued Vacation	63,764
Short-Term Investments	6,667,940	Deferred Revenue	33,462
Accounts Receivable	6,750	Deferred Dues	892,834
Accounts Receivable - Insurance Agency	10,000		
Prepaid Expenses	9,428	Total Current Liabilities	1,009,515
Total Current Assets	8,038,117		
FIXED ASSETS:		**NON-CURRENT LIABILITIES:**	
Land	83,000	Non-Qualified Deferred Compensation Agreement	340,915
Building and Improvements	605,078	Pension Benefit Liability	797,153
Furniture and Equipment	270,545		
Less: Accumulated Depreciation	(801,577)	Total Non-Current Liabilities	1,138,068
Total Net Fixed Assets	157,046	Total Liabilities	2,147,583
OTHER ASSETS:			
Note Receivable - MSMA Ins. Agency	199,610		
Investment in Subsidiary - MSMA Insurance Agency	(257,663)	**NET ASSETS:**	
Long-Term Investments	2,474,603	Unrestricted	8,464,130
Total Other Assets	2,416,550	Total Net Assets	8,464,130
TOTAL ASSETS	$ 10,611,713	**TOTAL LIABILITIES AND NET ASSETS**	$ 10,611,713

MSMA Annual Financial Reports to Membership
Missouri Physicians Health Foundation 2012

ASSETS		LIABILITIES AND NET ASSETS	
CURRENT ASSETS:		**CURRENT LIABILITIES:**	
Cash and Cash Equivalents		Accounts Payable	$ 5,330
Cash - Checking	$ 51,369	Total Current Liabilities	5,330
Cash - McIntosh Fund	10,328		
Mutual Funds - McIntosh Fund	3,920	**NET ASSETS:**	
Certficates of Deposit	215,000	Unrestricted	439,252
Accounts Receivable	141,324		
Allowance for Doubtful Accounts	(17,950)	**Total Liabilities and Net Assets**	$ 444,582
Total Current Assets	403,991		
NON-CURRENT ASSETS:			
Investments - McIntosh Fund	26,141		
Property and Equipment			
Office Furniture and Equipment	33,457		
Less: Accumulated Depreciation	(19,007)		
Net Property and Equipment	14,450		
Total Non-Current Assets	40,591		
TOTAL ASSETS	$ 444,582		

MSMA Annual Financial Reports to Membership

Missouri State Medical Foundation 2012

ASSETS

CURRENT ASSETS:		
Cash	$	298,639
Investments		80,893
Notes Receivable - Current		380,000
Accrued Interest		212,176
Total Current Assets		971,708
EQUIPMENT:		
Office Equipment		1,608
Software		10,692
Less: Accumulated Depreciation		(12,300)
Total Net Fixed Assets		-
NON-CURRENT ASSETS:		
Investments		2,097,943
Total Non-Current Investments		2,097,943
Notes Receivable - Long Term		2,829,443
Allowance for Doubtful Accounts		(155,435)
Notes Receivable - Long Term (Net)		2,674,008
TOTAL ASSETS	$	5,743,659

LIABILITIES AND NET ASSETS

LIABILITIES:		
Funds Held for Others	$	129,789
TOTAL LIABILITIES		129,789
Unrestricted		5,613,870
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TOTAL LIABILITIES AND NET ASSETS	$	5,743,659

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- Internal Medicine
- Maternal Fetal Medicine
- Neonatology
- Neurology
- Neurosurgery
- OB/GYN – Traditional
- OB/GYN Hospitalist
- Occupational Medicine
- Ophthalmology
- Optometry
- Oral & Maxillofacial Surgery
- Orthopedic Surgery
- Otolaryngology
- Pain Management
- Pathology
- Plastic Surgery
- Podiatry
- Psychiatry
- Pediatrics
- Pediatric Emergency Medicine
- Pediatric Endocrinology
- Pediatric GI
- Pediatric Hem/Onc
- Pediatric Internal Medicine
- Pediatric Neurology
- Pediatric Surgery
- Pediatric Urgent Care
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- Rheumatology
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- Trauma Surgery
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