Missouri Medicine

The Journal of the Missouri State Medical Association www.msma.org/missouri-medicine November/December 2016



Advocacy

2017 Physician Advocacy Issue

Strategic Medicine: Legislative Forecast
Meet Your Fellow Physician Legislators
Report: Missouri Delegation to the AMA
Advocacy: What Is Important to Medicine
Nurse Practitioners and Their Independence
Generic Drugs | Marijuana | Opioids | Fentanyl
159th MSMA Annual Convention Program
Tax Identity Theft Scam Targets Doctors
Evolution of Lung Cancer Screening
Future for Acute Ischemic Stroke
History: Fifty Years of Trauma
Prevent Physician Burnout

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2017 Physician Advocacy Issue

EDITOR'S DESK

Belonging to MSMA and Advocating for Medicine: Why It Matters for All Physicians
by **John C. Hagan, III, MD** 242

2016 LEGISLATIVE PREVIEW

Forecast for 99th General Assembly
by Kenny Jackson 426

BE A PHYSICIAN OF THE DAY 428
GIVE TO MMPAC 428
GET TO KNOW YOUR PHYSICIAN LAWMAKERS 425

PRESIDENT'S FORUM

Advocating for What Is Important to Medicine
by **Ravi S. Johar, MD** 429

AMA REPORT

Physician Advocacy: The AMA Interim Meeting 2016
by the Missouri Delegation to the AMA 430

GUEST EDITORIAL

Fifty Years of Trauma
by **Charles Van Way, III, MD** 434

PERSPECTIVE

Should Nurse Practitioners Be Allowed to Practice Independently?
by **Samer Cabbabe, MD** 436

FROM YOUR ASSOCIATION

Missouri Medicine In the News 466
In Memoriam 467
Correspondence 467
Physicians Beware of Tax Scams 455
2017 Annual Convention Preliminary Program 468
2017 Annual Convention General Sessions 469
Missouri Medicine Index 493

PERSPECTIVE

Physicians Present Opposing Views of Hospitalists
by **Arthur Gale, MD** 438

Research of Note: Physician-Owned Surgical Hospitals Outperform Other Hospitals in Medicare Value-Based Purchasing Program
Journal of the American College of Surgeons 442

Sidebar: Inspector General: Medicare Spends Hundreds of Millions on Medically Unnecessary Chiropractic Services
Wall Street Journal 443

How Obama's FDA Keeps Generic Drugs Off the Market
by Scott Gottlieb, MD 444

A Brave New Weed
by Allysia Finley 447

Measuring and Mattering
by David W. Parke II, MD 448

The Joint Commission Deserves Some Blame for the Opioid Crisis
by Skeptical Scalpel, MD 449

Prevent Physician Burnout: 4 Work-Life Balance Tools
by Dike Drummond, MD 450

MEDICAL | LEGAL

Medical Patents and How New Instruments or Medications Might Be Patented
by Denise L. Mayfield, JD 463

MEDICAL SCHOOL PERSPECTIVE

Missouri's First New Medical School in Nearly 50 Years Comes to Joplin
by **Marc B. Hahn, DO** 463

SCIENCE OF MEDICINE

The Evolution of a Regional Lung Cancer Screening Program
by **Mitchell Botney, MD** 471

Low Dose CT for Lung Cancer Screening Could Provide Substantial Benefit
by **Jim Blaine, MD** 474

Boys at Risk: Fatal Accidental Fentanyl Ingestions in Children
by **William V. Stoecker, MD**, David E. Madsen, BS, Justin G. Cole, BS & Zachary Woolsey 476

Acute Ischemic Stroke: Current Status and Future Directions
by Brandi R. French, MD, Raja S. Boddepalli, MD & **Raghav Govindarajan, MD** 480

Understanding Patient Perceptions of Hypertension for Optimal Management in a Student-Run Free Clinic
by Vritti Gupta, MD, Karen B. Williams, PhD, Miranda Huffman MD, Rebecca R. Pauly, MD & Lakshmi Venkitachalam, PhD 487

MSMA member names in bold

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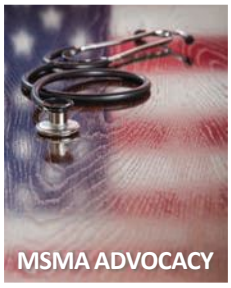
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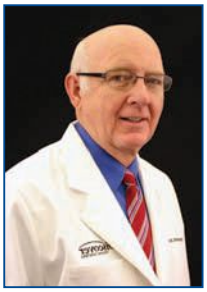


Belonging to MSMA and Advocating for Medicine: Why It Matters for All Physicians

by John C. Hagan, III, MD

With the elections mercifully behind us, we can now turn our attention to new year membership matters and advocacy in the 2017 Missouri legislative session. Let's start by making sure that all members have paid their 2017 dues and that all members of your group belong to the Missouri State Medical Association (MSMA). To all non-members, I extend a sincere invitation to join on behalf of the leadership and members of MSMA. Do come aboard!

MSMA is widely acknowledged as one of the top five most effective state medical associations. MSMA dues are among the lowest in the nation. MSMA staff is highly competent, dedicated, and responsive. Physicians of all stripes need to be MSMA members. Private practice physicians have been the traditional model for representation and advocacy. However, as times change MSMA changes and has become the leading advocate for medical education. All six state medical school deans belong to MSMA, and all six medical school faculty regularly contribute to *Missouri Medicine*. MSMA and its Alliance have granted over $771,000 in medical school scholarships to medical students and loaned $11.8 million in medical student loans to physicians in training at low interest rates. Membership in MSMA is especially important to hospital-employed and agency/industry-employed physicians. The younger a physician and the longer she/he will be practicing, the more important it is to have an advocate for employed physicians.



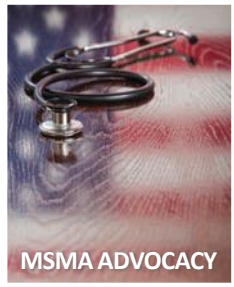
John C. Hagan, III, MD, FACS, is a Kansas City, Mo., ophthalmologist and *Missouri Medicine* Editor since 2000. He is a multi-year Super Diamond Contributor to MMPAC.
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MSMA membership is heavily discounted for medical students and residents/fellows. Non-members should contact Director of Membership Haley Wansing (hwansing@msma.org) or Cassie Williams (cwilliams@msma.org) to join MSMA or learn more of the many benefits of membership.

Our MSMA lobbyists Jeff Howell and Kenny Jackson are widely respected by legislators on both sides of the political aisle. Both did the heavy lifting that, for the second time, got tort reform into law in Missouri. Be sure to read Kenny Jackson's Legislative Preview to learn the vital issues that will be in play this legislative session. Legislators highly respect physicians, especially those from their own districts. Contact MSMA and arrange a day to come to Jefferson City and be "Physician of the Day." Or just come, even on short notice, to roam the halls and offices advocating for medical issues and fair reimbursement. We need something besides trial lawyer and insurance company lobbyists visiting Missouri's Senators and Representatives. Kenny Jackson (kjackson@msma.org) can furnish details and make arrangements or visit www.msma.org/advocacy.

Finally, I issue my annual challenge to MSMA officers, Council Members, Committee Chairs, and MMPAC Board. Set a good example by donating your time and your money. Recruit new members. Make an off-election year contribution of $500 to MMPAC to replenish its funds; donate another $500 to Missouri Physicians' Health Foundation. Lead from the front. Set a good example for all our MSMA members.

A special thank you to our Missouri physician legislators: Senator Rob Schaaf, MD, Senator Bob Onder, MD, Representative Keith Frederick, DO, and Representative Jim Neely, DO. The sacrifices they make while maintaining their practices and representing their constituents and all physicians are extraordinary. The good they do is incalculable. Many thanks. **MM**



Get to Know Your Physician Legislators

Bob Onder, MD, Assistant Senate Majority Floor Leader

Sen. **Bob Onder, MD,** R-Lake Saint Louis, and MSMA member since 1992, is Assistant Majority Floor Leader for 2017. The position is responsible for assuming the Majority Floor Leader's role in his or her absence. The support from his Senate colleagues' to this position is a direct reflection of the hard work and commitment he has shown after only two years in the Senate.



In 2006 he was elected State Representative, representing western St. Charles County.

Dr. Onder founded his private medical practice in 1992, specializing in allergy and asthma.

Contact: Bob.Onder@senate.mo.gov or 573-751-1282.

Representative Keith Frederick, DO (R) House District 121 (Rolla)

Rep. Keith J. Frederick, DO, represents parts of Pulaski County and parts of Phelps County (District 121) in the Missouri House of Representatives. He was elected to his first two-year term in November 2010.



In addition to his legislative duties, Rep. Frederick is a practicing orthopedic surgeon in Rolla at the Phelps County Regional Medical Center, where is also chair of the Department of Surgery. He received his BS from St. Louis College of Pharmacy in 1976 and his DO from the Chicago College of Osteopathic Medicine in 1981. He also attended the University of Missouri for graduate studies.

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Senator Rob Schaaf, MD (R) State Senate District 34 (St. Joseph)

Robert Schaaf, MD, graduated from Saint Louis University School of Medicine in 1983. A family practice physician, he is also the director of the Missouri Doctors Mutual Insurance Co.



He was first elected to the Missouri House of Representatives in 2002, winning reelection in 2004, 2006, and 2008. He currently represents the 34th district in the Missouri Senate, which began in 2011. Dr. Schaaf also represents District #1 on the MSMA Council and is the Council Chair.

Contact: rob@schaaf.com or 573-751-2183.

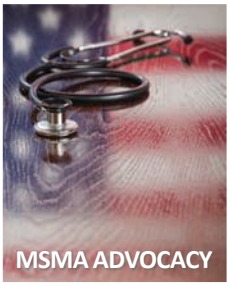
Representative Jim Neely, DO (R) House District 8 (Cameron)

Jim Neely, DO, a Republican, represents Clinton and Caldwell counties and parts of Clay and Ray (District 8) in the Missouri House of Representatives. He was elected to his first two-year term in November 2012.



Rep. Neely is a graduate of the University of Missouri School of Medicine and received his DO from the Kansas City University of Medicine and Biosciences. In addition to his legislative duties, Rep. Neely is a physician at Cameron Regional Medical Center and a veteran of the US Army.

Contact: jim.neely@house.mo.gov or 573-751-0246.



Forecast for 99th General Assembly

by Kenny Jackson

Tort Reform, Scope of Practice, Physical Therapy Ownership, PDMP.... *the List Goes On*

The results are in. Missouri, along with the rest of the country, made it through the tumultuous election of 2016. Missouri Republicans will control the legislative branch and the executive branch for the first time in eight years. Republicans won every statewide office on the November 8 ballot. Missouri's "red sweep" further solidified the GOP's supermajority in both legislative chambers. The veto pen will presumably be kept in the newly elected Governor's desk, as most GOP priorities have a relatively clear path to becoming law.

Of the 197 seats in the 99th General Assembly, four will be held by physicians. Senator Rob Schaaf, MD, will represent the 34th district, encompassing Buchanan and Platte counties. Senator Bob Onder, MD, will continue to represent St. Charles County's 2nd senatorial district. In the House of Representatives, Representatives Keith Frederick, DO, and Jim Neely, DO, will again be representing districts in Rolla and Cameron, respectively. Missouri physicians are incredibly fortunate to have four doctors in the legislature, protecting the practice of medicine from outside forces. Your MSMA lobby team looks forward to working with them again this coming year.

In no particular order, here are some of the issues we are anticipating during the 2017 legislative session.

Tort Reform

Your MSMA lobby team has been actively involved in a large tort reform coalition for a couple of years. Last session, the collateral source rule and expert witness reform were two issues that MSMA supported and were subsequently passed by the legislature. However, both were vetoed by the Governor, and did not receive overrides during the 2016 veto session. We are optimistic that both bills will pass again, and are hopeful they will garner the Governor's signature.

Collateral source would allow a defendant in a medical malpractice case to introduce evidence of the plaintiff's actual medical costs when calculating damages. In the past, courts have relied upon the value of medical services when determining the plaintiff's damages. That value has historically been defined as the amount required to fulfill the financial obligation to the health care provider. As a result, damage awards for plaintiff's have been greater than their actual costs for the treatment in question in the case. This bill will allow for more certainty and coherence while making sure plaintiffs are not unjustly enriched for economic damages they didn't actually pay.

Our expert witness reforms seek to change the evidentiary standards in many types of civil cases, including medical malpractice. Missouri was one of only nine states which has not adopted the same expert witness standards as the federal courts. Today, a non-scientific expert can be used as a witness. A judge could decide if that person's experience is sufficient and relevant enough to rely upon his or her testimony. This new standard, known by the courts as the Daubert standard, will improve the reliability, consistency, and predictability for the admissibility of expert evidence, as opposed to the old standard, which made evidentiary junk science easier to introduce.

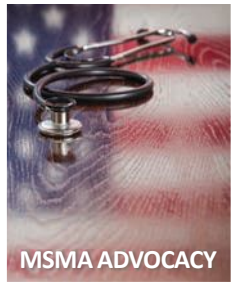
Predetermination of Benefits

This bill will give patients the ability to know their cost-sharing requirements before receiving a health care service.

It would require insurance companies to provide an estimate of costs of medical care to patients that seek it. Providers would receive this information on behalf of the patient using the same HIPPAA-mandated codes that are required for the reimbursement of claims. It would give patients more transparency while helping them to direct



Kenny Jackson is MSMA's Director of Legislative Affairs.
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their own health care decisions. Knowing these costs ahead of time would give patients the chance to set funds aside in advance of a procedure, instead of receiving a bill for an unknown amount from their insurance company after the fact. This information will be provided in realtime, having the potential to eliminate the financial uncertainty that currently plagues the health care system and would remove another layer of complexity and anxiety for patients at a time when they should be focused on their health. As insurance companies continue to push patients into high-deductible insurance products, it's only right that patients be able to easily find out how much is coming out of their own pockets.

Nurse Scope of Practice

For close to a decade now, the nurse lobby has unsuccessfully lobbied for expanded practice authority. At times, they have asked for a complete end to physician collaboration in their desire for complete independent autonomy. Other times, they have asked for a lessening of what they consider barriers to care, and overly burdensome restrictions on APRN practice.

Last year, language moved through the House of Representatives that required APRNs to be in collaborative arrangements, but completely repealed the statutory requirements for those agreements. The removal of the 50-mile geographic proximity requirement also moved hastily through the House of Representatives. In a show of compromise, MSMA has put forward the concept of APRN licensure under the Board of Healing Arts. The nurses however proclaim this is a non-starter. They received overwhelming support in the House of Representatives on these issues last year, and will most likely get that support again. With any compromise we may put forth, we will also expect something in return. If both sides dig their heels in the sand, then things in May will likely be no different than they are today.

Physical Therapy Ownership

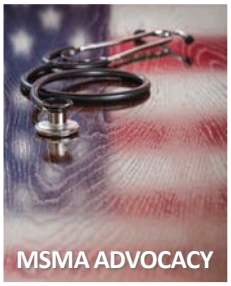
This bill would repeal a section of state law which prohibits physicians from possessing an ownership interest in a physical therapy practice. Congress repealed the corresponding portion of the federal Stark Law back in the 1990s, but Missouri never followed suit. The ability to offer in-office physical therapy provides a number of benefits to physicians and patients. By scheduling physical therapy and physical appointments at or near the same time and in same office, patients will be able to immediately discuss their therapy with their physician. The team environment is intact. Patient care can become fragmented when patients must travel in between facilities for care. In-house therapists can meet regularly with physicians to discuss patient treatment plans, reinforcing their place in a patient's continuum of care. When providers can communicate frequently and in a more timely fashion, errors and over-utilization will decrease. Physicians would know immediately if a change in therapy modality is appropriate, or if it should be discontinued altogether. This bill didn't have much traction last year, but we hope to get the ball rolling earlier this year.

Prescription Drug Monitoring Program

Missouri remains the only U.S. state or territory that hasn't passed or implemented a prescription drug monitoring program. Prescription Drug Monitoring Program (PDMP) legislation will most likely originate from the House of Representatives, as it has in years past. It will require dispensers to submit required information with 24 hours. It will allow providers to access the system in accordance with a patient's treatment. Those in the legislature who oppose the creation of a government-sponsored database have concerns that the privacy of Missouri patients will be at risk. Senate leadership usually avoids this bill as it takes up floor time with lengthy filibusters.

Medicaid Managed Care

As you know, the MO HealthNet program will be moving to a statewide managed care model in the near future. Although there has been some grumbling about the bid process, statewide managed care for the pregnant women and children populations will occur. In the meantime, we expect a language to be introduced again that would implement specific standards and guidelines on these MO HealthNet managed care companies. These standards include: utilization review protocols, a timely appeals process, network adequacy, actuarially-sound capitation rates, penalties for failure to reduce ER visits, required medical loss ratios, mandated data sharing, and timely provider payments. The state Auditor would be



required to perform an annual evaluation of the savings and costs attributed to the state, health care providers, and MO HealthNet participants as a result of statewide MO HealthNet managed care.

Summary

These are just a few of the issues we expect to encounter this year. We anticipate having our yearly discussions over the worthiness of state's motorcycle helmet law. We'll be battling against the insurance companies and high deductible HMOs. Athletic trainers, optometrists, and radiology technicians will probably seek to expand their scope of practice in one way or another. We'll be advocates for a comprehensive texting while driving ban. Pharmaceutical, hospital, and tobacco issues will most likely be under our watchful eyes as well. The last day of the 2017 session is Friday, May 12…this also happens to be the best day of the year.

Be sure to read MSMA's weekly *Legislative Report* during the 2017 session. It will keep you in the loop on all the above and then some. Also, don't forget to volunteer as the MSMA Physician of the Day at the Capitol. It's not difficult, and the legislators love seeing their hometown doctors in the building. You can find the sign-up sheet on the MSMA website. If you have any questions about our advocacy efforts on your behalf, feel free to give me a call anytime at 573-636-5151, or email kjackson@msma.org. **MM**



Volunteer to spend a day in the Capitol as MSMA's Physician of the Day in 2017!

Between January 4 and May 11, 2017, MSMA needs volunteers to be "Physician of the Day" in the Capitol. Sign up at www.msma.org/physician-of-the-day.

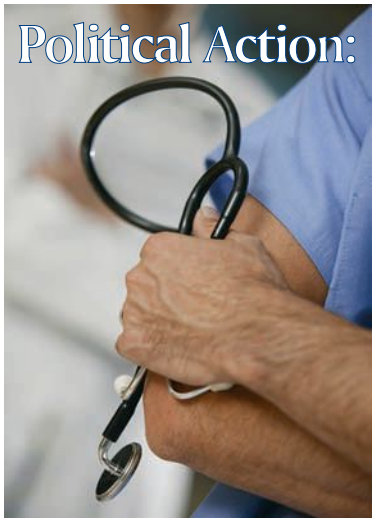
This excellent program is warmly received by the General Assembly and participating physicians. Lawmakers and their staff benefit from knowing good medical attention is always at hand, and physicians enjoy spending a day in the Capitol, experiencing the political process on a personal basis.

Would you consider helping us? Plan to spend a day in Jefferson City as the Legislature's physician, and bring your family and let them see the Capitol, too.

One physician per day is needed every Tuesday, Wednesday, and Thursday during the legislative session. Plan to arrive in the Capitol around 9:00 or 9:30 a.m., and stay until 2:00 or 3:00 p.m. (except Thursdays, when the House and Senate typically adjourn around noon).

NEW FEATURE: Some of our medical students have expressed an interest in shadowing the Physician of the Day. If you are willing to allow a student to shadow you, please check the box at the bottom of the sign-up sheet at www.msma.org/physician-of-the-day. If you would rather not have a student follow with you, just leave the box unchecked.

Contact MSMA's Kenny Jackson at 800-869-6762 or kjackson@msma.org. He will coordinate with you to outline the responsibilities and offer dates available.



Medicine's Muscle

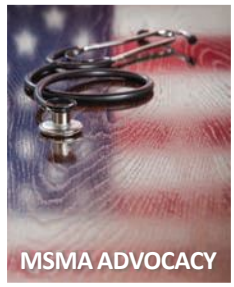
Join hundreds of your physician peers who belong to the Missouri Medical Political Action Committee

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Contributions or gifts to MMPAC are not deductible as charitable contributions for Federal income tax purposes. MMPAC is a separate segregated fund established by the MSMA. Contributions to MMPAC can be made on either personal or corporate checks. Your corporation must have a corporate resolution regarding PAC donations if your contribution is made from a corporate account. Contributions are not limited to the suggested amount. MSMA will not favor or disadvantage anyone based upon the amounts of or failure to make PAC contributions.



Advocating for What Is Important to Medicine

by Ravi S. Johar, MD

On a larger basis, advocacy is how we advance our practice of medicine.

This issue of *Missouri Medicine* is our advocacy issue. But what exactly does that mean? What is advocacy? Webster's defines advocacy as: the action of advocating, pleading for, or supporting a cause or proposal.

OK, but what does that really mean, what does it mean to advocate for medicine?

All of us are advocates every day in our jobs as physicians where we advocate with our patients to try to get them to follow our treatment plans or convince them to modify their lifestyle. We are advocates in our personal lives as parents when we plead with our kids to do the right thing (at least as we see it), or even in our social lives as we try to come to an agreement with friends or family on what we have planned for that evening.

On a larger basis, advocacy is how we advance our practice of medicine. Advocacy is trying to convince lawmakers, or the judicial branch to move according to our desires or interests. We attempt to do this not only as individuals, but also as organizations like the Missouri State Medical Association or the American Medical Association. Unfortunately, individually we are too busy to be able to meet with all the legislators and their staff or to attend and testify at all the various hearings in Jefferson City or Washington D.C. in person. Our organizations use lobbyists to advance our arguments and concerns. There was considerable discussion concerning lobbyists during the recent election season and much of that discussion was negative. Well, why would that be if they are only advocating what we want?

I believe this has to do with the fact that many lobbyists don't have the personal connection or passion concerning the issues they are advocating for. Legislators can sense quite quickly if the person trying to convince them to do something truly believes in it or is just doing it for a paycheck. We have seen the same thing with some of the thought leaders in our specialties. One month they are speaking about a medication being the greatest one ever, the next month after they receive a grant from a competitor, they are speaking for that competitor and touting it as the greatest one ever. Obviously, they lose a fair amount of credibility.

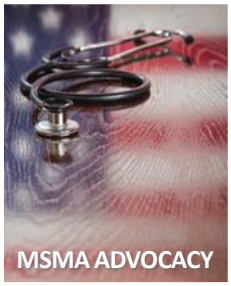
However, the person who truly believes in his or her cause and can articulate those beliefs can be a very powerful advocate. This is why I believe that the organized medicine advocates are so successful at what they do. The individual physicians that are able to find time to talk to their legislators at home or in Jefferson City can relay compelling personal stories of why we need certain legislation or changes in the system. Our lobbying team led by Jeff Howell and Kenny Jackson truly come across as a resource for the legislators, and are perceived as steadfast in representing the views of the physicians in MSMA. By not trying for political expediency but by doing what is right, at least as far as physicians believe, they gain tremendous credibility on the hill and help us advance our agenda forward.

I encourage you to read the 2016 MSMA Legislative Review that summarized the last legislative year to see what we as medical advocates were able to accomplish - not only what we were able to get passed but even more importantly, what we were able to stop from being passed. Most, if not all, of the legislative priorities that we are fighting for come directly from the physicians that make up MSMA. Resolutions that are brought before the House of Delegates at the Annual Meeting, phone calls or e-mails to the MSMA offices in Jefferson City, or conversations with members of the MSMA Council all give opportunities for physicians to advocate for what are concerns of theirs. We can then collectively take these concerns and advocate with a powerful voice at the state Capitol. For the really big issues, we can join with the other state societies and make a powerful statement on a national level.

We have an unprecedented opportunity to address issues this year with the seismic upheaval in our election process. It is critical that we hear about what is important so that we advocate for what is important to our members, and not make any of the missteps that may have occurred in the past. I urge all of you to let us know what you would like to see in medicine as we go forward. Let's work together to get that accomplished. **MM**



Ravi S. Johar, MD, MSMA President and member since 1995, practices OB/GYN in St. Louis, Mo.
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Physician Advocacy: The AMA Interim Meeting 2016

by the Missouri Delegation to the AMA and compiled by Charles Van Way, III, MD

Your Missouri Delegation to the American Medical Association continues to have a strong voice in the AMA, because in our midst is President-Elect David Barbe, MD, of Mountain Grove. As usual, other members of the delegation have served in various ways. Dr. Van Way, your correspondent, served on the Committee on Rules and Bylaws, which performs several functions at the meeting itself.

The AMA has two meetings each year. This Interim meeting, held this year in November in Orlando, Florida, is intended to focus on the political and legislative arena. Advocacy is its purpose. The results of the election, a week before the meeting, stirred up the House of Delegates (HOD). Few expected the result.

Andrew Gurman, MD, President of the AMA, and James Madura, MD, Executive Vice President, both spoke. They expressed relief at the end of the awful election campaign, and optimism going forward. A public statement released by Dr. Gurman committed the AMA to working with the new administration, and to the "core principle" that "any new reform proposal should not cause individuals currently covered to become uninsured." Disturbingly, there seemed little acknowledgement by the leadership that the Affordable Care Act has failed in many respects, and should be fixed.

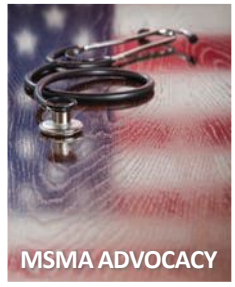
A highlight of the meeting was the presentation of the AMA's highest award, the Meritorious Service Award. This year, it was given to Bennet Omalu, MD, the discoverer of the new disease of chronic traumatic encephalopathy. CBI has changed our views of such disparate subjects as professional football and military casualties. Dr. Omalu was met with opposition from the National Football League, medical experts, sports figures, and even some universities. Dr. Omalu expressed his gratitude for the support of the AMA. His passionate acceptance speech was given a standing ovation.

The Reference Committee on Constitution and Bylaws considered several issues, including end-of-life care, ethical conflicts of employed physicians, and the definition of female genital mutilation. The Board of Trustees has recommended increasing specialty society representation, and further increasing the relative representation of the larger societies, such as the American College of Physicians and the American College of Surgeons. Shifting the HOD further towards specialty organization has risks, and is opposed by many. The HOD approved this recommendation, and it will be implemented. Stay tuned.

Reference Committee B considered many legislative and regulatory issues. Physician offices have been classified by the FDA as "compounding facilities," and are now subject to a whole host of regulations. A resolution was passed to lobby the FDA to change this classification. The AMA is already working on the problem. Falsely adding physicians to the National Data Bank was highlighted. Documentation using the problem-oriented medical record is still not recognized as valid by CMS. Using SOAP may cause denial of payment. And then we have MACRA.



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Missouri Delegates to the AMA at the House of Delegates in Orlando. Back row, from left: Matt Faubion, David Barbe, Charles Van Way, Jared Lammert, Bill Huffaker, and Warren Lovinger. Front row, from left: Drs. Ravi Johar, Ted Groshong, Lent Johnson, Ariel Carpenter, Edmond Cabbabe, and Jim Conant.



In 2014, the Medicare Access and CHIP Reauthorization Act, MACRA, eliminated the SGR formula. But it then created new ways for paying physicians: Merit-Based Incentive Payment Systems (MIPS) and Alternative Payment Models (APM). To make things more confusing, MACRA is now re-named QPP, Quality Payment Program. The final rules have just been released, and will take effect in January 2017. All that said, push-back from the AMA has softened the blow somewhat. Smaller practices may be able to exempt themselves from the requirements. Required reporting measures have been made simpler. There is more flexibility. Physicians will be able to participate to different degrees in the program next year, and will not, at least in the short term, be exposed to losing money. This is a work in progress. MACRA passed Congress with large bipartisan majorities. It is unlikely to go away, although ongoing modifications are very likely in the new political environment.

Unfortunately, many physicians simply don't realize this is coming. Many have delegated this to practice managers. Others are involved in group, corporate, or employed practices. There was widespread concern that practices will be hurt by their failure to prepare for reporting. Much information is available on the AMA website, https://www.ama-assn.org/practice-management/understanding-medicare-payment-reform-macra, as well as from the CMS website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html

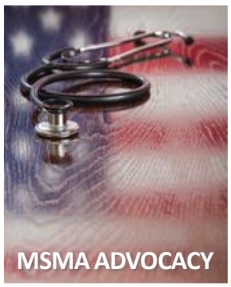
One Missouri resolution was considered. This asked for a study of extension of the Family Medical Leave Act to businesses now exempt. The intent clearly was to advocate extension. The resolution was amended to "encourage" study. We may find out in another few months whether or not the AMA thinks this is a good idea.

Committee C considered medical education. Maintenance of Certification (MOC) was again a major concern. Besides several resolutions, there were several presentations about the problems with MOC. One of our colleagues from Oklahoma, Woody Jenkins, MD, presented the successful opposition of physicians to an attempt in the legislature to mandate MOC as a condition of licensing. A strong resolution committed the AMA to promote state legislation and hospital staff bylaws discouraging the use of MOC status in decisions about licensure, hospital privileges, and re-credentialing. Missouri medical students were instrumental in adopting policy encouraging mental health screening and treatment for medical students and residents.

Committee F considered finance and governance. A resolution was adopted calling for financial oversight and audit of the American Board of Internal Medicine, other medical boards, and the American Board of Medical Specialties. This reflects a profound distrust of the accrediting boards, in part driven by their expansion of MOC.

Committee J considered medical practice issues. There was particular interest in the plight of medical students and residents who are protected from deportation under Deferred Action for Child Arrivals. DACA, enacted by executive action in 2012, has resulted in a number of students entering medical education. There are 31 such individuals in medical schools, and perhaps as many more in residency programs. If DACA is abolished, as seems likely, these students will likely be unable to complete their educations. The HOD voted to advocate for their exemption from any changes in DACA.

Another resolution concerned communication



Below: The view from the AMA President-Elect's point of view, David Barbe, MD, of Mountain Grove, MO.





Above: Dr. Barbe (right) has been traveling representing U.S. physicians, here at the World Medical Association in Taipei, Taiwan, along with Steve Stack, MD, (left) AMA Immediate Past President and Andrew Gurman, MD, (center) President.

among physicians in the age of compartmentalized EHRs, strongly advocating improvements in interconnection and transparency. There were resolutions about ensuring equal access to high quality care, in such disparate settings as veterans, same sex couples, prisons, and breast reconstruction. A very popular resolution called for insurance plans to collect co-pays and deductibles from their plan enrollees, rather than requiring doctors to do it for them. Good luck with that.

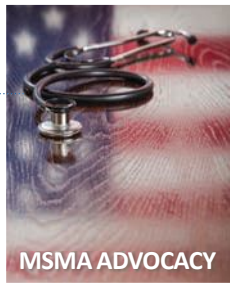
Committee K studied issues of science and public health. Probably the most controversial was a resolution that the AMA cease to oppose the legalization of marijuana, as was done in a number of states in the last election. The question was referred to Council. It was said that a report from the National Academies of Science, Engineering, and Medicine will be released in the next few months. Expect further debate at the next Annual Meeting, in June 2017.

As usual, a number of resolutions were passed to make small improvements in the practice of medicine and public health. There were brisk discussions on such issues as opioid abuse, early childhood education, neuropathic pain as a new diagnosis, environmental exposures to lead and to polycyclic aromatic hydrocarbons, and youth incarceration in adult prisons. There was concern over the October 17 action by the DEA which mandates a 25% decrease in opioid production. This action is very likely to have unintended adverse effects. Graphic warning levels on tobacco packages were strongly supported, although these have not survived court challenges in the past.

The Physicians Foundation of the AMA supports physicians and health care in general. It has been particularly active in the area of costs. A recent book by the late Richard Cooper, MD, "Poverty and the Myths of Health Reform" is a must-read for any concerned with the continuing rise in health care costs. The Foundation's biennial physician survey was completed in 2016. Almost two-thirds were pessimistic about the future of medicine. The major sources of dissatisfaction were paperwork and third party interference with the practice of medicine. The major source of satisfaction was their relationships with their patients. The direction of future AMA advocacy should be obvious.

Firearm-related injuries remain a health concern of the AMA. There were resolutions to further regulate firearms. Perhaps the best of these was a resolution to facilitate studies on firearm injuries and interpersonal trauma. Research in this area has not been funded by the Federal government, for a variety of reasons which include political pressure. Current and proposed legislation continues to be guided by untested assumptions. Debates about restrictions and other measures to reduce gun violence are singularly uninformed by data.

Surprisingly little attention was paid to graduate medical education. No one at this meeting appeared to be very concerned that we do not have enough training positions. We cannot accommodate even all U.S. graduates, much less international grads. There is a growing number of young physicians who can neither work nor pursue further training. The lack of training positions has become a barrier to increasing the physician workforce. A report on this issue is forthcoming, and we may expect more action on this issue at the Annual Meeting next year. **MM**



17 ways your life would be *different* without MSMA

1 Tort Reform - You'd spend another year without any professional liability protections. MSMA's 2015 tort reform effort will result in incalculable savings for Missouri physicians; worth far more than MSMA's annual dues.

2 Medicaid Fraud - You would be living in constant fear of frivolous lawsuits at the hands of disgruntled employees and patients willing to exaggerate claims of fraud in hopes of hitting a lawsuit jackpot. MSMA led the fight against legislation that would have allowed any citizen to file a lawsuit in the name of the state against any health care provider suspected of Medicaid fraud. As a reward for doing so, the person bringing the lawsuit would have been rewarded with at least 25% of the state's recovery.

3 Medicare Physician Fees - You might have suffered a terrible cut in Medicare payments. MSMA - and others - fought successfully to replace the flawed SGR formula and to forestall payment cuts that would have cost the average Missouri physician $27,000. That would pay your MSMA dues for more than 71 years.

4 Legal Expense Fund/ Immunity - There would not be state Legal Expense Fund coverage for family physicians and others donating primary care in certain not-for-profit settings, and there would not be civil immunity for physicians volunteering services in certain free clinics.

5 Motorcycle Helmets - Countless individuals would be deceased or severely injured and in emergency rooms across Missouri. MSMA has fought for numerous years to keep the state's mandatory motorcycle helmet law in place.

6 Immunizations - The children in your practice would not be required to have any childhood immunizations.

7 Physician Impersonators in Your Community - APRNs would be practicing medicine independently throughout Missouri. The Licensed Professional Counselors would be performing the same services as psychiatrists and other mental health professionals. Your neighborhood chiropractors would have large signs on their offices, touting them as licensed primary care physicians. And they would drain Medicaid physician fee coffers even more. The psychologists would be prescribing drugs - including controlled substances - for your patients.

8 Spinal Procedures - CRNAs would have had the ability to perform fluoroscopically-guided injections into the spinal column, the ablation of targeted nerves, and laser discectomies on patients in your community without the supervision and collaboration of anesthesiologists.

9 HMO Cost Sharing - Insurance companies would have the ability to initiate cost sharing in their HMO products. They can do this presently, but only if it is paired with a fully funded Health Savings Account (HSA). Without this first dollar coverage afforded by the HSA, you would be on the hook for increased bad debt from missed co-pays and co-insurance.

10 Tanning Beds - Missouri would be one of the only states without some restrictions on indoor tanning. Now parental consent forms must be used by tanning salons before children under 17 years of age can use their facilities.

11 ECHO Program - Utilizing current telehealth technology, you and other multidisciplinary experts can collaborate with local primary care physicians. This expands the ability to safely and effectively treat chronic, common, and complex diseases in rural and underserved areas without the need for patients to travel long distances to see specialists.

12 Investigational Drugs - You have the ability to prescribe an investigational drug or device for terminally-ill patients who seek these alternatives, with limited liability protections.

13 Medical Test Results - You would be required by law to forward the results of all medical tests directly to the patient within five business days.

14 Clean Indoor Air Act - You and your patients would not enjoy the benefits of clean indoor air. MSMA helped pass the original Missouri Clean Indoor Air law, and has worked to both defend it and strengthen it over the years.

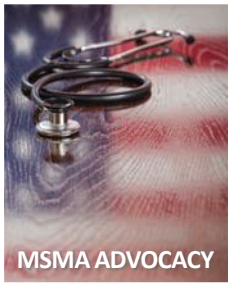
15 MSMA Insurance Agency - You would not have the MSMA Insurance Agency which was created and is custom-made to help you find the most appropriate and best-valued insurance coverage for everything from medical malpractice to health insurance for your practice staff.

16 Missouri Physicians Health Program - Tragically, there wouldn't be a Missouri Physicians Health Program. This outstanding MSMA program assists physicians with a variety of personal issues ranging from substance abuse to family and marital relations to professional boundary issues. It has saved careers, practices, and even lives.

17 Missouri State Medical Foundation - And there wouldn't be this valuable source of aid for medical students with financial needs. The Foundation has issued more than $11 million in student loans, and might well be the support that keeps your next practice partner in medical school.

Member Benefits for Physicians: 800-869-6762 | www.msma.org/membership-perks

MSMA Missouri State Medical Association



Fifty Years of Trauma

by Charles Van Way, III, MD

"Violence is as American as cherry pie."
- H. Rap Brown, ca 1965

Long ago, in a city far away, I was introduced to trauma. It was the 1960s, my first rotation as a surgical intern. A man came in, beaten up. (Today, we call it "interpersonal blunt trauma") Big scalp laceration. Slightly depressed skull fracture. Drunk, but awake and alert. I called the neurosurgeon, who said, "Now, Dr. Van Way, you do know how to elevate a skull fragment, don't you?" In the day, that was attending-speak for, "it's the middle of the night, boy, and I'm not going to come in." In fact, I did know how to do it. A couple of hours later, I'd actually done it. Once. Nobody turned a hair, and the patient did just fine. It was a simpler time.

Even though I don't really think of myself as a trauma surgeon, I've done my share of trauma, and a bit more. I've been chief of surgery in two different trauma hospitals (Denver General Hospital and Truman Medical Center). I've headed up a shock-trauma research center. Still do, for that matter. I've had research grants. Co-edited a book on trauma.[1] Since the 60s, I've been a sometime participant and an always-interested observer of the trauma scene. It has been a very active 50 years in the world of trauma care. So… with that lead-in, let me reflect on that last half-century.

We emerged from a decade of war into the mid-1950s, with a large amount of military experience in trauma. But the civilian trauma system was decades out of date. This changed, although it wasn't particularly easy, nor was it painless. Understand that 1950 to 1980 was a difficult time in many ways. Trauma was rising. Death rates rose for motor vehicle accidents (MVAs), homicides, and suicides were at century's high. (See Figure 1.) The health system was severely challenged.

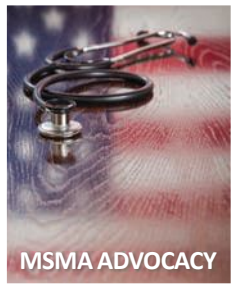
From World War II through Korea and most particularly Vietnam, surgeons went off to war, and returned as experienced trauma surgeons. When they came back, they were appalled at the poor quality of civilian trauma care. And because most of them were young, they had the energy and the drive to make things better. Dr. Kendall McNabney, for example, came back from the Vietnam war, and began one of the nation's first emergency medicine programs at Truman Medical Center. The American College of Surgeons, and many other professional organizations, worked hard to improve things. Advanced Trauma Life Support (ATLS) dates to the 1970s. As does accreditation of civilian trauma systems. And emergency medical technician training. After a certain amount of turmoil (well, a whole lot of turmoil), the medical system responded by increasing and expanding emergency departments, intensive care units, and emergency medical services. By the 1980s the system had changed. Besides the growing specialty of emergency medicine, trauma surgery had become a sub-specialty of general surgery. Hospitals poured resources into space, equipment, and staffing. Our present-day trauma system is the beneficiary of these changes.

But an odd thing happened. The incidence of trauma began to drop off. Most importantly, deaths from MVAs fell by almost two-thirds. These were the largest cause of trauma death, and this dramatic drop was very significant. Much was due to better safety features (seat belts, air bags, and other things), as well as to better evacuation and trauma care. Drunk driving became more and more unacceptable. It never was actually acceptable, but it was far more tolerated in the 50s than it is today. In fact, the overall numbers and incidence of motor vehicle crashes have also fallen, not only the deaths resulting from them.

Interpersonal violence also changed. Homicide deaths initially rose, but then fell by half. The drop in homicide rates was paralleled by a decrease in all violent



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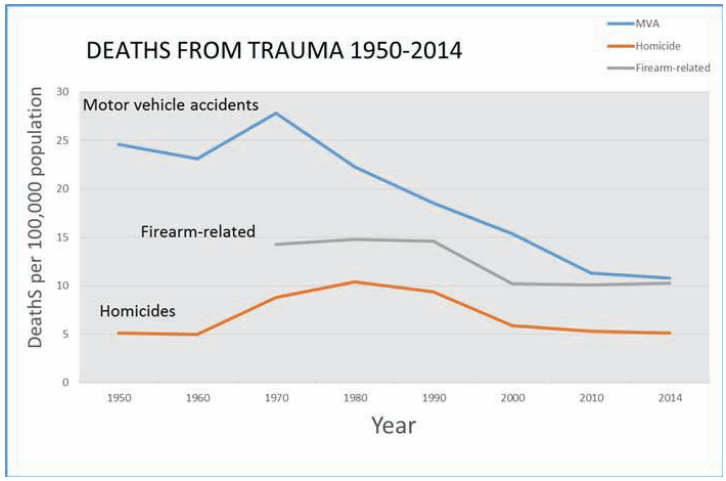


crimes. Firearm-related deaths fell by a third. They decreased with the drop in violent crime overall.

The media and politicians wring their collective hands incessantly, and it seems that things are worse than ever. But the figures say otherwise. Have we in fact become safer? In a word, yes. We are safer, both because the incidence of trauma has dropped, and because we have a much better trauma system. Granted, it is not fashionable to point these things out. But they are nonetheless true.

Trauma system improvements have been truly amazing. I believe it was at that city hospital that I learned to look in the back of the ambulance first. Because, it was in the back of the ambulance that we found the worst-injured patients. In those days, ambulances were likely to be doing day duty as hearses, and their drivers were virtually untrained. Today? The ambulance is staffed by trained emergency medical technicians. Now, the sickest patient comes out first. And all patients are better cared for even before they arrive at the emergency department.

Figure 1



But motor vehicle crashes, interpersonal violence, and other causes of injury are still with us. A lowered incidence is all very well, but the total number of victims remains large. We are certainly better able to take care of those hurt in an auto crash, or shot in a barroom fight. But a look at Figure 1 confirms that the improvements of the past 40 years are tapering off. Yes, it's been a good 50 years. But no, the work has not yet finished.

What is trauma? To most of us, trauma connotes accidents, or intentional violence. To the trauma surgeon, an injury is a problem to be solved. We've become really skilled at that. But looking at society as a whole, trauma is a disease. And more than that, it's a chronic and recurring disease. We've done a pretty good job on trauma from motor vehicles. As noted above, a lot of safety features are now built in to vehicles. People now pay some attention to driving safely (I know, not on your morning commute). But when I was young, there were no designated drivers. How did we survive? Well, some didn't. Most of us knew someone who was killed in an auto crash. That's much less true today.

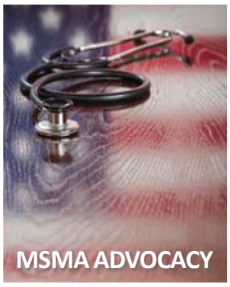
Consider homicide. Among men 20-25 years-old, the incidence of homicide is four times that of the general population. Some subgroups in the population have considerably higher rates than that. It's a disease of poverty, we say. But that's an association, not a cause. We could equally say that a tendency to violence is one of the causes of poverty. Perhaps so. All of this is just playing with words. The incidence of homicide, and other sorts of violent crime, has indeed decreased. What did we do right? Ask the experts, and you'll get as many theories as you have experts. The truth is, we don't really know. What would we do if the rates start to go up again? If we don't know what worked before, we're going to have a hard time figuring out what to do next.

So, fifty years of trauma. We can, and should, complement each other for all of the great accomplishments in the care of injured people. And we can be very happy that the incidence of trauma has dropped. We still take care of too many victims. But at least, the problem isn't getting worse. Yet, we have to recognize that we have far to go. Our country still has a homicide rate far in excess of most of the "civilized" countries of Western Europe. Some 2,500 people die each month from motor vehicle crashes. Part of the solution for these problems will come from us, or from the health care system. But health care is not the whole answer. As physicians, we are expected to be leaders in this effort. And so we should be.

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Should Nurse Practitioners Be Allowed to Practice Independently?

by Samer Cabbabe, MD

For several years, health care experts have been concerned about an impending shortage of physicians. This concern accelerated in 2014 due to expanded health coverage available as a result of implementation of the Affordable Care Act. Policymakers have suggested that nurse practitioners (NPs) could fill this gap. They have argued that since their reimbursement is lower, nurse practitioners could also help reduce health care costs.

Advocates for NPs note that they could fill the growing primary care shortage more quickly than physicians, since it takes NPs, on average, six years to complete their education and training, including undergraduate and graduate degrees, compared to an average of 11 to 12 years for physicians, including schooling and residency training.

Medicare pays NPs, practicing independently, 85 percent of the physician rate for the same services. Medicaid fee-for-service programs pay certified pediatric and family practice NPs directly, but these rates vary by state. Some states pay them the same rates they pay physicians for some or all services, but more than half of the states pay NPs a reduced fee. Health insurance plans have significant discretion to determine what services they cover and which providers they recognize. Some plans do not cover NP services, and many managed care plans require their enrollees to designate a primary care provider but do not always recognize an NP in that role.

Background and Training

In order to become a nurse practitioner, students with a high school diploma usually study for a Registered Nurse (RN) certification, or for a degree in nursing. These degrees include the Associate Degree in Nursing (ADN) and the Bachelor of Science in Nursing (BSN) which can be completed in approximately two and four years, respectively. After the completion of a degree program, students must first obtain the RN certification and then enroll in a Master of Science in Nursing (MSN) program. The Master's degree in nursing is normally completed in about two years, but for enrollees who already have some work experience in a health-care-related field, the degree can be completed in as little as 18 months.[1,2]

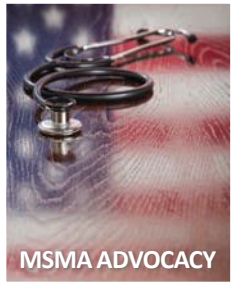
A new nurse practitioner, without any other nursing experience, acquires between 500 and 1,500 hours of clinical experience in a minimum of 1.5 years of post-graduate training, an equivalent of less than a third-year medical student. In contrast, a new family physician acquires more than 15,000 hours of clinical experience in a minimum of seven years post-graduate training. This amounts to a difference of at least 13,500 hours in clinical experience.[3]

Currently, there are 21 states where NPs have the statutory authority to practice without physician collaboration, supervision or oversight. The other 29 states require physician supervision for prescribing but have various requirements for physician involvement for diagnosing and treating.[4] According to the AMA, only a handful of states require independently practicing NPs to submit information regarding their location of employment. Of those states, none keep track of the number of independently practicing NPs.[5]

Current Missouri law prohibits NPs from independently prescribing, diagnosing or treating patients without physician supervision or collaboration. Furthermore, Missouri NPs are governed by the Missouri Board of Nursing and do not fall under the jurisdiction of the Board of Healing Arts.



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Reports Debate Expanded NP Scope of Practice

In 2010, the Institute of Medicine (IOM) issued a report in conjunction with the Robert Wood Johnson Foundation, entitled, "The Future of Nursing: Leading Change, Advancing Health." The goal of this joint effort was to explore options to increase access to health care as a result of the passage of the Affordable Care Act. Their conclusion was that "Advanced Practice Registered Nurses (NPs) should be called upon to fulfill and expand their potential as primary care providers across practice settings based on their education and competency."[6] Of the 18 committee members, only two were physicians, one of whom was the chief medical officer for CVS Caremark.

The Council of Medical Specialty Societies (CMSS), which represents 34 societies with an aggregate membership of more than 650,000 U.S. physicians, believes that "non-physician clinicians are critical stakeholders in the health of our nation and that nurses are irreplaceable members of a high-performing, patient-centered health-care team." In their rebuttal of the IOM report, CMSS states that "nurses, within the context of the physician-led medical home, are ideally suited to help deliver these newly covered preventive services."[7]

Existing studies of the geographic distribution of NPs in the United States show that they are more concentrated in urban areas than are physicians: 85 percent of NPs work in metropolitan counties and only 5.5 percent of NPs practice in remote rural counties.[2,8] Furthermore, according to CMSS, the IOM report "lacks detail concerning the necessary clinical and educational standards which would undergird such an expansion, and does not give sufficient attention to the cost ramifications associated with its recommendations." The CMSS points out, in criticizing the IOM report, that a recently graduated NP with only 500 hours of clinical experience would be permitted to legally admit patients to a hospital or hospice, lead the patient-care team, and receive the same level of reimbursement as a physician.[7] Other studies have shown that NPs tend to order more laboratory and diagnostic tests than physicians, defying the concept of reducing health-care cost.[9,10]

The American Medical Association (AMA) acknowledges that non-physician practitioners, including NPs, can provide essential patient care, but that such care is "most appropriately provided as part of a physician-led team." In addition, the AMA states that, "nurses are critical to the health care team, but there is no substitute for the education and training of physicians. With a shortage of both nurses and physicians, increasing the responsibility of nurses is not the answer to the physician shortage. Research shows that in states where nurses can practice independently, physicians and nurses continue to work in the same urban areas, so increasing the independent practice of nurses has not helped solve shortage issues in rural areas. Efforts to get health care professionals in areas where shortages loom must continue in order to increase access to care for all patients."[11]

In conclusion, we all desire excellent patient care but must remember that physicians are indisputably the most educated and trained to lead the health care system. We must not confuse accessibility with quality in health care by allowing NPs to practice without physician supervision.

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Physicians Present Opposing Views of Hospitalists

by Arthur Gale, MD

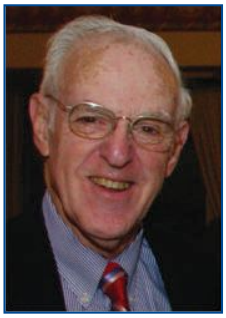
Physicians' views don't really matter. In a democracy, consumers, not experts, should have the final say.

Two articles in the September 15, 2016, issue of the *New England Journal of Medicine* present opposing views on hospitalists.

The pro-hospitalist authors, Robert Wachter, MD, and Lee Goldman, MD, MPH, wrote an article titled, '"Zero to 50,000 - The Twentieth Anniversary of the Hospitalist."[1] The zero to 50,000 stands for the number of hospitalists 20 years ago and today. Wachter, an internist, is chief of the medical service and chief of the division of hospital medicine at the University of California, San Francisco. Goldman, a cardiologist, is professor of medicine, executive vice president and Dean of the Faculties of Health Sciences at Columbia University Medical Center.

The authors write, that in the 1990s, "The combination of managed care privately-insured patients and Medicare's Diagnosis Related Group-Based Payment System for inpatients pushed hospitals to manage care more efficiently without sacrificing quality or alienating patients."

The authors then report that "within a few years evidence showed that using hospitalists could result in reduced costs, shortened lengths of stay, and preserved quality of care and patient satisfaction." Wachter and Goldman then cite two articles that support their conclusions. Both articles are authored by Wachter and Goldman.



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The con-hospitalist article is by Richard Gunderman, MD, PhD. Gunderman is Chancellor's Professor of Radiology, Pediatrics, Medical Education, Philosophy, and Medical Humanities and Health Studies at Indiana University.[2]

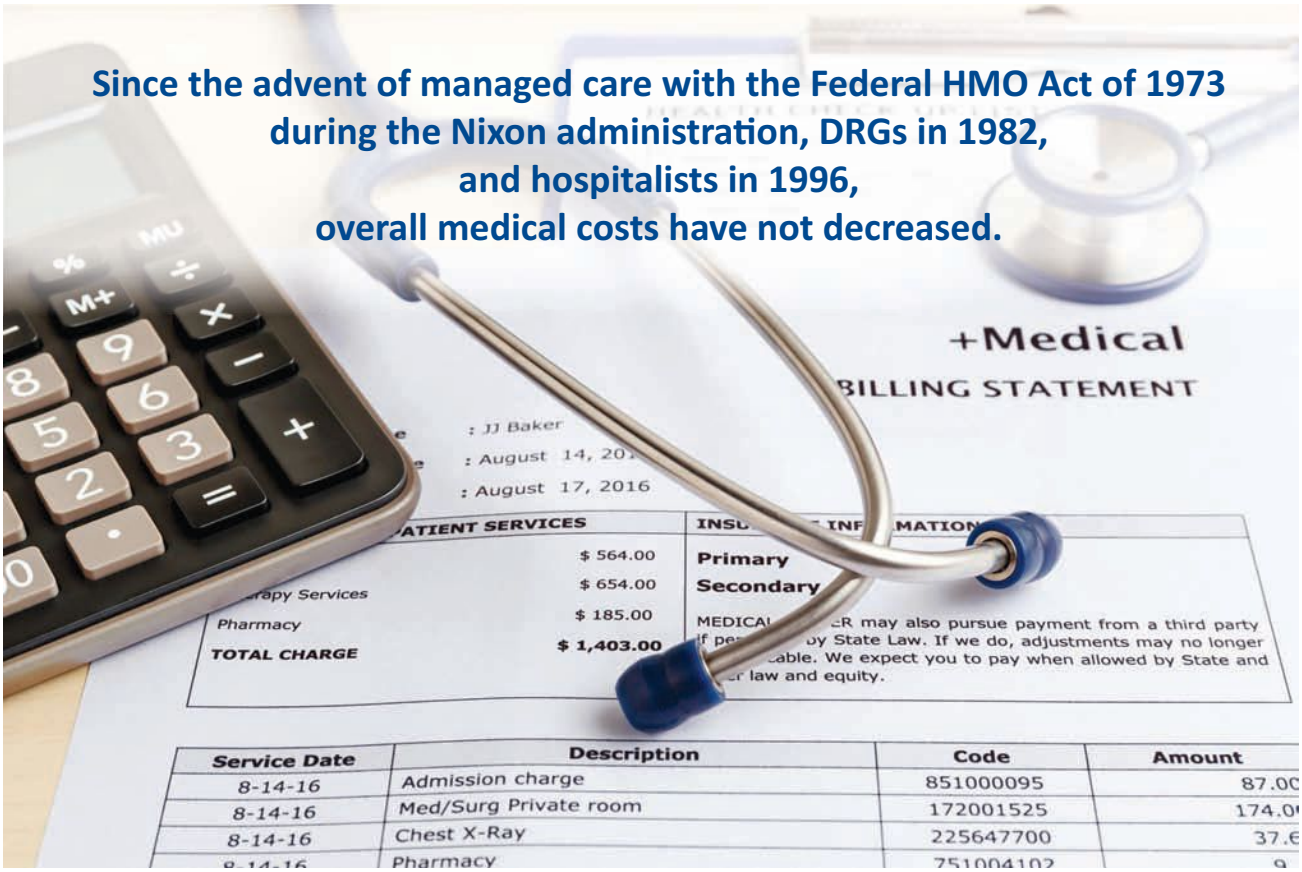
The title of Gunderman's article is "Hospitalists and the Decline of Comprehensive Care." Gunderman writes: "The hospitalist model has provided such putative benefits as reductions in length of stay, cost of hospitalization, and readmission rates…What we don't know well is…the total costs and the well-being of patients and physicians."

Gunderman continues: "Some physicians may be captured by the hospital, whose incentives to increase market share and profits are not always well aligned with the best interests of patients and communities… *The true core of good medicine is not an institution but a relationship between two human beings*." (Emphasis added)… "Models of medicine that ensconce physicians more deeply in spatial and temporal silos only make the prospects for and a relationship even dimmer."

The prime reason for the creation of hospitalists was Diagnostic Related Groups commonly known as DRGs. DRGs were intended primarily to lower costs not to improve quality. DRGs were created by two so-called experts, Robert B. Fetter, PhD, of the Yale School of Management and John D. Thompson, MPH, of the Yale School of Public Health.[3] DRGs are a form of capitation that pays hospitals a fixed sum of money for a particular diagnosis. Their purpose was to lower health care costs which government and academic experts stated had reached a crisis level in 1982.

As a matter of record there was no medical crisis in the U.S. in 1982. In 1982 health care costs in the U.S. were essentially the same as in other developed countries. DRGs were tried first in New Jersey with mixed or at best minimal success in lowering hospital costs. Despite their lackluster performance in New Jersey they were nevertheless implemented in hospitals throughout the U.S. in 1982.[4]

Since the advent of managed care with the Federal HMO act of 1973 during the Nixon administration,



DRGs in 1982, and hospitalists in 1996, overall medical costs have not decreased. They have markedly increased and far surpass medical costs in other OECD (Organization for Economic Cooperation and Development) countries. The U.S. also ranks last in quality compared to other O.E.C.D. countries. It is difficult to reconcile Wachter and Goldman's glowing appraisal of managed care, DRGs, and hospitalists, with historical facts.[5]

Although DRGs have not succeeded in significantly lowering hospital costs they have had a major effect on the medical professions. They have tipped the balance of power in hospitals from doctors and nurses to hospital administrators. DRGs enable hospital administrators to dictate to doctors how they must work rapidly to achieve optimal turnover of patients so that the hospital does not lose money. This is often referred to as the turnstile effect or throughput.

Since many primary care practices are owned by hospitals today and since administrators hold the power of the purse, it makes little difference either pro or con what doctors think about hospitalists. Medicine is no longer an independent profession. Hospital administrators are not going to give up their control of physicians based on what doctors think constitutes good medical practice. They will continue to blame doctors for the high cost of health care. They will have hospitalists see more and more patients faster and faster, and discharge them sooner and sooner. The same requirements for seeing more and more patients faster and faster also apply to hospital-owned physicians who treat outpatients.

Efficiency is laudable so long as it does not harm patients or doctors. But the rapid turnover of patients, as pointed out by Dr. Gunderman above, can affect the well being of both patients and doctors. Much of physician depression and burnout which is estimated to be as high as 50% is related to the turnstile effect.[6] Treating physician depression and burnout without changing the system is doomed to fail.

The goal of DRGs and managed care in general was to introduce the efficiencies of competition and free markets into health care and thereby lower costs. Most Americans would agree with this laudable goal. But public frustration with high health bills has reached the boiling point.

In a recent article titled, "Pay More Get More? Not for U.S. Health Care," long-time *St. Louis Post Dispatch* Business Section columnist Jim Gallagher writes: "Competition keeps quality up and costs under control. That's free market economics. It doesn't work in health care."[7] In another article of his three-part series he writes, "We ignore proof that people in other developed nations get equal or better health results at half the price."[8]

This indictment of our current health care system comes from a business reporter who for his entire career has steadfastly supported competition and free markets as the best way for consumers to get both value and quality. And now he sees our health care system for what it actually is, not what so-called experts tell us it is. He points out what is obvious to every consumer-managed care has failed. The managed care emperor has no clothes.

Under pressure from DRGs and hospitals administrators, hospitalists may discharge patients too soon. Patients may then return to the hospital within 30 days of discharge. In order to cope with this problem CMS (the Centers for Medicare and Medicaid Services) then enacted another rule that financially penalizes hospitals if a patient is readmitted within 30 days. To get around this penalty hospitals may employ another strategy by admitting the patient to the observation service which does not count as a real admission.[9]

But then the patient is penalized. Medicare won't cover bills from a skilled nursing facility if a patient is admitted directly from the observation service of a hospital. For many elderly patients these bills can and do seriously deplete their finances[10] and even result in bankruptcy. This state of affairs is unconscionable. CMS has forgotten that the main purpose of Medicare as conceived by President Harry Truman and implemented by President Lyndon Johnson was to pay the health bills of Americans when they become old and sick not to pad the bottom line of hospitals.

So we see that DRGs are a complex web of affairs. The financial ramifications of DRGs extend well beyond a single hospital admission. When one takes into account all of the strategies hospitals use to increase revenues and avoid penalties DRGs may actually increase costs. Neither the experts who devised DRGs nor the hospital administrators address these problems in factoring in the total costs of DRGs. They like Wachter and Goldman as noted above just continue to sing the praise of DRGs, hospitalists, and managed care in general. On the other hand Gunderman states more realistically that we do not really know the total costs of DRGs.

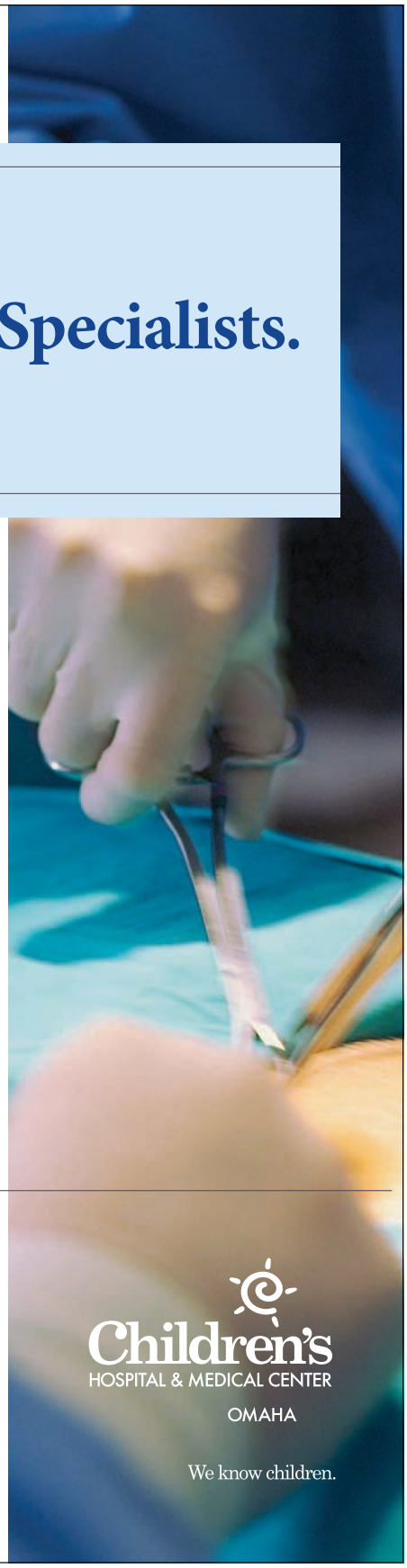
CMS could control spiraling hospital costs by means other than DRGs. For starters, it could stop reimbursement for unnecessary building projects, unnecessary advertising and marketing, and paying hospital-owned physicians almost twice what it pays independent physicians in private practice as recommended by the MedPAC, the Medicare patient Advisory Commission.[11] CMS should also clamp down on excessive administrative costs. Hospitals in the U.S. employ 25% more administrators than hospitals in other developed countries.[12] CMS should also demand transparency in hospital pricing which would help to control hospital monopolistic practices.

The article by Gallagher cited above shows that the debate on health care is moving to the public sphere. This means that it has moved to politics. Politics is messy and does not ensure ideal results. But in a democracy the public (consumers) should have the final say in determining the value of DRGs, hospitalists, and our entire managed care health system The public certainly could do no worse that the self-anointed experts who are responsible for our current dysfunctional, unsustainable health care system.

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Physician-Owned Surgical Hospitals Outperform Other Hospitals in Medicare Value-Based Purchasing Program

Source: Journal of the American College of Surgeons 2016;223:559-567. Adriana G. Ramirez, MD, Margaret C. Tracci, MD, JD, FACS, George J. Stukenborg, PhD, Florence E. Turrentine, PhD, RN, Benjamin D. Kozower, MD, MPH, FACS, R. Scott Jones, MD, FACS. Read full study at http://www.journalacs.org/article/S1072-7515(16)30720-7/abstract

Background

The Hospital Value-Based Purchasing Program measures value of care provided by participating Medicare hospitals and creates financial incentives for quality improvement and fosters increased transparency. Limited information is available comparing hospital performance across health care business models.

Study Design

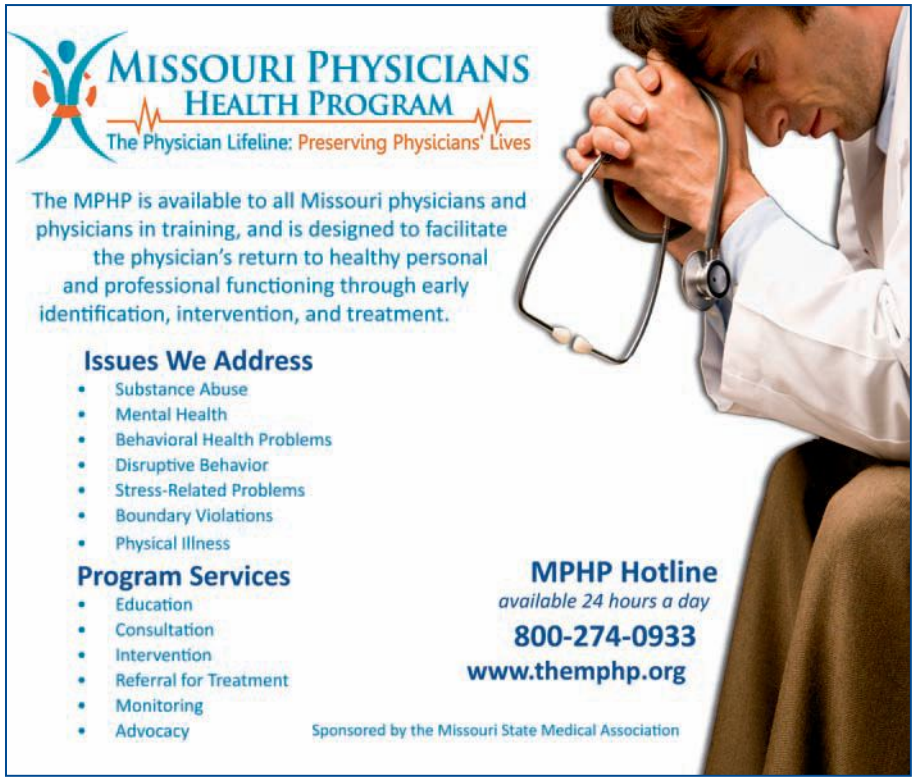
The 2015 Hospital Value-Based Purchasing Program results were used to examine hospital performance by business model. General linear modeling assessed differences in mean total performance score, hospital case mix index, and differences after adjustment for differences in hospital case mix index.

Results

Of 3,089 hospitals with total performance scores, categories of representative health care business models included 104 physician-owned surgical hospitals, 111 University Health System Consortium, 14 US News & World Report Honor Roll hospitals, 33 Kaiser Permanente, and 124 Pioneer accountable care organization affiliated hospitals. Estimated mean total performance scores for physician-owned surgical hospitals (64.4; 95% CI, 61.83–66.38) and Kaiser Permanente (60.79; 95% CI, 56.56–65.03) were significantly higher compared with all remaining hospitals, and University Health System Consortium members (36.8; 95% CI, 34.51–39.17) performed below the mean ($p < 0.0001$). Significant differences in mean hospital case mix index included physician-owned surgical hospitals (mean 2.32; $p < 0.0001$), US News & World Report honorees (mean 2.24; $p = 0.0140$), and University Health System Consortium members (mean 1.99; $p < 0.0001$), and Kaiser Permanente hospitals had lower case mix value (mean 1.54; $p < 0.0001$). Re-estimation of total performance scores did not change the original results after adjustment for differences in hospital case mix index.

Conclusions

The Hospital Value-Based Purchasing Program revealed superior hospital performance associated with business model. Closer inspection of high-value hospitals can guide value improvement and policy-making decisions for all Medicare Value-Based Purchasing Program Hospitals.



Inspector General: Medicare spends hundreds of millions on medically unnecessary chiropractic services

Source: Wall Street Journal, October 16, 2016

In October, the Department of Health and Human Services Office of Inspector General (OIG) issued a scathing audit report that found that "hundreds of millions in Medicare payments for chiropractic services did not comply with Medicare requirements." The audit examined Medicare Part B payments in 2013, specifically the $439 million that was paid for chiropractic services nationwide. The OIG found that an estimated $385.8 million, or approximately 82%, of those payments were medically unnecessary and thus should have been denied.

Medicare pays for chiropractic manipulation of the spine only if a documented subluxation is present and the treatment has a direct therapeutic relationship to the patient's immediate condition. Maintenance therapy – any treatment plan that seeks to maintain or prevent deterioration of a chronic condition – is not considered "medically reasonable or necessary," and therefore is not payable.

Chiropractors are required to add an AT (Acute Treatment) modifier to any claim for active or corrective treatment for subluxation. The OIG found that a very large percentage of the sampled chiropractor claims that were submitted with the AT modifier and paid by Medicare were in fact either maintenance treatments or services provided in the absence of a properly documented subluxation. Either way, those claims should have been denied.

Compounding the problem is that Medicare does not limit the number of chiropractic services a beneficiary can receive. Many commercial insurance plans impose annual limits, if they cover chiropractic at all. Medicare does allow its eight regional intermediaries to establish treatment thresholds that trigger a demand for documentation, but the OIG found that only two do so.

The OIG criticized CMS for lax Medicare controls and failing to adequately educate chiropractors on how to code properly. It recommended CMS set treatment limits for episodes of acute care, hard limits for any chiropractic services in a given year, a more effective set of system edits to differentiate between acute and maintenance treatments and raise red flags, and a better effort to educate chiropractors on how to code claims. It will be interesting to see how CMS acts to correct this colossal waste of tax dollars and precious health care resources.

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Practice in a health model of the future.

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How Obama's FDA Keeps Generic Drugs Off the Market

by Scott Gottlieb, MD

A flurry of new regulations is raising production costs and reducing competition for branded drugs.

One of the biggest factors fueling the angst over drug prices in the U.S. is that some older medicines that should be sold cheaply as generics are still priced very high, often owing to a dwindling number of generic competitors and the rising cost of producing these drugs. Bernie Sanders and Hillary Clinton like to blame generic-company mergers and greedy drugmakers. But a closer look reveals that a series of regulatory policy blunders is at fault.

The modern generic-drug industry emerged after the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman. The law created a cheaper and faster path for bringing generic copies of branded drugs to the market. By keeping regulatory barriers low, Hatch-Waxman enabled vigorous competition from multiple firms, each one vying to sell drugs for close to the cost of manufacturing.

Yet in recent years the Food and Drug Administration has imposed on generic firms many of the same costly requirements that the agency applies to branded-drug makers. For example, in a push to reduce the risk of contamination, the agency in 2009 forced generic-drug makers to retool their sterile manufacturing plants and make production lines less intricate. The abruptness of the change caused many facilities to be shut down, creating drug shortages and driving up prices.



Scott Gottlieb, MD, a practicing physician, has served in various capacities at the Food and Drug Administration, including senior adviser for medical technology; director of medical policy development; and, most recently, deputy commissioner for medical and scientific affairs. Dr. Gottlieb has also served as a senior policy adviser at the Centers for Medicare & Medicaid Services.
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The complexity and cost of completing a generic-drug application has also grown enormously. In 2003, when I began working at the FDA, we estimated that it cost less than $1 million for a firm to file a generic-drug application. A drug would have to fetch about $10 million in annual revenue before it would be subject to generic competition. Today, filing a generic application requires an average of about $5 million and can cost as much as $15 million. This means that a drug may not face brisk generic competition until it exceeds $25 million in annual revenue. Thanks to these changes, infrequently used generics—such as clomipramine for major depression—may now have only one competitor and cost as much as branded drugs.

When the price of a drug rises, it becomes profitable and the target of new competition. The FDA recently committed to review new generic-drug applications in a 15-month cycle, an improvement over a median of more than two years for applications submitted in 2013. For generics filed in 2009, the median review time exceeds three years. Yet generics launched in 2015 took about four years for the FDA to approve, since less than 2% of applications were approved on their first submission. The agency has committed to improve first-cycle approvals, but it still rejects most applications before demanding resubmissions, further stymieing competition.

The key to the generic-drug economic model is to keep entry prices low enough to attract multiple competitors. One FDA study estimated that consumers pay 94% of the branded drug's price for a generic if there is only one generic entrant. But the price falls to about 40% if there are four competitors, and 20% when there are eight.

Yet of the more than 1,300 branded drugs on the market, about 10% have seen patents expire but still face zero generic competition, according to the Department

of Health and Human Services. New regulations have, in many cases, made it no longer economically viable for more than one generic firm to enter the market.

The FDA should prioritize applications for generic categories where competitors are exiting. Companies that pursue copies of "abandoned" generics could receive a voucher that gives them expedited review of another generic drug. The value of this voucher would give firms more incentive to market copies of low-volume generics.

It gets worse. Generic-drug makers usually manufacture dozens of different drugs on each production line and hundreds of drugs in a single plant. The FDA is now trying to require production lines to be dedicated to one or two drugs, citing potential safety hazards. But generic-drug makers say this can triple manufacturing costs. While brand companies typically run only one or two products on each manufacturing line, generics run 30 to 50 products. The FDA's safety concerns could be addressed through better quality controls and improving its inspection capabilities.

Things may get worse before they get better. A new FDA draft regulation is artfully crafted to expose the generic-drug industry to the same kind of costly product liability suits that plague branded-drug makers. This political sop to the trial bar would force the generics to clutter their drug labels with defensive advisories to avoid "failure to warn" lawsuits. Legal fees stemming from the regulation would add over $5 billion to annual health-care costs, rising to $8.6 billion by 2024, according to the American Enterprise Institute's Alex Brill. The FDA should scrap this draft rule immediately.

ObamaCare's political architects blame its high costs on the rising price of prescription drugs. Yet the biggest drug-price increases come from a small number of very old medicines that would be cheap if not for careless policy-making. **MM**



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A Brave New Weed

by Allysia Finley

The costs so far from marijuana legalization are higher than advertised.



Marijuana is now legal in 25 states for medicinal purposes and in four for recreational use. Voters in another five have a chance on Nov. 8 to legalize the retail consumption of pot, but the evidence rolling in from these real-time experiments should give voters pause to consider the consequences.

In 2012 Colorado and Washington voters legalized recreational pot, followed by Alaska and Oregon two years later. Initiatives this year in California, Arizona, Nevada, Maine and Massachusetts would allow businesses to sell and market pot to adults age 21 and older.

Adults could possess up to one ounce (more in Maine) and grow six marijuana plants. Public consumption would remain prohibited, as would driving under the influence. Marijuana would be taxed at rates from 3.75% in Massachusetts to 15% in the western states, which would license and regulate retailers.

Marijuana is a Schedule I drug under the federal Controlled Substances Act of 1970, which prohibits states from regulating possession, use, distribution and sale of narcotics. However, the Justice Department in 2013 announced it wouldn't enforce the law in states that legalize pot. Justice also promised to monitor and document the outcomes, which it hasn't done. But someone should, because evidence from Colorado and Washington compiled by the nonprofit Smart Approaches to Marijuana suggests that legalization isn't achieving what supporters promised.

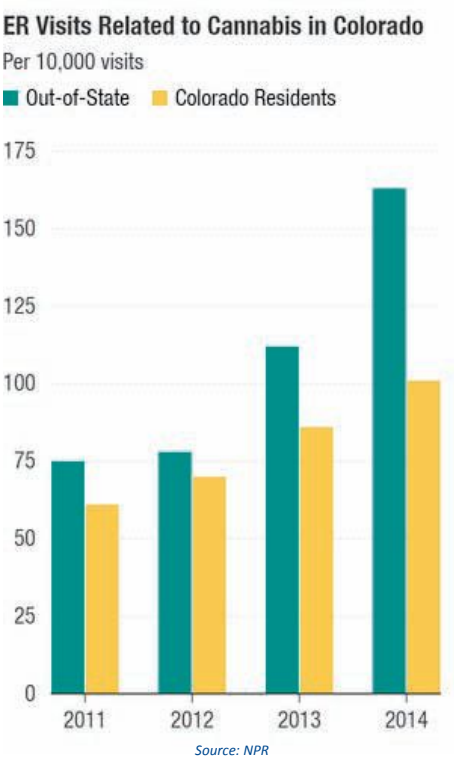
One problem is that legalization and celebrity glamorization have removed any social stigma from pot and it is now ubiquitous. Minors can get pot as easily a six pack. Since 2011 marijuana consumption among youth rose by 9.5% in Colorado and 3.2% in Washington even as it dropped 2.2% nationwide. The Denver Post reports that a "disproportionate share" of marijuana businesses are in low-income and minority communities. Many resemble candy stores with lollipops, gummy bears and brownies loaded with marijuana's active ingredient known as THC.

The science of how THC affects young minds is still evolving. However, studies have shown that pot use during adolescence can shave off several IQ points and increase the risk for schizophrenic breaks. One in six kids who try the drug will become addicted, a higher rate than for alcohol. Pot today is six times more potent than 30 years ago, so it's easier to get hooked and high.

Employers have also reported having a harder time finding workers who pass drug tests. Positive workplace



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drug tests for marijuana have increased 178% nationwide since 2012. The construction company GE Johnson says it is recruiting construction workers from other states because it can't find enough in Colorado to pass a drug test.

Honest legalizers admitted that these social costs might increase but said they'd be offset by fewer arrests and lower law enforcement costs. Yet arrests of black and Hispanic youth in Colorado for pot-related offenses have soared 58% and 29%, respectively, while falling 8% for whites.

The share of pot-related traffic deaths has roughly doubled in Washington and increased by a third in Colorado since legalization, and in the Centennial State pot is now involved in more than one of five traffic fatalities. Calls to poison control for overdoses have jumped 108% in Colorado and 68% in Washington since 2012.

Colorado Attorney General Cynthia Coffman has said that "criminals are still selling on the black market," in part because state taxes make legal marijuana pricier than on the street. Drug cartels have moved to grow marijuana in the states or have switched to trafficking in more profitable drugs like heroin.

One irony is that a Big Pot industry is developing even as tobacco smokers are increasingly ostracized. The Arcview Group projects that the pot market could triple over four years to $22 billion. Pot retailers aren't supposed to market specifically to kids, though they can still advertise on the radio or TV during, say, a college football game. Tobacco companies have been prohibited from advertising on TV since 1971.

The legalization movement is backed by the likes of George Soros and Napster co-founder Sean Parker, and this year they are vastly outspending opponents. No wonder U.S. support for legalizing marijuana has increased to 57% from 32% a decade ago, according to the Pew Research Center.

We realize it's déclassé to resist this cultural imperative, and maybe voters think the right to get high when you want is worth the social and health costs of millions of more stoners. Then again, since four states have volunteered to be guinea pigs, maybe other states should wait and see if these negative trends continue.

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Measuring and Mattering

by David W. Parke II, MD

"All initial results are positive." Legions of medical students have had this aphorism beaten into their brains as they (we) learned to evaluate the scientific literature. A *British Medical Journal* article in 1978 introduced the term "therapeutic illusion" to describe unwarranted enthusiasm for positive intervention by both physicians and patients—ignoring coincident causative factors.

Measurement of physician performance is a perfect example of these phenomena. Every practicing physician in the United States is measured. His or her resource use (aka "cost"), processes of care (did the patient get a glycosylated hemoglobin this year?), coordination of care (did you send a letter to the primary care physician?), and outcomes of care (return to the OR rate) are collected, sampled, and analyzed. They are increasingly linked to access to patients and to payment and are used as proxies for determining "value."

Bending of the health care cost curve, changes in patient satisfaction, and avoidance of surgical errors have all been attributed to 1 or more "quality measurement" metrics. How many times have you heard the maxim "If you can't measure it, you can't manage it"? It's attributed to W. Edwards Deming, PhD, a leader in the field of quality improvement. However, as Robert A. Berenson, MD, recently pointed out in the JAMA Forum,[1] Dr. Deming actually said, "It is wrong to suppose that if you can't measure it, you can't manage it—a costly myth." Further, according to Dr. Berenson, Dr. Deming cautioned that the most important data needed to manage often are unknown and unknowable.

Those of us who deal almost constantly with health care policy and regulations have long decried an even more perverse factor in some health care metrics: They are not just useless and time consuming, but they lead to harmful conclusions and actions. How can you compare the costs and outcomes for two equally capable physicians with different practices types without adjusting for case severity? The tertiary care expert who manages the most complex patients could have her or his access to patients and payments restricted as a result of faulty metrics and analytics.

This is not to say that metrics have no place. They are critically important, but great care must be taken to ensure that they are well constructed, appropriately adjusted, accurately tallied, standardized, and thoughtfully reported. Most important, they must be clinically meaningful! And, finally, the entire process should be designed primarily not to be punitive, controlling, burdensome, and even threatening. It should be designed and implemented to recognize the genuine desire of physicians to practice nothing but the best medicine and to assist in our lifelong struggle to maintain scientific currency and to improve quality.

In a recent *Health Affairs* article, Casalino et al. concluded that reporting quality measures cost the physician practices in only four specialties $15.4 billion—mostly in time devoted to the task.[2] Over 90% of that burden was attributed to entering information. This is not just a financial burden; a 2014 Merritt Hawkins survey found that 5% of physician time is spent dealing with external quality measures—or an annual "loss" of 40,000 full-time equivalent physicians at a time when many specialties acknowledge a manpower shortage.[3]

One of the goals of all physicians, their organizations, and our Academy's primary health policy and advocacy objectives will continue to be battling against poorly conceived, badly designed, and erroneously analyzed physician performance measures. At the same time, we will work to promote those few metrics that are clinically meaningful to patients and physicians, are not burdensome, can be accurately measured and risk adjusted, and will help each of us render better care in a value-sensitive system.



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The Joint Commission Deserves Some Blame for the Opioid Crisis

by Skeptical Scalpel, MD

Recently, the Joint Commission issued a statement[1] written by its executive VP for health care quality evaluation Dr. David W. Baker, explaining why it was not to blame for the opioid epidemic.

If you haven't already read it, you should. Here is the first paragraph of that document: "In the environment of today's prescription opioid epidemic, everyone is looking for someone to blame. Often, the Joint Commission's pain standards take that blame. We are encouraging our critics to look at our exact standards, along with the historical context of our standards, to fully understand what our accredited organizations are required to do with regard to pain." With the help of an anonymous colleague, I looked at some of the historical context.

In December 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies) combined to issue a 101-page monograph[2] entitled "Pain: Current understanding of assessment, management, and treatments." Here in quotations are some excerpts from it.

Page 4: In 1968, McCaffery defined pain as "whatever the experiencing person says it is, existing whenever s/he says it does. This definition emphasizes that pain is a subjective experience with no objective measures. It also stresses that the patient, not clinician, is the authority on the pain and that his or her self-report is the most reliable indicator of pain." This set the tone for clinicians: Patients are always to be trusted to report pain accurately.

Page 16: For example, "some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction."

Table 6: "Common misconceptions about pain: Use of opioids in patients with pain will cause them to become addicted."

Page 17: "In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low." We now know that everything in the paragraph above is untrue.

Page 38: "Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain and often allow the patient to sleep through the night."

Page 67: Table 38. "Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible." We now know that long-acting pain medications often do not last as long as they are supposed to, and the use of long-acting drugs may create more addicts. The recent Joint Commission statement says it never endorsed the concept of pain as a vital sign. While an explicit endorsement of pain as the 5th vital sign is not contained in the JC/NPC monograph, it is mentioned five times.

Page 21: In 1996, the American Pain Society introduced the phrase "pain as the fifth vital sign." This initiative emphasizes that pain assessment is as important as assessment of the standard four vital signs and that clinicians need to take action when patients report pain.

Page 29: "Reassessing pain with each evaluation of the vital signs (i.e., as a fifth vital sign) is useful in some clinical settings. Routine screening for pain with a pain rating scale provides a useful means of detecting unidentified or unrelieved pain." I read these as strong recommendations to assess pain levels frequently in conjunction with the standard vital signs.

Dr. Baker alleges another misconception about the Joint Commission is that it said pain must be assessed for all patients. He wrote, "The original pain standards stated, 'Pain is assessed in all patients.' This requirement was eliminated in 2009 from all programs except Behavioral Health Care Accreditation." Therefore, "pain is assessed in all patients" was a standard that existed for almost the entire first decade of this century, a time when opioid deaths were increasing with each passing year.

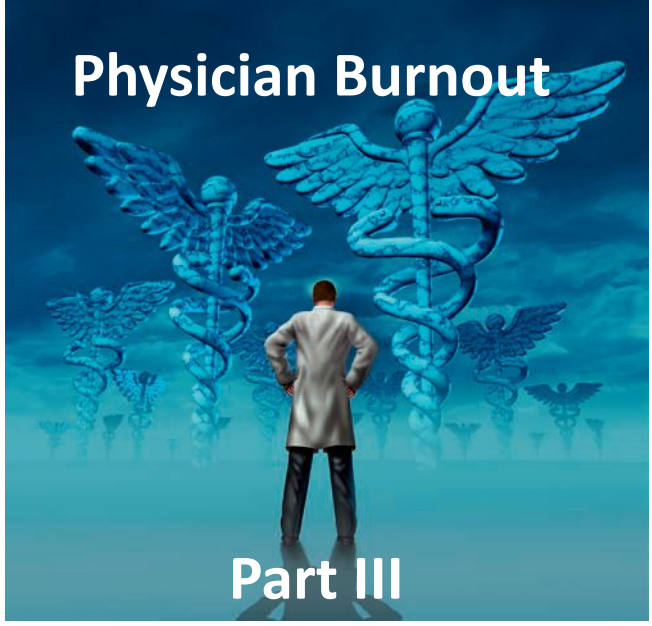
The Joint Commission deserves at least some of the blame for the opioid crisis.

Skeptical Scalpel is a retired surgeon and was a surgical department chairman and residency program director for many years. He is board-certified in general surgery and critical care and has re-certified in both several times. He blogs at SkepticalScalpel.blogspot.com and tweets as @SkepticScalpel.
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by Dike Drummond, MD

Prevent Physician Burnout: 4 Work-Life Balance Tools

A new study has found that, between 2011 and 2014, the burnout rate among family physicians increased from 45 to 54 percent. Yes, you read that right. Over half of us are experiencing burnout.

In previous articles in this series on physician burnout, we learned that burnout occurs when our mental, physical, or spiritual energy accounts have a low balance over time. To prevent burnout, we have two options:

1) Decrease our energy expenditures by reducing stress (see article two in this series),

2) Increase our energy deposits by finding ways to recharge and create more balance in our lives.

In this article, we will discuss the latter, specifically, four tools for creating work-life balance.

To implement the tools effectively, it is important to understand that work-life balance is not a "problem." Problems have solutions, but there is no simple, one-step solution to work-life balance. Instead, work-life balance is a dilemma. It is something you must attend to regularly using a multi-part strategy. If you are not paying attention to it at least twice a month, you will be out of balance very quickly. For many of us, this tendency to be out of balance began as early as our premed days.

The reason work and life seem in direct conflict so often is simple. The time and energy required for each comes out of the same pie. Each must take from the other because the pie is finite. Managing this give and take is an ongoing process, but the tools presented in this article can make it easier. We'll get to those in a minute, but first let's address a gorilla.

The 800-Pound Gorilla

Imagine that live with an 800-pound, silverback lowland gorilla in your house for a moment. This is a wild gorilla. He is not a circus animal and doesn't know a single trick. Imagine how much of your house this gorilla would leave you and your family. You would be relegated to just the outside edges of each room and he would make a mess wherever and whenever he wanted to.

Here is the metaphor. Your choice to be a physician that created this gorilla: the gorilla is your career, the house is your life.

Without strong boundaries and good balance habits, your career will tend to crowd out your life, leaving you just scraps and making messes at the most inopportune times. The career that was supposed to enable an extraordinary life now dominates the house leaving little room for anyone or anything else.

By the way, here are two very important questions to contemplate: Whose gorilla is this? Who else has to live with this gorilla?

Gorilla Taming

All is not lost. Gorillas can be house-trained, tamed, and shown healthy boundaries. It is your job to do this for your family. It will take a strategy to manage this balancing

act. Here are four tools that have been field tested and found effective. These are the first life balance techniques I teach all of my coaching clients.

Tool #1 - The Schedule Hack

One of the laws of your work-life balance strategy is "the strongest structure wins." By "structure" I mean the calendar you are probably carrying on you right now.

If I asked you to hand me your calendar, what would I find on it? It would have your work and call schedule for sure. What else is on your calendar right now?

- Your spouse or significant other's schedule?
- Your children's schedule?
- Your workout schedule?
- Your next date night?
- Your next vacation?
- Some blocked off free time for yourself to be with friends, take a walk, hike, bike ride, yoga or cooking class, yoga, nap, or read a book for pleasure (heavens, just imagine that for a moment will you)?

If you have all of those on the calendar you carry at work, congratulations. Take a moment to pat yourself on the back, because I have never seen it happen—and I have asked thousands of doctors what is on their calendar.

Understand this as an actual law of life balance. Anything not on the calendar you are carrying is not going to happen, period. One of the keys to taming the gorilla is to carry your Life Calendar with you at all times.

The Schedule Hack is a process to ensure you always have your Life Calendar in your pocket or purse—without having to purchase or learn any new technology. It only takes 20 minutes a week. This is the first step in showing that gorilla some healthy boundaries.

Schedule Hack Materials

1. The paper calendar you have hanging at home on the side of the fridge. If you don't have one, they are very inexpensive and just the tool for the job.
2. Some colored pens.
3. Your cell phone.

Schedule Hack Procedure

Step One: Build Your Life Calendar for the Week Ahead

Pick a time in the week where everyone in your family or household is available. A popular time is on Sunday after church and before football. Pull that paper calendar off the fridge, grab the pens, and put them all on the kitchen table. Gather everyone in the household and build your Life Calendar for the week ahead.

What do you want in your life outside of medicine in the upcoming week? Remember, if you don't put it on your Life Calendar right here and now, it will almost certainly not happen.

- Workouts, massage, mani/pedi
- Free time
- Coffee with a friend or relative
- Time to read a book
- A class or hike
- A date night

Whatever you want, you must put it down on the calendar. Do it now.

The last thing you put on the calendar is the date and time of your next Schedule Hack session. Everyone needs to be clear on when you will meet again. If I meet you in the street and ask you to show me your Life Calendar, it must have your next Schedule Hack session on it—agreed?

Step Two: Take a Picture of Your Life Calendar with Your Cell Phone

Yes, it really can be that easy. Your Life Calendar can now be in your pocket at all times right there on your cell phone, probably just a push of a button away from your work calendar.

Step Three: Defend Your Life Calendar

Now you are prepared to say the two-letter magic word of work-life balance. That word is "No." You will benefit from practicing saying "No" in front of a mirror until you are comfortable with a phrase or two that work for you.

With your Life Calendar in hand, if someone at work asks you to cover a few extra hours on Thursday, you can pop your cell phone open and say, "Hang on a second, and let me check my calendar." If you are already booked, you say, "I'm sorry, I have another commitment at that time. I won't be able to help out."

As you read the conversation above, does it make you a little uncomfortable? Most doctors stop breathing when I demonstrate this bit of dialogue. We are horrible at saying no. Our discomfort has several sources.

- We are completely out of practice at saying no. That is okay. Saying no is a skill you can practice. Remember, "practice makes better."
- You don't want to be perceived as not being a team player. This is a variation on the prime directive of never show weakness.

And let's face it—you won't always say no, even if you have a conflict on your Life Calendar. Here are several common situations where you will most likely say "Yes" instead:

• You owe this person. They covered for you at an earlier date and you want to settle the debt.

• You want this person to owe you down the road, so you can call on that debt in the future.

• You are not confident enough in your ability to say no yet to give it a shot. Time for more practice.

Power Tip

Role-play with your spouse or significant other. Have them be one of your partners—perhaps the one most likely to ask you to cover for them. You be yourself saying, "No." Rehearse until your spouse or significant other gives you at least a B+ for your performance.

Here is what will drive your discipline. When you carry your Life Calendar, see a conflict, and say yes anyway, you will know immediately which member of your family you need to contact, apologize to, and reschedule with because you just threw your plans under the bus.

The Schedule Hack works every time you use it. You will have a more balanced week when you hack your schedule than if you don't. This simple process also allows you to live your life in alignment with your complete circle of priorities. This is a key source of happiness and fulfillment.

Action Steps

• Who are the people on your Life Calendar?

• When is a good time for you all to do the Schedule Hack together?

• If you need to buy a paper calendar or pens, when will you do that?

• When will you do your first Schedule Hack? How can you make it fun?

• What things will you put on the calendar just for you?

• When will you practice saying no? (I dare you to practice with your spouse or significant other and find a way to make it fun!)

• Journal on your experience.

Tool #2 - Intentional Date Nights

If you think being intentional about date nights isn't a serious issue or has no relation to physician burnout, think again. A healthy relationship can recharge and strengthen you, while an unhealthy relationship can quickly deplete you, and even cause health problems.[1]

My coaching clients have found the optimum frequency for a quality date night is twice a month, minimum. If it has been more than two months since your last date night, you are way overdue. Date nights are not the only way to strengthen your relationship, but they are critically important, so do not skip them.

If you do not have a significant other, date night could be a date with someone you'd like to know better, time with a friend, or doing something nice or unexpected all by yourself. (Yes, you can take yourself out on date night, too.)

When you are really busy, figuring out what to do on your date night can seem like just another item on your task list. I encourage you to do an attitude check here. What is more important to you – the 800-pound gorilla or some love, romance, adventure, and fun? Date night is a chance to break out of survival mode and do something extraordinary.

A Few Ideas

• Take turns planning your date nights but keep your plans a secret. The one who is planning the date only reveals when to be ready and what to wear.

• Each of you put three date night ideas on slips of paper and drop them into a hat. Pick one, raffle style, and go for it.

• Make it a game and set rules. Here is a fun one: your date night can't involve calories or money.

Mandatory First Date Night Action

On any date night, even before you order drinks or appetizers, your first action is to schedule the next date night. This way you will always have a date night on your calendar. If I meet you on the street and ask you to show me your Life Calendar, it must have your next date night on it, agreed?

Power Tips

The Six Pack: Instead of putting just the next date night on your calendar, go for a six pack. That's right, schedule out six date nights – three months' worth. Put this article down, walk over to the calendar on the fridge and mark them out right now. Then your first date night action is to schedule the next one so you always have six on your calendar.

Buy them in Bunches: Use season tickets to book date nights in bunches. If you have a shared interest and there is a season ticket option, buy them. This will take care of multiple date nights in a single purchase.

Tool #3 - Bucket List Secrets

Bucket List (noun): The list of things you want to do before you "kick the bucket."

My clients and I find it very useful to build two bucket lists and use them as additional work-life balance tools.

1. Your BIG Bucket List

These are the classic things I must do before I die. The challenge with creating a meaningful BIG Bucket List is that most people put way too many things on it. This sets you up to use the BIG Bucket List to beat yourself up. If you put too many items on there, you will notice you are never crossing any of them off and feel guilty.

Here is a reality check that will dramatically shorten your BIG Bucket List.

- Make your BIG Bucket List. Write it down. I encourage you to keep it in the folder with your Ideal Practice Description and Master Plan
- Give someone else the list and have them read your list back to you one at a time
- Take a moment to imagine failure on this item. Imagine you die before you accomplish this one. How does that feel?
- Which ones break your heart to contemplate them left undone?

Those are your authentic BIG Bucket List items, and if you are like most people, your list just got much shorter.

BIG Bucket List Check Off

Now, it is time to get one of these BIG bucket list items on your Life Calendar. Normally, these are pretty big-ticket items that take a significant amount of time, energy and money to accomplish. That is why they lay dormant for so long. Here are two keys to nailing your next BIG Bucket List item.

Schedule it anyway

Pick your first BIG Bucket List item. Look out on your calendar as far as you need to in order to fine a time that will actually work. I could be one, two, three years out or more. Schedule it anyway. Print out a calendar for that year or month, use a brightly colored pen and mark off the dates. Hang it in a highly visible spot at home. Go into work and block it off your schedule on the work computer as well. Put a stake in the ground now.

Put skin in the game

The next step is to buy the tickets. Put money down immediately. If there is one thing that will get a doctor to actually take a trip, it is having money down. If you can't buy the tickets yet, open a savings account and start putting money away.

Block off the time and buy the tickets now. Whether it is Machu Picchu, Africa, the running of the bulls in Pamplona, visiting the country of your family's origin, a Spanish immersion school in Costa Rica, rafting the Grand Canyon …get it scheduled and paid for, and it is highly likely to actually take place. Afterward, it will take its rightful place in your memories as a peak experience, rather than a heartbreaking regret.

2. Your Weekly Bucket List

Is there an activity or experience that turns your whole week around every time you do it? The thing that makes you say, "Man, I wish I could do that every week. It would make a huge difference for me." Most people know what this "weekly bucket list" item is and yet only manage to squeeze it in every once in a while. Common examples are a workout, massage, date night, hot yoga, alone time with your children, coffee with an old friend, walk the dog, nap, meditation, mani/pedi. What are two to three of your weekly bucket list items?

The Schedule Hack is where you make sure these happen. Hacking these Weekly Bucket List items onto your Life Calendar is part of carving out time and space for your life in your busy week. Defend these items just as vigorously as you do your work schedule to show that gorilla some healthy boundaries.

Guilt Can Come Up Here

Some people have problems with guilt as they contemplate this concept of doing something just for themselves. A little voice saying, "What makes you think you are so special?" can pop up when you are blocking off time for your own personal use. This is your programming, pure and simple. You can tell that voice, "thank you for sharing," and do it anyhow. It is only when you are able to experience the pleasant things in your life that you can understand the difference that can make for you, your patients, your team, and your family.

Tool #4: The Boundary Ritual

One of the keys to being able to recharge when you are not at work is creating a clean, solid, functioning boundary between work and home. This is how you take the white coat off, leave work at work, and come all the way home.

Here is how you know you have missed this boundary; when you are sitting at home and thinking about work. You can't recharge in this situation. Instead of recovery you are still being drained by work stress even

though you are not in the office or hospital.

Creating a Boundary Ritual is a mindfulness skill you can learn and practice. It is the energetic equivalent of an off switch on your role as a doctor. Your Boundary Ritual marks the transition from the environment where the patient comes first to one where you come first.

Fortunately, we have an excellent role model of a Boundary Ritual, i.e., Mr. Rogers. Yes, that Mr. Rogers from Mister Rogers' Neighborhood, the children's television show on PBS.

You really don't know who Mr. Rogers is before he walks through that door. It only takes a couple of shows to realize he is not the real Mr. Rogers until he has completed his personal three-part Boundary Ritual. Remember those three steps?

1. Put on his zip-up sweater
2. Change his shoes
3. Sing his song, "It's a beautiful day in the neighborhood, a beautiful day for a neighbor - would you be mine . . ." With his Boundary Ritual complete, he is the Mr. Rogers we know and love for the rest of the show.

I have heard of physicians who naturally understand the importance of a Boundary Ritual. One friend's father - a small town family doc - would shower and change clothes after coming home every day. He wouldn't talk to his family until this Boundary Ritual was complete. After the shower he was just "dad" again.

I strongly encourage you to develop your own Boundary Ritual. The most effective rituals involve three things: an intention, a releasing breath, and an action.

Here is a Boundary Ritual example if you drive home from work. I encourage you to imagine you are actually driving your car and taking these steps as you read them below.

Park the car. Put your hand on the keys or off button. Say to yourself, "With this breath, I am coming all the way home." Take a deep breath. As you exhale, release all thoughts and feelings about work with your out breath, turn the car off, take the keys and step out of the vehicle.

This is another tool that works every time you use it. You will be more relaxed and thinking less about work if you perform your boundary ritual than if you had not. And, as usual, practice makes better.

Power Tip

Any action can be an effective Boundary Ritual as long as your intention is to take off the white coat and come all the way home.

- Take a shower
- Walk the dog
- Take out your contacts and put on your glasses
- Mr. Roger's three-part ritual
- Make a nice dinner

What is your Boundary Ritual and when will you start practicing?

Pick an Idea and Take Action

As discussed in previous articles, it is easy to read an article like this one, with multiple suggestions, and get overwhelmed. The key is to take just one step at a time. Pick just one action from the options above and put it into action. That is all. The first step might be to call your family together and create a life calendar for next week.

Once you have taken the first step, the second one will become clearer. You will know exactly what to do next. It might involve taking an afternoon off and thinking about your bucket lists. Whatever it is, just take the next step, and the next, and the next … to put one of these tools into action in your life. With just these simple actions, you'll be on your way to a healthier, more balanced life. Constructing a strategy to build and maintain life balance is one of the keys to preventing physician burnout.

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BEWARE

Tax Identity Theft Scam Targets Physicians Again

MSMA has learned that a large-scale federal tax scam that hit physicians in the last two years will rear its ugly head again. Physicians in Missouri and other states have again been made victims of an identity theft scam involving federal income tax returns.

In most instances, tax returns have been filed fraudulently by crooks – using physician names, addresses, and Social Security – in an attempt to recover tax refunds. Victims don't realize they've been scammed until they attempt to file their own tax return, only to be told by the IRS that a return has already been filed.

MSMA is working with the U.S. Secret Service on this matter. If you have any reason to believe you are a victim of this scam, take the following action as soon as possible!



Take these steps as soon as possible:

1. Call the IRS at (800) 908-4490, and report your suspected identity theft.
2. Call the Social Security Administration at (800) 772-1213, and let them know.
3. Place a fraud alert on your credit file by contacting one of the three credit reporting companies. The company you contact is required to contact the other two, which will then place a full alert on your credit report. The three companies are:
   - Equifax - (800) 525-6285 – http://www.equifax.com/home/en_us
   - Trans Union - (800) 680-7289 – http://www.transunion.com/
   - Experian - (888) 397-3742 – http://www.experian.com/
4. Fill out and submit the IRS Form14039, which can be found at this site: http://www.irs.gov/pub/irs-pdf/f14039.pdf
5. Please e-mail MSMA Executive Vice President Tom Holloway at tholloway@msma.org and provide your full name, home address, and telephone number. MSMA is working with the U.S. Secret Service and has been asked to provide the names of suspected victims.

Consider visiting these websites for more information and tools to help you:

- Federal Trade Commission
  http://www.consumer.ftc.gov/articles/0008-tax-related-identity-theft

- Internal Revenue Service
  http://www.irs.gov/Individuals/Identity-Protection

- Social Security Administration
  http://www.socialsecurity.gov/pubs/EN-05-10064.pdf

Medical Patents and How New Instruments or Medications Might Be Patented

by Denise L. Mayfield, JD

Introduction

A patent is a legal instrument that conveys to the patentee (the patent holder) the right to exclude others from making, using, selling, or offering to sell the subject matter of the patent "claims." Medical patents, for purposes of the present article, will be defined broadly to include patents that relate to pharmaceuticals; methods of making and using them; medical treatment regimens; surgical procedures; medical devices; health care information technology for hospital and health care management systems (including software for managing hospital bed utilization, care distribution, medical staff allocation, and cost containment), and combinations of these (e.g., an "app" that includes the use of a "medical device" like an attachment that interacts with an iPhone for preforming a medically related function/measurement, such as blood pressure measurement, insulin level monitoring, etc.).

A patent provides the patentee a unique marketing advantage for his/her invention, as others may be prevented from utilizing any aspect of the patented subject matter unless a license, or other "right to use" is conveyed. Thus, a patentee may effectively preclude potential competitors from making, using or selling the patented item or process, while providing the patentee a mechanism (e.g., licensing) for capturing the value of the invention and incurred development costs.

In the United States, the main categories of patents are utility patents (machines, processes/methods and manufactured objects), design patents (ornamentation), and plant patents (under the Plant Variety Protection (PVP) Act, not to be confused with a plant utility patent). The present article will focus on medical "utility" patents.

Biotech companies, universities and physicians use patents to protect their patented inventions against competition for a finite number of years.[1] Sophisticated patent and/or technology licensing strategies and other arrangements (e.g., collaborative research agreements), with one or more other parties, are vehicles that the patentee may use to generate revenue. Financial rewards are available to patentees who create new products in the form of higher product sale prices. However, critics of this system argue that the extraordinarily high prices of new drugs/new medical products protected by a patent seriously limit access of the best forms of health care to poorer populations, and are therefore unethical.

The Food and Drug Administration (FDA), upon approval of a New Drug Application (NDA), provides medical product applicants perhaps the most important element needed to bring the product to the public. The FDA is responsible for assuring that a new drug or new product is safe and effective.[2] The FDA approval process requires compliance with rigorous testing programs (clinical trials) and compliance with a lengthy administrative approval process, and is most times very costly. The FDA approval process oftentimes runs concurrently with the patent application procurement process before the United States Patent and Trademark Office (USPTO). Because of the occasionally lengthy time frame involved in obtaining FDA approval, the period during which a patented drug or device may be commercialized under the effective patent term may be shortened. To correct for this delay, the patent term restoration provision was created under the Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act, under 35 U.S.C. § 156. This provision grants patent term extensions for patents



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on human drug products, medical devices, food and color additives, and processes for making or using such products.[3] This provision serves to restore a part of the patent term to the patentee for the period over which the patentee was unable to sell or market a product while awaiting FDA approval.[4] The Hatch-Waxman Act also provides a "safe harbor" provision for patentees under 35 U.S.C. § 271(e)(1), and serves to shield a party from a charge of patent infringement for making, using, offering to sell or selling another's patented product/process where these activities are conducted for the purpose of developing and submitting information related to obtaining FDA approval for a product.[5]

Many types of biotechnology patents (e.g. regenerative medicine, human manipulation, embryonic stem cells) are extremely controversial. The cost of developing products related to these kinds of medical patents is often extremely high, and years are typically required before the product is ready to be sold to the public. However, because of the profound impact this class of inventions has on diseases historically considered untreatable and/or fatal, and the immense improvement many of these products make to our quality of life, the choice of pursuing these kinds of medical patents continues to be made by companies and individuals involved in the health care industry around the world.

Obtaining a Patent

The first step towards obtaining a patent is to file a patent application with the USPTO. With the implementation of the America Invents Act (AIA), the first inventor to file a patent application has priority over another person who gets a patent application filed after that initial date, but who nonetheless may assert he/she was the first to "invent" the technology covered in the patent application.[6] With this change in the law (prior to AIA, the race to get a patent application on file was not paramount to establishing right of priority), it is important for the potential patentee to expedite the filing of his/her patent application on the earliest date possible.

1. Requirements of "patentability"—"Patentable subject matter," "novelty," "non-obviousness," and "enablement."

In drafting the patent application, one of the first questions to ask, especially in the field of medical patents, is does the invention qualify as "patentable subject matter", as that term is defined (and interpreted) under the patent statute.[7] If the answer is yes, then the potential patentee must determine if the invention is "novel" (e.g., it was never disclosed to another before the patentee was able to get a patent application filed).[8] A patent search should be done by a registered patent professional to determine of the invention is "novel."

The subject matter of the invention must also be "non-obvious."[9] The interpretation of what is "non-obvious" follows a strict legal definition that differs from what might be considered "non-obvious" from only a scientific point of view.

The subject matter described in the patent application must also be "fully enabled" and meet the "written description" requirement for the invention that is described and claimed in the patent.[10] Section 112 of the patent statute requires that a patent application include a detailed description of the invention, including the process of making and using it, such that this description is written in a manner that a layperson would be able to understand and practice the invention.

Once the patent application is filed and the formal examination process (called "patent prosecution") begins, these statutory legal requirements for a patent will be assessed by a patent examiner.

2. The Provisional Patent Application (PPA) and the Non-Provisional Patent Application (NPA)

An initial patent application filing may take the form of a provisional patent application (PAA) or a non-provisional patent (NPA) application. Both the PPA and the NPA will provide the applicant with a "filing date." However, the PPA will not be examined (i.e., will not begin the "patent prosecution" process). A PPA will expire at the end of one (1) year, but the "priority" of the filing date obtained for the PPA may be preserved by filing a NPA if the NPA is filed before the expiration date of the PPA. The less expensive PPA alternative to filing a NPA is used by many entrepreneurs and/or academic institutions, giving them time to gauge commercial interest in the invention, among other things.[11]

The PPA filing includes a USPTO form, termed a "cover sheet" (identifying information, the names of all inventors), a written description of the invention and drawings (as described above), and is submitted along with a relatively modest filing fee. The filing of a PPA alone will not result in the issuance of a patent.

The NPA must include a written description of the invention and drawings (as described above), and

must include at least one "claim." A patent "claim" is a highly stylized sentence that defines the subject matter the inventor regards as the invention (the "novel" and "non-obvious" elements). The features/advantages of the invention as defined in the "claim" should be readily discernable in the detailed description (i.e., the "specification") of the patent application. The NPA filing also requires an oath or declaration of the inventors to be filed, the payment of additional fees ("search" and "examination" fees), drawings (if needed for an understanding/full disclosure of the invention), and in some cases, a "sequence listing" (in the case where the invention relates to or includes a novel nucleic acid or novel amino acid sequence, or includes either of these; e.g., a genetic molecular construct used to make a new pharmaceutical).

3. The NPA USPTO Patent Prosecution Process

Once the NPA is filed, an examination, or "prosecution" process before the USPTO will begin. This process can take anywhere from one to six, or more years, and is a series of "office actions" from the USPTO examiner, and responses and amendments from the patent practitioner, ultimately identifying a patentable set of "claims." A potential patentee is not guaranteed that a patent will ever be granted to the invention sought to be protected, and on occasion, a potential patentee will decide to abandon the process because of time and financial constraints.

In the event patentable claims are identified through the patent prosecution process, a Notice of Allowance will issue from the USPTO, identifying the subject claims that are to be allowed, and identifying a date on which an "Issue Fee" must be paid. Soon after the Issue Fee is paid, the patent will officially "publish" on a specific date. The patent becomes enforceable for a term that begins on the date the patent is issued, and ends on the date that is 20 years from the earliest priority date (filing date). The beginning date for measuring this 20-year span does not begin on the filing date of the PPA, but instead begins on the filing date of the earliest filed NPA to which priority is claimed.

Preparing and "prosecuting" a proper patent application may be accomplished by working with a registered patent professional (patent attorney or patent agent). A patent professional is one who has a Registration Number issued by the USPTO, which evidences that he/she has taken and passed a USPTO Examination. This examination tests the person's knowledge of the patent laws and procedures, and establishes the person possesses at least the core knowledge of the patent laws. Attorneys who are not registered patent attorneys cannot represent a client before the USPTO. A patentee can check to see if the person the patentee is working with is a registered patent attorney or agent on the USPTO website, at no cost.

To make the process as efficient as possible, a patentee may prepare and provide to the patent professional some written form describing the invention, such as an "Invention Disclosure" document. In this way, both the inventor and the patent professional may develop a patent application more quickly, and the application may be filed more quickly to obtain the earliest filing date possible. The patent application preparation process is most effective when the patent professional has a technical background or experience with subject matter similar to the subject matter of the invention. Here, due diligence in the selection process of the patent professional should be done to assure he/she has the appropriate technical background needed to understand and draft the potential patentees patent application.

On June 29, 2016, the USPTO announced a new "fast-track" review process for patent applications related to cancer treatments, in support of President Obama's "cancer moonshot" program to combat cancer.[12] More than 1.6 million Americans are estimated to be diagnosed with some form of cancer in 2016, and the "fast-tracking" of medical patents related to cancer is anticipated to spur faster commercial development of new cancer drugs/therapies.

Types of Medical Patents

While not intended as an exhaustive list, the main categories of "medical patents" described here are medical devices, chemical/pharmaceuticals, health care information technology, surgical methods, and regenerative medicine technologies.

1. Medical Devices

This category of medical patents includes physical devices used by physicians, hospitals, and an other providers, and includes such items as diagnostic instruments, stents, implantable devices (prostheses), surgical tools, surgical suite equipment (sterilization hoods, patient lifts, patient or monitoring devices), drug and food delivery devices and systems (IV bags, tubing,

patient feeding apparatus, assisted breathing equipment, etc.), heart/breathing monitoring equipment, artificial heart valves, heart pacemakers, and many others.

Patented products in this category generally have smaller profit margins (compared to new pharmaceutical drug products, discussed below), but tend to be "commercializable" much sooner that other types of products under the "medical patent" umbrella.[13]

2. Chemical Products and Pharmaceutical Drugs

Inventions under this category include chemical compounds (vitamins, compounds used to manufacture drugs, tissue sterilization and cleaning materials) and the more complicated group of products categorized here as pharmaceuticals. Pharmaceuticals include materials that will be used to treat infectious disease (e.g., antimicrobials, vaccines, antibiotics), or a physical condition (such as conditions related to aging, chemical/hormonal imbalance, e.g., insulin/diabetes, high blood pressure, dementia, Alzheimer's, Parkinson's disease).

Patents that relate to pharmaceutical drugs and methods of using pharmaceutical drugs form an important part in the economic success of a pharmaceutical company, and of the pharmaceutical industry as a whole. Among other things, medical patents in these and related categories permit businesses to recoup the huge costs associated with research/development, clinical trials, patent associated expenses and regulatory approval process costs, by providing a finite period during which the patent protected products may be commercialized free of competition from other products in the same space as the patentee's patented product.

3. Health care Information Technology

Patents that focus on streamlining the flow of medical history information through electronic medical records, patient data picture archiving, health information exchange systems within or among hospital systems and/or physicians, web-based medical software applications, computerized physician order entry and digital imaging, are some examples of healthcare information technology related patents. This category of medical patents has been the fastest growing category of medical patents in recent years, and the number of medical patents in this area is expected to continue to grow.

The exponential growth of medical patents in this category stems partially out of a need to find new methods and systems designed to contain and manage medical costs more efficiently.[14] Medical patents in this category function to reduce the administrative costs of providing health care, while at the same time increasing the ease of access to medical services for greater numbers of patients.

4. Medical and Surgical Methods

This category includes, for example, methods and techniques for providing and performing medical and surgical procedures, as well as streamlined procedures for administering care or diagnosing a medical condition, whether or not the condition is medically categorized as a disease.[15] Surgical methods for repairing a rotator cuff, as well as methods for performing spine surgery to avoid contact with nerves, are some specific examples that fall within this category of medical patents.

While the United States allows the patenting of medical procedures and treatment methods, more than 80 countries exclude medical procedures from patentability.[16] In these situations, a "second medical use" patent claim format may be used as an alternative for obtaining roughly equivalent patent protection in these countries.

5. Regenerative Medicine

This category includes stem cell therapeutics, as well as tissue transplant technologies, including knee cartilage replacement rejuvenation and cosmetic reconstructive procedures. Stem cell therapeutics is considered to be the next best and biggest medical frontier in human health care. As with any new medical treatment modality, these technologies are not only confronted with existing regulatory and legal requirements, but in many cases face additional, newly implemented requirements (by the FDA and USPTO, for example). Unfortunately, this results in even greater expense and time delays in bringing these innovative technologies to the public.

Stem cell therapeutics have been described for the treatment of arthritis, loss of hearing, cancer, and other serious conditions for which existing medical science has poor treatment alternatives. In the United States, the world of accessible stem cell therapeutics continues to lag behind other countries for a number of reasons, one of which is the added burden of the path to market. The Center for Biologics Evaluation and Research (CBER), a specialized department within the FDA that regulates biological products including stem cell products, has approved some limited stem cell related products, and the number of these approved products is expected to grow as

historical clinical data is made available. Growing societal acceptance (among both doctors and patients) of these types of alternative therapeutic modalities has resulted in a wider acceptance of these alternative treatment modalities, with the delay to access of these modalities in the United States driving many to seek treatment elsewhere.[17]

Recent Trends in Medical Patents

Between 2009 and 2014, there was a 170% increase worldwide in medical device patents granted in the United States.[18] The dramatic change in the number of patents granted started in 2010, which corresponds to a jump in the number of patent applications filed in 2007. This was in part influenced by the Affordable Care Act signed into law in 2010, and the medical device tax that became effective January 2013. Most patents granted during this period were of domestic (US) origin; 68% coming from within the U.S. in 2014. California obtained the most medical device patents, followed by Minnesota, then Massachusetts.

A number of notable medical patent developments have recently made headlines. Some of these medical patents include:

- The superbug test: Australian patent received by Translational Genomics Research Institute (TGen) and Northern Arizona University (NAU).[19]
- Reprogramming human skin cells: Converts human skin cells into engines of tissue regeneration (patent number 9,290,740).[20]
- BioStack 4 Microplate Stacker: Unique technology associated with automatic microplate de-lidding and re-lidding (patent number 9,366,686).[21]

A controversial Congressional bill recently introduced would shorten the exclusivity period for expensive biologic medications from 12 to 7 years.[22] Rep. Janice Shakowsky (D-IL) introduced the bill on June 23, 2016 in an effort to allow manufacturers of drugs to market lower-cost versions of drugs more quickly to help reduce healthcare expenses. Biologic medications cost tens of thousands of dollars and are used to treat various forms of illnesses such as multiple sclerosis and cancer. Biosimilar versions of the drugs are predicted to cost between 10 to 30 percent less. Rep. Shakowsky cited data from the U.S. Department of Health and Human Services showing that reducing the exclusivity period for biologic medications would save taxpayers nearly $7 billion over the next ten-year period.

The 12-year exclusivity period was initially introduced as part of the Affordable Care Act, and the White House has routinely proposed shortening the period to 7 years to save federal health care dollars.

Physicians and Medical Innovation—Patented Surgical Methods and Other Types

Physicians continue to create new medical innovations that find their way into granted medical patents. In addition, the actions of physicians and surgeons have become implicated in establishing liability for patent infringement when disputes arise between companies involved in obtaining and commercializing surgical methods in a medical patent. Legal protections exist that shield physicians/surgeons from patent infringement liability and other types liability in some circumstances. For example, in Warsaw Orthopedic, Inc. v. NuVasive, Inc.(decided on June 2, 2016), a U.S. Court of Appeals explored whether NuVasive could be charged with infringement of Warsaw Orthopedics' patent as a consequence of teaching physicians/surgeons how to perform the procedure protected in Warsaw's existing patent.[23] In this case, evidence that the surgeons were instructed by NuVasive on how to perform Warsaw's patented surgical procedure was used to support a charge of patent infringement against NuVasive.

Medical practitioners are shielded from patent infringement liability for performing a medical/surgical procedure that infringes a patented medical procedure on a body under 35 U.S.C.A. § 287(c).[24] However, medical practitioners are not shielded from liability when performing a medical activity using a patented machine or medical device, including a pharmaceutical device. Device manufacturers could be found guilty on an inducement to infringe under 35 U.S.C. § 271(b) if they direct or influence doctors to infringe on another company's existing patent.[25] Device manufacturers who provide physicians with tools/devices and instructions for using those tools/devices in a method that infringes another's patent could be liable for inducing the infringing activities of those physicians. Thus, providing instructions on how to perform a patent-protected method may be considered infringement-inducing conduct.[26] On a related note, caution should be taken

when physicians become shareholders of pharmaceutical companies and/or medical device manufacturers, so as to preserve the individual physician's immunity to patent infringement under the statute, among other potential protections to liability.[27]

A Case Study on Insulin: From Patent-Protected Product to Non-Patent-Protected Product.

Significant medical patents expired in 2015. The top 10 patent expirations risked $44 billion in sales for holders of those patents, from the possibility of generics being released into the market and being consumed by the public instead of the patented drugs and devices.[28] However, generics are expected to take a much smaller bite from the drugs losing exclusive access to their respective markets because several involve biotech drugs. Even if biosimilar drugs make it to market, their impact on sales will be limited because they may not be automatically substitutable for the brands they are seeking to replace.

Insulin was one of the more significant products that lost patent protection in 2015. Companies are racing to produce new forms (analogs) and formulations of non-native insulin to obtain new patents, and in this way, secure a new "exclusivity" market for the new insulin-like products.[29] Due to the expiration of the patent, off-patent (generic) insulin will become much more affordable as the insulin product may be made freely by competitors at lower prices. From a public healthcare policy perspective, greater availability of insulin products will improve health care for a large population of diabetic persons previously unable to afford the cost of this medication. Pharmaceutical companies will now need to commit greater resources to research and development of new drug products, and to patent these new products, in order to maintain the level of profitability they had become accustomed to.[30]

Innovation vs. Culture and Societal Norms

The use of regenerative medicine/stem cell technologies in patents is an international source of heated controversy, and there is a stark division among countries on what is and is not protectable by patents related to this subject matter.

In the United States, three stem cell patents are held by the Wisconsin Alumni Research Foundation on primate and human embryonic stem cells (hESCs).[31] Two patents dominate most of the anticipated commercial uses of hESCs in the U.S. While many scientists work with human embryonic stem cells in conducting non-profit, federally funded research, few have been able to reach agreements with providers and/or commercial partners to conduct the collaborative research needed for human treatment.

The landscape of intellectual property law related to hESCs differs between various countries. For instance, in Canada there is a complete ban on granting patents on hESCs.[32] The United Kingdom bans patents directed to totipotent embryonic stem cells (i.e., those stem cells that could theoretically turn into humans), while Sweden allows patents on all kinds of stem cells. New guidelines for stem cell research were released by the International Society for Stem Cell Research in May 2016.[33] These guidelines relate to defining embryo research oversight projects, as well as supporting research entailing gene editing of nuclear genomes of human sperm, egg, and embryos.

In an effort to seek health care procedures and/or therapies not available in the United States, patients and their families have been willing to travel to those areas where they can be provided. The CDC estimates approximately 750,000 U.S. residents travel abroad for medical care each year.[34] Clinics worldwide, especially in China, India, the Caribbean, Latin America, and the former Soviet Union, provide stem cell treatments for conditions such as autism, brain damage, cerebral palsy, Chron's disease, diabetes, genetic disorders, Huntington's, lupus, muscular sclerosis, Parkinson's disease, spinal cord injuries, stroke, and cancer, among others.[35] While some cancers have been shown to respond to stem cell therapy, sparse literature exists documenting the effectiveness of this therapy in treating these cancers or other ailments. Additionally, the content and quality of stem cell-containing preparations used by these clinics is often unknown and unregulated. A Harvard panel concluded that the practice of stem cell tourism hurts the legitimacy of the entire field of stem cell science and medicine. Clinics providing these treatments are often accused of financially exploiting desperate people with grave illnesses, people who many times after treatment are ultimately left in the same medical condition or worse.

Within the United States, a form of national medical tourism has sprung up related to access to medical cannabis.[36] Twenty-five states have passed laws allowing some degree of use of marijuana, and 14 states have acted

to decriminalize the substance in some degree.[37] Alaska, Colorado, Oregon and Washington have legalized the sale and possession of cannabis for both medical and non-medical use. Washington, D.C. has legalized personal use, but not commercial sale.

As with the controversies surrounding stem cell/regenerative medicine, the medicinal marijuana in the United States continues to face challenges. However, these challenges do not preclude the issuance of U.S. patents to medicinal (and non-medicinal) marijuana products and methods for making them, as over 970 THC- and cannabis-related patents have issued to date.[38]

Conclusion

Medical patents and innovations in health care improve the quality and delivery of medical care and the quality of life for millions of people around the world, and especially in the United States. Challenges remain in finding the most effective manner for making these advances available to individuals in greatest need, primarily because of cost constraints. The United States system governing innovation and implementation of medical patents, in balance with commercial interests and safety/efficacy concerns, while time consuming and expensive, provides a measured framework within which societal health care benefit through products created through medical patents may be realized.

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MM

Kansas City University
OF MEDICINE AND BIOSCIENCES

Missouri's First New Medical School in Nearly 50 Years Comes to Joplin

by Marc B. Hahn, DO

KCU and the Joplin community have established an innovative approach to expanding medical education that not only serves as a model for our country, but also ultimately advances the University's mission of "improving the well-being of the communities we serve."

As early as 2008, concerned business leaders and medical professionals in Joplin, Missouri, began dedicated conversations about the growing problem of providing adequate health care to its residents for the long term. The area's population was on the rise; moreover, much of the largely rural four-state region was aging. Compounding the problem was the looming shortage of physicians facing our country — a number projected to reach between 14,900 and 35,600 for primary care physicians and between 37,400 and 60,300 for other specialties by 2025.[1] With well over 60 percent of our alumni practicing in a primary care specialty and 40 percent practicing in rural or underserved areas, Kansas City University of Medicine and Biosciences (KCU) was a logical participant in those early discussions.

At the same time, studies revealed that osteopathic medicine ranked as the fastest-growing health care profession in the country, positioning it well to help close the country's physician supply gap. Since 1985, the number of DOs in practice has grown an average of 25 percent every five years, from 24,014 in 1985 to more than 100,000 today.[2] Enrollment in osteopathic medical schools is also witnessing exceptional growth. Between 2002 and 2015, first-year enrollment grew 137 percent (from 2,968 students to 4,057) and is projected to continue its upward trend through 2020.[3] KCU's own experience bears out that trend. Between 2014 and 2015 alone, applications to our College of Osteopathic Medicine increased 39 percent and remained high for 2016.

Indeed, medical centers and many smaller hospitals in the Joplin region all reported difficulty in recruiting and retaining qualified physicians. When community leaders and medical professionals turned their attention to the pipeline of young, new doctors entering the area, local university administrators revealed that interested undergraduates were being forced to relocate to Little Rock, Arkansas; Columbia, Missouri; Kansas City, Missouri; Tulsa, Oklahoma; and St. Louis for their training. What's more, studies show that approximately 50 percent of physicians choose to permanently locate within 75 miles of where they complete their residency, leaving little hope for a critical mass of Joplin area graduates to return to their local community to practice medicine.[4]

The solution became clear: If the region was to strengthen and expand high-quality medical care for its growing, aging and rural population, it needed to attract medical students and provide local opportunities for them to study, complete their residencies and practice as physicians in the area. It needed its own world-class medical school.

A Community Rallies

Although conversations with KCU stalled for several years, those initial discussions resulted in the first major step toward the realization of a new medical school for



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Right, rendering of main entrance. Below, construction photo of main entrance.





southwest Missouri: the creation of the Joplin Regional Medical School Alliance (JRMSA) in 2010. The goal of the not-for-profit JRMSA was to develop ways to support a new medical school and serve as a community advisory body committed to achieving the mission. Comprised of more than 30 dedicated community and medical sector leaders, JRMSA was poised for action.

However, the evening of May 22, 2011, marked a devastating turn of events when an EF5 tornado destroyed nearly 25 percent of the town. By all accounts one of the deadliest tornados in U.S. history, it cut a 13-mile swath three-fourths of a mile wide through town leaving 161 fatalities and more than $2 billion in damage in its aftermath. Joplin lost five of its schools and one of its two hospitals in the destruction, as well as 7,500 homes and 500 businesses — all in the span of 20 minutes.

As often happens in communities as tightly woven as Joplin, the town and its citizens rallied. Despite taking a direct hit, the medical community persevered. Within six days of the tornado, the Missouri Medical Assistance Team had deployed an 8,000-square-foot field hospital to temporarily replace the destroyed Mercy Health System's St. John's Hospital. In short order, the tent hospital gave way to portable buildings and finally a modular structure. During that time, plans also were conceived for an 880,000-square-foot permanent hospital on a new site, built to withstand tornadic winds with safe zones on every floor. The new 207-bed Mercy Hospital opened in March 2015.

In January 2014, discussions had resumed between JRMSA and KCU's new administration to determine the resources and commitments necessary for developing a successful, world-class medical school with a focus on primary care and rural health. The confluence of events leading up to those discussions served to galvanize support for the project.

The proposed medical school had garnered strong interest by a large number of regional leaders. The area's two health systems — Mercy and Freeman — and local physicians had agreed to provide student rotation slots, as well as develop additional graduate medical education positions. KCU, one of the oldest osteopathic medical schools in the country, had offered an accredited program and a proven, century-long history of educating physicians to help quell the region's projected shortage. And a resilient town had united around the rebirth of its community, including a commitment to train physicians locally to improve access to health care for its residents.

With that, JRMSA pledged — and extraordinarily raised in less than one year — $30 million to assist in the construction of the medical school. And, most generously, Mercy Health System donated both its 150,000-square-foot temporary structure valued at $10 million, and the 40-acre plot of land it sat on, for use by KCU in the creation of a new Joplin campus.

Rising From The Ashes

On March 30, 2015, ceremonial shovels dug into the earth as KCU officials, Joplin community partners, government officials, and a cheering crowd of supporters kicked off the start of construction. To be built on the very grounds of the destroyed St. John's Hospital, the first new medical school in Missouri in almost 50 years was embraced as both a boon to the region and a jewel in the crown of southwest Missouri.

As the 12th largest medical school in the U.S., KCU has distinguished itself as a national leader in the education and



Rendering of the osteopathic manipulative medicine lab.

training of osteopathic physicians, having graduated more than 10,000 highly skilled, compassionate doctors since its founding in 1916. KCU-Joplin will welcome its first class of 150 students in the fall of 2017. Once fully operational, the Joplin campus will infuse an estimated $111 million annually into the regional economy and add approximately 100 new jobs in the area.

A Continued Commitment To Academic Excellence And Student Success

At the beginning of the 2014-2015 academic year, KCU adopted a new Modified Systems-Application Based curriculum with the goal of best preparing medical students for a lifetime of future learning and patient care. This innovative curriculum will be integrated into the Joplin campus as well.

Using a proven trans-disciplinary, system-based/interactive model, new students will be immersed in hands-on clinical experiences from their first day. Clinical enhancements, such as human patient simulation and standardized patient training, will augment the teaching of vital patient-physician skills. In third and fourth years, students will train in both ambulatory and hospital sites in Joplin and the surrounding region. Advanced clinical training will be provided through both inpatient and outpatient clerkships in a variety of medical settings.

KCU-Joplin's physical campus also is being developed with student success at the forefront, encouraging learning through active experiences. Classrooms have been designed with flexibility and technology in mind, enabling students to work in small pods that encourage discussion and collaboration.

The school's simulation suite will include 24 standardized patient exam rooms and three simulation rooms featuring high-fidelity, programmable robots in fully equipped medical, surgical, obstetrical and trauma settings. Audio-visual capabilities will allow instructors to interact in real time with students while recording procedures to be used as learning opportunities in separate classrooms. Extensive video conferencing capabilities will connect the Joplin campus to the Kansas City campus, allowing students, faculty and staff to share learning opportunities.

The Fruition Of A Shared Vision

Because of a 100-year history of success in medical education and the ability to share existing resources, KCU has accelerated the process of fully establishing a four-year medical school in Joplin as an additional site for its accredited Kansas City program, thus reducing the overall development timetable by approximately two years. With construction scheduled for completion in May 2017, KCU-Joplin will become the seventh medical school in the state and the first in the southwest region of Missouri.

At its heart, KCU-Joplin is a story of unity, community and collaboration. It represents a shared purpose and vision, from which Joplin has never wavered. It is the result of a genuine grassroots effort led by tireless individuals and local organizations, whose remarkable determination and generosity is a symbol of the amazing rebirth that has come from the ashes of tragedy. And it is an example of collaboration at its best, whereby two health systems, area physicians, and local institutions have shown creativity and cooperation to help educate "homegrown" physicians to address the primary care and rural health needs of its four-state region.

In doing so, KCU and the Joplin community have established an innovative approach to expanding medical education that not only serves as a model for our country, but also ultimately advances the University's mission of "improving the well-being of the communities we serve."

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MSMA Members in the News

Read more about what our members are doing at www.facebook.com/momedical



Missouri Medicine announces a new member of its Editorial Board. Board members are selected on the basis of exceptional professional accomplishment and expertise in their specialty.

Jose M. Dominguez, MD, MSMA member since 2005, is the new Colon and Rectal Surgery board member. Dr. Dominguez practices at the Ferrell-Duncan Clinic with Cox Health Systems in Springfield, Missouri.

Missouri Medicine would like to publicly thank non-Editorial Board experts who have done peer-review of submitted manuscripts in 2016: Lenard Politte, MD, Doug Bogart, MD, and Jim Blaine, MD.



Lindsay Allan, MD, recently joined Community Hospital-Fairfax. She's been an MSMA member since 2014. MSMA is proud to have her as a part of our young physician section.



MSMA member since 1976, Kenneth Azan, MD, has added Bothwell Regional Health Center in Sedalia to the places where he practices and treats patients.



Drs. John Bennett, Laura Maple, and Julie Viehmann (left) have found their calling at Hannibal Regional Medical Group. MSMA appreciates their membership for a combined total of 30 years.



Michael Bukstein, MD, MSMA member since 1976, spoke at the Northeast Missouri C.H.A.R.T. Partnership meeting about cancer trends for northeast Missouri residents. He has served in many leadership roles, including Vice President of MSMA and Past President of the Northeast Missouri Medical Society, the Missouri Chapter of the American College of Surgeons, and the Missouri Surgical Society. In 2011, he was honored with the President's Award at MSMA Annual Convention.



Congratulations to MSMA member since 1980, David Caplin, MD, on the hosting of another successful event with the Gateway to Hope Gala, called KaleidoHope, held Oct. 1, in St. Louis.

Drs. Charles F. Cockerell, Michelle McIntosh, and Hoanh Nguyen, recently held a ribbon cutting for their new office in Higginsville. Their combined years of membership in MSMA - more than 45 years - is wonderfully appreciated.



Humam Farah, MD, of Hannibal, recently traveled to Israel as part of a worldwide study of lung disease Alpha-1, with the goal of developing a cure. Dr. Farah has been an MSMA member since 2014.



One of MSMA's very own student members, Alex Goodson, was published in the *Columbia Missourian* on Oct. 23 with his guest commentary, titled, "Real value in med school review lies in guiding improvement."



MSMA wishes Warren Hagan, MD, all the best at his new practice with Blessing Physician Services in Quincy, Ill. We thank him for his continued loyalty as an MSMA member since 2003 and, in advance, for the extended leadership he provides to the northeast part of our state.



Ron Jones, MD, MSMA member since 1978, now sees patients at Nevada Regional Medical Center Mondays and Thursdays.



Donald Kuenzi, MD, MSMA member since 1977, received the University of Missouri - Columbia School of Medicine Distinguished Service Award at the MU Alumni Awards program. He is a retired family physician in Kansas City, and a longtime volunteer and board member of Health Teams International, a Christian-based medical and dental mission organization that seeks to provide medical and dental services in underserved countries worldwide.



A new member to MSMA, Lisa Lemons, DO, has joined the team at Cox Medical Center in Branson.

In Memoriam



MSMA Past President Thomas J. Cooper, MD, passed away on October 31, 2016. He was 92. Dr. Cooper was installed as MSMA President in April 1988, and was a pathologist from St. Louis. He served as President of the St. Louis Metropolitan Medical Society and was active in the state and national chapters of the College of American Pathologists.



MSMA Past President Stephen E. Vilmer, MD, passed away on November 12, 2016. He was 73. Dr. Vilmer was installed as MSMA President in April 1998, and was an orthopaedic surgeon from Shawnee, Kansas. He was a Past President of the Clay/Platte County Medical Society and Chief of Surgery at North Kansas City Hospital.

- Carle H. Schroff, MD, 86, July 7, 2016, Springfield, Family Practice
- Mark L. Friedell, MD, 65, July 10, 2016, Kansas City, Vascular Surgery
- Ramon A. Shane, MD, 84, August 27, 2016, Springfield, Cardiovascular Surgery
- Glenn O. Turner, MD, 97, August 20, 2016, Springfield, Internal Medicine
- Gary L. Hoos, MD, 61, August 2, 2016, Springfield, Oncology
- Jerome H. Schmidt, MD, 87, May 18, 2016 Jefferson City, Urology

MSMA Members in the News, continued



Congratulations to Geoff Lloyd-Smith, MD, MSMA member since 2007, for joining Phelps County Regional Medical Center.



In just a few short years, Bradley J. Moore, MD, has not only joined MSMA, but also expanded his practice from Phoenix Urology in St. Joseph to now treating patients at Carroll County Memorial Hospital in Carrollton.



Michael Nellestein, MD, a new MSMA member, recently opened Nellestein Vein Institute in St. Joseph.



Jeffrey Piontek, MD, MSMA member since 2010, has joined Lake Regional Health System at its Lake Ozark clinic.

Congratulations to Rick Wright, MD, inductee into the 2016 Missouri Sports Hall of Fame. Dr. Wright has been the team physician for the National Hockey League's St. Louis Blues since 1997. He also was a team physician with the St. Louis Cardinals from 1998 to 2006 and the NFL's St. Louis Rams from 1994 to 2016. What an honor to call this physician an MSMA member since 1996. **MM**



CORRESPONDENCE

Burnout, Suicide Impact Medicine

Significant changes are impacting the practice of medicine in this country.

During 2016, we have seen a worsening of the conditions that physicians and physicians-in-training are facing. Burnout, which is the foundation for many other dysfunctional behaviors that may potentially impair physicians, has become severe. At least five physician suicides have occurred in Missouri. The calls for our services have intensified as hospital medical staffs are asking for help in developing a concerted effort to reach out to their practitioners.

As you know, the Missouri Physicians Health Program is dependent on donations to finance our work. The need has never been greater. Please help us to help others. We cannot do it alone. Your support is vital to our continued existence.

I hope we can count on you once again. Thank you for your compassion for your colleagues.

Charles Sincox, MD
MPHP Medical Director

Robert Bondurant, RN
Executive Director

Visit www.themphp.org to donate to the program.



www.msma.org/annual-convention

Pre-Convention Meetings

Thursday, March 30

2:15 pm	MSMA Insurance Agency Board Meeting
3:30 pm	MSMA Executive Committee
3:30-6:00 pm	Convention Registration
3:30-6:00 pm	Exhibitor Setup & Registration
5:00 pm	**MSMA Council Meeting**
6:30 pm	Alliance Dutch Treat Dinner [Offsite]
6:30 pm	**MSMA Council Reception & Dinner**

Convention Meetings

Friday, March 31

6:30 am-4:00 pm	Convention Registration
6:45 am	Moneta Breakfast
7:00 am	**Exhibit Hall Opens/Continental Breakfast for all Conferees**
8:00 am	**Opening Session MSMA House of Delegates**
8:30 am	Alliance Board Meeting
10:00 am	Alliance General Assembly - Session I
10:00 am	**Reference Committee A**
10:30 am	**Reference Committee B**
Noon	SLMMS Caucus & Luncheon
Noon	KCMS Caucus & Luncheon
Noon	"Spirit of the Alliance" Awards Luncheon
1:30 pm	**MSMA General Session**
2:00 pm	Missouri Million Hearts Meeting
2:45 pm	Alliance Past President's Reception
3:30 pm	**MSMA General Session**
5:00 pm	OMSS Business Meeting
5:30 pm	Medical School Alumni Receptions
7:00 pm	Alliance Foundation Fundraiser/Dinner

Saturday, April 1

6:30 am-4:00 pm	Convention Registration
7:00 am	**Exhibit Hall Opens/Continental Breakfast for all Conferees**
All Day	CME Programs, Lectures & Meal Functions
8:00 am	**MSMA General Session**
8:30 am	Alliance General Assembly - Session II
9:00 am	International Medical Graduate Section Meeting
10:00 am	**MSMA General Session**
10:00 am	MMPAC Meeting
10:00 am	Medical Student Section Meeting
10:30 am	Exhibit Hall Closes
Noon	Alliance Installation Luncheon
1:00 pm	AMA Issues
1:00 pm	Resident Fellow Section Meeting
1:00 pm	Young Physicians Section Program & Meeting
1:30 pm	**MSMA General Session**
2:00 pm	Missouri State Medical Foundation Meeting
2:30 pm	Alliance Board Meeting
3:00 pm	Component/Specialty Society Leaders Meeting
3:30 pm	OMSS Educational Session
5:15 pm	Reception: 50-Year Pin Recipients & MSMA Past Presidents
6:30 pm	**MSMA Presidential Inauguration**
7:30 pm	**MSMA Presidential Reception** *Entertainment, Hors d'oeuvres & Cash Bar*

Sunday, April 2

7:00 am	District Breakfasts & Caucuses
8:15 am	**Second MSMA House of Delegates**
Immediately Following Closure of the HOD	MSMA Council Meeting

Complete Program at www.msma.org/annual-convention

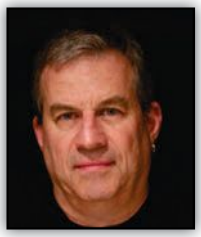
Subject to Change. Refer to Convention Official Program for times and meeting locations. All meetings held at the Sheraton Kansas City at Crown Center unless otherwise noted. Updates on CME program, lectures, and meal functions at www.msma.org/annual-convention. For more information, contact MSMA's Benita Stennis, at 800-869-6762 or bstennis@msma.org.

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Rates start at $151 per night plus charges and taxes.
If calling, mention "MSMA 2017 Annual Annual Convention."

Missouri State Medical Association
159th Annual Convention

GENERAL SESSIONS & EVENTS



Friday, March 31 | 1:30 pm

Dreamland: The Opiod Epidemic

Sam Quinones
Journalist and Author
Los Angeles, California

CME MOC ACCREDITED



Friday, March 31 | 3:30 pm

Breast and Ovarian Cancer Prevention

Joshua Cohen, MD
Obstetrician-Gynecologist
Ronald Reagan UCLA Medical Center,
Los Angeles, California

CME MOC ACCREDITED







Saturday, April 1 | 8:00 am

Economic and Health Impact Addressing Under-Treatment of Sleep Apnea

Lirong Zhu, MD
Medical Director, Mercy Sleep Center, Rolla, Missouri

David Kuhlmann, MD
Medical Director of Sleep Medicine, Bothwell Regional Health Care, Sedalia, Missouri

Thomas Gotsis, DDS
Midwest Dental Sleep Medicine
Bridgeton, Missouri

CME MOC ACCREDITED



Saturday, April 1 | 10:00 am

Exciting Years in Cancer Treatment

Joseph J. Muscato, MD
Founding Partner, Missouri Cancer Associates, Columbia, Missouri

CME MOC ACCREDITED



Saturday, April 1 | 1:30 pm

Patient Engagement

Peter Anderson, MD
Founder and President, Team Care Medicine, Yorktown, Virginia



Paul Grundy, MPH
Global Director, Healthcare Transformation, IBM, Washington, DC

CME MOC ACCREDITED



Saturday, April 1 | 3:30 pm

OMSS Presentation MACRA: The Shift to Value-Based Payment

Michael Munger, MD
Family Medicine, Saint Luke's Health System, Overland Park, Kansas

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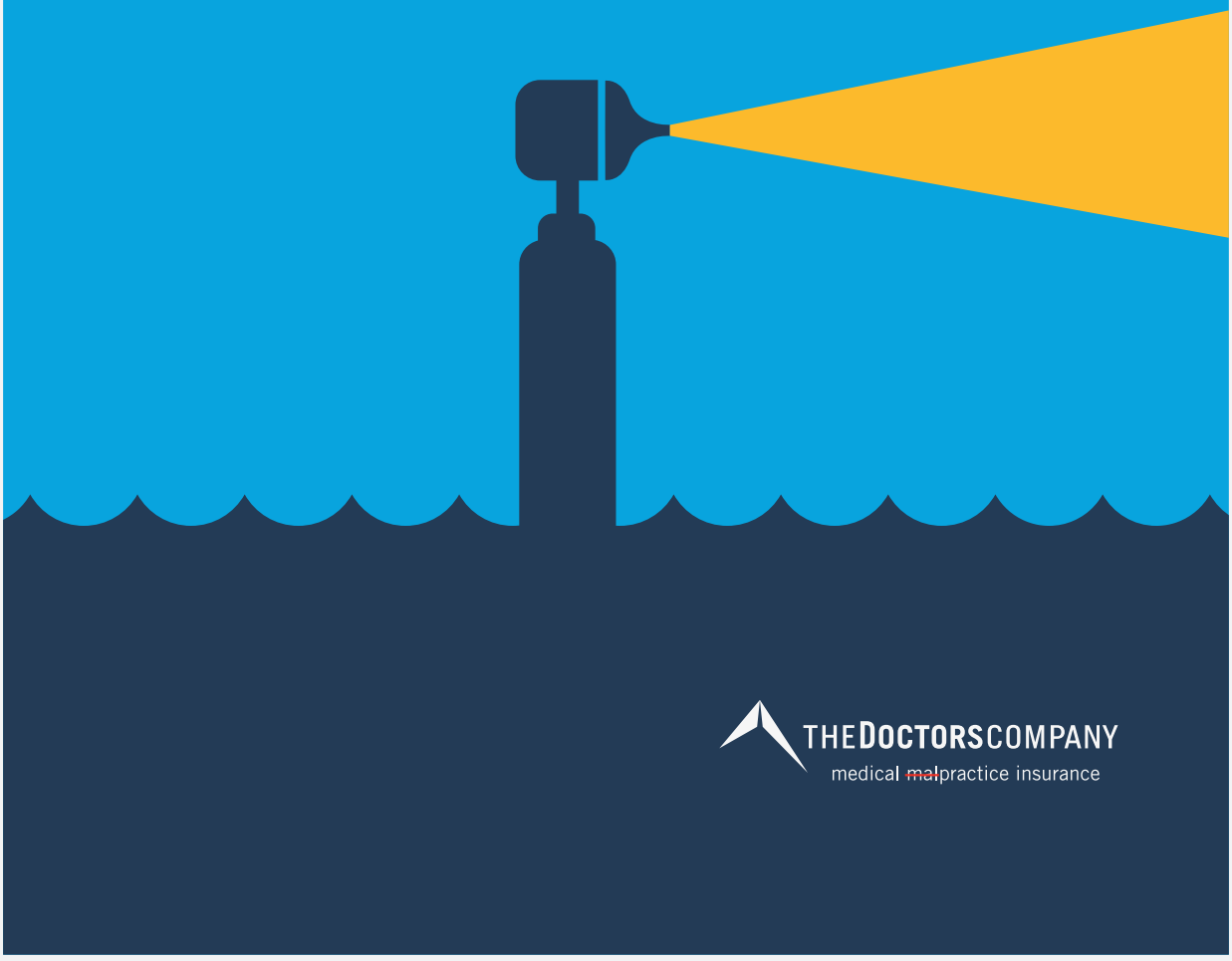
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The Evolution of a Regional Lung Cancer Screening Program

by Mitchell Botney, MD

The goal of cancer screening presumes that a test can detect cancer at a stage when cure is possible, can detect suspicious abnormalities in asymptomatic persons at risk for cancer, that people with a positive result can be further evaluated to determine whether they actually have cancer, and that early intervention should change the course of the cancer, resulting in decreased mortality.



Mitchell Botney, MD, MSMA member since 2003 and *Missouri Medicine* Editorial Board member for Pulmonary Medicine, is Chief Medical Officer, Missouri Baptist Medical Center, St. Louis, Missouri.
Contact: mitchell.botney@bjc.org

Lung cancer in the United States remains an epidemic with roughly 14% of all new cancers in both men and women occurring yearly in the lung or bronchial tree (American Cancer Society). Lung cancer is the most common cause of death in both men and women, responsible for more than a quarter of all cancer deaths in both men and women. The epidemiology demonstrates a tight correlation between smoking, lung cancer frequency and deaths—including Missouri. The percentage of smoking Missouri adults lies near the U.S. median for all states,[1] roughly 20%, but it ranks in the top 10 states for lung cancer rates and lung cancer deaths.[2] Considerable heterogeneity in the annual death rate per 100,000 population exists between Missouri counties, ranging from a high of 118 in Carter County to a low of 37 in Barton County. The overall annual death rate in Missouri (from 2007-2011) is 58 compared to the U.S. annual death rate of 48. Despite considerable public health work since the original Surgeon General's report in the 60s, the incidence of smoking remains high and, consequently, so is the rate of lung cancer and lung cancer deaths.

There are reasons why public health measures have been only partially successful. Nicotine is extremely addictive, ranked most addictive on the Henningfield-Benowitz Scale ahead of heroin (#2), cocaine (#3), and alcohol (#4).[3] Peer group pressure is only slowly swinging against cigarette smoking and the extent to which cigarette smoking is considered socially acceptable remains mixed, although overall the trend is encouraging. Advertising is still a potent social force encouraging cigarette smoking: in 2013 the tobacco companies spent over $9 billion marketing cigarettes and smokeless tobacco in the U.S. or more than $1 million every hour.[4] Cigarette advertising in Missouri totaled $355 million, roughly $1 million dollars a day. The monies spent on anti-smoking advertising pales in comparison, especially in Missouri. A new report by the Campaign for Tobacco-free Kids ranks Missouri 50th in the amount of money spent discouraging smoking: roughly $100,000 per year despite an estimated $235 million in yearly revenue from cigarette sales.[5] There is a rough inverse correlation between cigarette consumption and excise tax rates for cigarettes—Missouri ranks last in the U.S. with the lowest cigarette taxes at just 17 cents per pack.[6] Finally, while there is an encouraging national trend in the approval of smoke-free laws applying to public places such as bars, restaurants and workplaces, coverage is spotty including in Missouri.

In other words, primary prevention of lung cancer is slowly achieving results by reducing cigarette smoking in the U.S. but many lives will be lost from lung cancer before these public health measures become

fully effective. This slow progress was a major impetus in examining the role of lung cancer screening as the primary tool of secondary prevention.

The goal of cancer screening presumes that a test can detect cancer at a stage when cure is possible, can detect suspicious abnormalities in asymptomatic persons at risk for cancer, that people with a positive result on screening can be further evaluated to determine whether they actually have cancer, and that early intervention should change the course of the cancer, resulting in decreased mortality. A successful randomized trial of screening for lung cancer should enhance detection of lung cancers, particularly asymptomatic early stage cancers, in the study group compared to the control group, during the screening phase. Later on, as the trial progresses and enters the post-screening phase, the number of lung cancers in the two groups should gradually equalize as asymptomatic early undetected lung cancers in the control group grow, spread and eventually present as symptomatic advanced stage cancers. Thus, there should be a "trade-off" of asymptomatic early stage screen-detected lung cancers in the study group for symptomatic advanced clinically detected lung cancers in the control group. Then, if treatment is more effective for asymptomatic early stage lung cancers than it is for symptomatic advanced lung cancers, there should be fewer deaths from lung cancer in the screened study group than in the non-screened control group.

There are biases inherent to the screening process which must be accounted for including lead time bias which occurs when two tests for a disease are compared, and one test (the new, experimental one) diagnoses the disease earlier, but there is no effect on the outcome of the disease—it may appear that the test prolonged survival, when in fact it only resulted in earlier diagnosis when compared to traditional methods. A second important bias occurs from overestimation of survival duration among screen-detected cases due to the inclusion of "histologic malignancy" that will not become overt ("biologic malignancy") before the patient dies of other causes.

There were multiple early lung cancer screening studies performed in 80s that reported an increased incidence of early-stage lung cancers, more resectable cancers and improved five-year survival rates in the screened groups as compared to control groups but in the final analysis there was no statistically significant difference in mortality attributable to lung cancer between the two groups—suggesting improved survival was due to some type of "bias."[7-10]

It was in this context of continued high numbers of lung cancer deaths and our inability to successfully screen for early lung cancers in smokers that the National Lung Screening Trial Research Team published their ground-breaking article, "Reduced Lung-Cancer Mortality with Low Dose Computed Tomographic Screening" in 2011.[11] The study was a randomized, non-blinded controlled trial comparing low dose CT scanning to conventional chest x-ray screening. Eligibility criteria included current smokers with $\geq$30 pack-year smoking history (or, if a former smoker, having quit $<$15 years ago) between age 55-74. Smokers could not have a history of prior lung cancer, no prior CT scan within 18 months of enrollment and had to be asymptomatic. Upon completion of the study, 25% of all deaths in the trial were secondary to lung cancer. There were 123 excess deaths in the chest x-ray arm compared to the CT scan arm, resulting in a 20% reduction in lung cancer deaths with CT scanning. Three hundred and twenty eligible smokers required screening to prevent one lung cancer-related death. As would be expected, subsequent studies showed that selected risk factors within the original enrollees could identify smokers at greater or lesser risk for developing lung cancer.[12-13] This refinement suggested that the number of screened participants needed to prevent one lung-cancer death decreases as prescreening risk of death from lung cancer increases, increasing the cost-effectiveness in higher risk patients.

Medicare's question was whether to pay for low-dose CT screening or not, with the debated focused on the applicability of the NLST results to the general Medicare population, the harm created by false-positive studies and cost-effectiveness. In February 2015, Medicare announced it would accept Medicare Part B claims for low-dose lung cancer screening and implemented that decision in January, 2016.[14] Criteria are outlined in Table 1.

Missouri Baptist Medical Center in St. Louis began developing a regional lung cancer screening program shortly after the results of the NLST were published and commenced operation beginning 2015. Our goal was to develop a standard screening approach with standardized radiology and IT platform infrastructures for all participating hospitals to allow easy portability within the region while, at the same time, respecting the autonomy of the local hospital within their community. Since inception we have seen steady growth in participating hospitals, applicants and screenings, and are now performing follow-up screenings on patients with suspicious

Table 1
Medicare criteria for initial low dose CT scan lung cancer screening

For Medicare coverage of lung cancer screening with LDCT, beneficiaries must meet all of the following eligibility criteria:

- Age 55 – 77 years;
- Asymptomatic (no signs or symptoms of lung cancer);
- Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current smoker or one who has quit smoking within the last 15 years; and
- Receives a written order for lung cancer screening with LDCT that meets the requirements described in the NCD.

Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary's medical records, and must contain the following information:

- Beneficiary date of birth;
- Actual pack – year smoking history (number);
- Current smoking status, and for former smokers, the number of years since quitting smoking;
- Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and
- National Provider Identifier (NPI) of the ordering practitioner.

Before the first lung cancer LDCT screening, the beneficiary must receive a lung cancer screening counseling and shared decision making visit, and if appropriate, receive the written order for his/her first lung cancer LDCT screen during such visit. Written orders for subsequent annual LDCT screens may be furnished during any appropriate visit with a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist).

lesions. Our low dose CT screening program follows the Medicare guidelines which recommends a structured, comprehensive screening program, not just scanning alone. A central Nurse Navigator actively follows enrolled patients from all participating hospitals and guides patients through appointments, answers their questions and ensures follow-up care when needed. To date (June 2016) 750 patients called inquiring about the program, 534 patients qualified for testing, and 429 patients screened. Of these 429, 51 (12%) were staged L1; 317 (74%) staged L2; 34 (8%) staged L3; and 27 (6%) staged L4[1]. Three patients have now been diagnosed with early stage lung cancers and undergone resection with curative intention—one for every 143 patients screened.

As a pulmonologist, the single most frequent and difficult job I had was to sit down with a patient, often with the family, to tell that patient they had lung cancer. Often, in response to the inevitable question, "how bad is it?", the next words were that the cancer was of an advanced stage and curative treatment was statistically not likely…but that we would do our best. My hope, and the hope of my program colleagues, is that our regional CT screening program will allow us to detect lung cancers at an early stage and we can start making a dent in our dismal lung cancer statistics. The high degree of cooperation between hospitals and between physicians at different hospitals has been focused by the common goal of preventing lung cancer deaths and provides a model for development of similar regional programs or, even, a statewide program to reduce lung cancer deaths. However, we should all remember this is a secondary prevention program and that equal efforts should be made to reduce cigarette smoking in the first place.

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Many thanks to Beth Arenas, Nurse Navigator, for her tireless work in support of the program as well as all the many patients she has helped. **MM**

Low Dose CT for Lung Cancer Screening Could Provide Substantial Benefit

by Jim Blaine, MD

The most effective way to prevent lung cancer is to prevent young people from starting smoking, and the best, and most cost-effective way to reduce the risk in current smokers is to stop smoking.

Smoking is the leading preventable cause of death on the planet. It is the number one cause of cardiovascular deaths and cancer deaths in men and in women in the United States, and approximately one in five Missourians over the age of 18 smokes. Missouri spends virtually nothing on tobacco prevention efforts. One in seven lifelong smokers (14%) will develop lung cancer, and almost all will die from their disease.

Mitchell Botney, MD, has presented an enlightening comprehensive article exploring the frustrations of public health efforts in Missouri to prevent lung cancer, and the dismal current success of treating late stage disease. He also details our hope for diagnosing early stage lung cancer with low dose CT (LDCT) screening and shares his Regional Lung Cancer Screening Program research at Missouri Baptist Medical Center in St. Louis. He has a healthy respect for tobacco prevention as a primary goal, but describes some of difficulties with changing the behavior of smokers.



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The National Lung Screening Trial in 2011 revealed that smoking patients who were screened with a low dose chest CT scan were 20% less likely to die from lung cancer than those screened with a chest x-ray. This is because the CT screenings result in an earlier diagnosis of lung cancer while still potentially curable; this provides, on the average, one cured lung cancer for every 312 patients (three screenings in five years) in the LDCT screening program. This is expected to improve as the program evolves and progresses.

The U.S. Preventive Services Task Force (USPSTF) has identified LDCT for lung cancer screening as a Grade B recommendation. This means that they think that there is a moderate to substantial net benefit for its use, and they recommend that it be provided. Therefore, as a result of the Affordable Care Act, Medicare, and most other insurance carriers are now paying for the annual screening free of charge for qualified patients. Any additional testing, treatment, etc., that occurs as a result of the findings discovered during screening is paid for with the usual co-pays, deductible charges, etc., that would be applicable for any other illness diagnosis and treatment.

The USPSTF is obviously in favor of LDCT; however, not everyone is convinced. The American Academy of Family Physicians posted in January 2013 that evidence is lacking to support or oppose low-dose CT screening for lung cancer," or specifically, it concludes that "the evidence is insufficient to recommend for or against screening for lung cancer with low-dose computed tomography (LDCT) in persons at high risk for lung cancer based on age and smoking history." Source: http://www.aafp.org/news/health-of-the-public/20140113aafplungcarec.html.

Although the AAFP points are well made, and worthy of consideration, the Centers for Disease and Prevention (CDC) and others have embraced the recommendation of the USPSTF. LDCT is, in my opinion, the first promising screening tool for a disease that has a notoriously high

mortality rate, and I am eager to see the results of the ensuing studies.

The premise for identifying smokers to be screened is straightforward. We primary care physicians identify our asymptomatic patients aged 50 to 77 who have smoked thirty pack years, and who are either currently smoking or who have stopped within the past 15 years. We attest that we have counseled the patient on the importance of tobacco cessation, informed him/her on the benefits and harms of screening, and refer the patient to a Lung Cancer Screening Program, (we have two in Springfield, Missouri - Cox and Mercy Health Systems), and there are several others across the state.

Estimated New Cases

	Males			Females	
Prostate	180,890	21%	Breast	246,660	29%
Lung & bronchus	117,920	14%	Lung & bronchus	106,470	13%
Colon & rectum	70,820	8%	Colon & rectum	63,670	8%
Urinary bladder	58,950	7%	Uterine corpus	60,050	7%
Melanoma of the skin	46,870	6%	Thyroid	49,350	6%
Non-Hodgkin lymphoma	40,170	5%	Non-Hodgkin lymphoma	32,410	4%
Kidney & renal pelvis	39,650	5%	Melanoma of the skin	29,510	3%
Oral cavity & pharynx	34,780	4%	Leukemia	26,050	3%
Leukemia	34,090	4%	Pancreas	25,400	3%
Liver & intrahepatic bile duct	28,410	3%	Kidney & renal pelvis	23,050	3%
All Sites	841,390	100%	All Sites	843,820	100%

Estimated Deaths

	Males			Females	
Lung & bronchus	85,920	27%	Lung & bronchus	72,160	26%
Prostate	26,120	8%	Breast	40,450	14%
Colon & rectum	26,020	8%	Colon & rectum	23,170	8%
Pancreas	21,450	7%	Pancreas	20,330	7%
Liver & intrahepatic bile duct	18,280	6%	Ovary	14,240	5%
Leukemia	14,130	4%	Uterine corpus	10,470	4%
Esophagus	12,720	4%	Leukemia	10,270	4%
Urinary bladder	11,820	4%	Liver & intrahepatic bile duct	8,890	3%
Non-Hodgkin lymphoma	11,520	4%	Non-Hodgkin lymphoma	8,630	3%
Brain & other nervous system	9,440	3%	Brain & other nervous system	6,610	2%
All Sites	314,290	100%	All Sites	281,400	100%

FIGURE 1. Ten Leading Cancer Types for the Estimated New Cancer Cases and Deaths by Sex, United States, 2016.
Estimates are rounded to the nearest 10 and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder.

Source: American Lung Association 2016

So is the effort cost effective? According to a November 2014 study of 53,452 patients published in the *New England Journal of Medicine* (*NEJM*), the cost is $81,000 per Quality Adjusted Life Year (QALY). Anything under $100,000 is considered cost effective. However, this is under the assumption that a non-contrast low dose CT of the chest costs $285. According to the same *NEJM* article, as the cost approaches $500 per CT, the screening expense becomes prohibitive. As a Family Physician, I know that the cost of ancillary tests is not usually transparent. The retail cost to a noninsured person in Springfield, Missouri, is between $500 and $1,000, but this may be much different from what the insurance companies actually end up paying. The devil is in the details.

The obvious comparison for CT screening for lung cancer is with screening mammograms. A very good study of three decades of screening mammograms, also published in 2014 by the *NEJM*, revealed that as many as 31% of all breast cancers are over-diagnosed, and says that the study raises serious questions about screening mammography. Source: http://www.nejm.org/doi/full/10.1056/NEJMoa1206809#t=articleDiscussion.

I am grateful that our profession constantly questions our diagnosis and treatment efficacies. The Regional Lung Cancer Screening programs will assist our efforts to extend the lives of our lung cancer patients with earlier diagnosis and treatment. Their registries and objective assessment will keep us informed and guide us to the most cost effective choices. One can imagine that there is a possibility that annual LDCT screenings for smokers may actually help them take ownership of their addiction and the serious impact that it is having on their health. It would extremely informative to concurrently study any effect this program may have on tobacco cessation.

The LDCT Screening Program for Lung Cancer like the one at Missouri Baptist Medical in St. Louis represents the most exciting news for early lung cancer diagnosis and treatment in my lifetime. According to the CDC, 80 to 90% of all lung cancer is caused by tobacco smoke, and the most effective way to prevent lung cancer is to prevent young patients from starting smoking (almost 90% of smokers begin smoking before age 18), and to persuade current smokers to stop smoking. I agree with Dr. Botney that it would be ideal to implement equal efforts applied to both; especially in Missouri. Show me some progress. **MM**

Boys at Risk: Fatal Accidental Fentanyl Ingestions in Children

Analysis of Cases Reported to the FDA 2004-2013

by William V. Stoecker, MD, David E. Madsen, BS, Justin G. Cole, BS & Zachary Woolsey

Our report shows that fentanyl accidents continue unabated, with most childhood cases occurring in boys, with most childhood victims either two or four years of age.



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Abstract

We analyze 25 accidental childhood fentanyl exposures reported to FDA, 2004-2013. These exposures had a case-fatality rate = 48%; male:female ratio = 7.3; 76% were within the 2-4 age range. The ability of fentanyl to kill children so quickly is explained by fentanyl's ability to suppress respiration—as quantified by the antinociceptive potency per milligram, fentanyl far and away leads all narcotics. FDA recommends for fentanyl disposal: flush all forms of fentanyl down the toilet.

Introduction: Fentanyl Ingestion

We first heard of the dangers of an ingested fentanyl patch through the 'grapevine' in Rolla, Missouri. The tragedy as we heard it was confirmed with our county coroner. The story began when a parent called her child's day care center and nobody answered the telephone. After several calls went unanswered, the concerned parent went to the day care center and found the babysitter lying unresponsive on the bed with the unsupervised children wandering around. Postmortem investigation revealed a chewed fentanyl patch in her mouth; the coroner ruled the death an accidental fentanyl overdose. A second case was related by a patient who reported that they were going to a funeral for a toddler who had retrieved a fentanyl patch from a wastebasket and had eaten the patch—again with fatal results. We were unable to reach the devastated family to find out more about this accident. We still wanted to know—what are the circumstances surrounding these tragic accidents? Can case reports give details that help us know more about avoiding these incidents and tell us who is at greatest risk? We first performed a literature search and found three recent cases of fatal fentanyl accidents in children.

Case Study

Three cases of fatal accidental fentanyl patch exposure in children: fentanyl as a Band-Aid, fentanyl pulled off a toy truck, fentanyl picked up off the floor.

Case 1
Fentanyl used as a Band-Aid

A two-year-old girl was found dead in her bed by her grandmother. The previous evening, the child had fallen and abraded her knee. The grandmother had placed a fentanyl patch on the largest abrasion to stop the bleeding sometime after 6:30 p.m. The child fell asleep at 9:00 p.m. By 1:00 a.m, the grandmother

heard the child breathing harder, wheezing, and snoring. By 7:00 am, the child was found unresponsive and declared dead. At autopsy, the 12 kg. child had multiple abrasions from minor trauma sustained the previous evening. The largest abrasion, 2x2 cm, was covered by a transdermal fentanyl patch. Drug analysis detected high systemic fentanyl in the child's urine.[1]

Case 2
Fentanyl patch pulled off a toy truck

A two-year-old boy was found unresponsive in his home and could not be resuscitated. A used transdermal fentanyl patch was found lodged in the child's mouth. Two days earlier, he had visited his great-grandmother in a nursing home. Detectives and the state health department determined that the child likely acquired the patch from the nursing home, where used patches were found stuck to bed rails and bedside tables. Analysis by the Institute for Safe Medical Practices (ISMP) determined that the most likely scenario was that the child rolled over the patch with a toy truck, and ingested it later, as the mother recalled seeing "what looked like a Band-Aid" on one of the truck wheels." [2]

Case 3
Fentanyl patch picked up off the floor and ingested

A1-year-old baby girl was put to bed and two hours later was found dead. Autopsy revealed a transdermal fentanyl patch in the girl's stomach. Investigation established that the child has unintentionally swallowed the patch, which had been lying on the floor. Drug analysis detected high systemic fentanyl in the child's heart and peripheral blood.[3]

Our small medical informatics research group of two pre-medical students, one computer science student and a dermatologist used the FDA adverse drug reaction database MedWatch (AERS) and the CDC Wonder data to learn more about these narcotic casualties.[4,5] We confined our study to children, who are most vulnerable to the powerful respiratory depression of fentanyl. We would try to answer these questions: Which children are primarily at risk for accidental fentanyl ingestion? What recommendations can we make that could reduce the number of these terrible events? The remaining sections of this report include methods, results, discussion, conclusions and recommendations, and limitations.

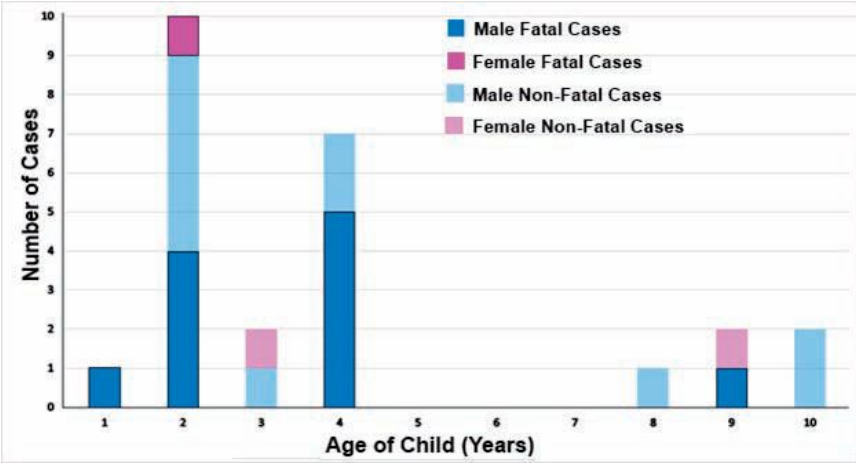
Methods

Data-mining techniques were applied to study childhood accidental fentanyl overdoses. All AERS reports of accidental childhood ingestions of fentanyl received by FDA and reported on MedWatch January 2004-June 2013 were analyzed. Cases were limited to children, ages 0-18, those where fentanyl was primary suspect, and those with the entry "accidental exposure" within the MedWatch field patient indication (INDI_PT). No cases had any indication such as pain, pain management, neuralgia, or any indication of chronic disease. Downloaded data was imported in SQLite, a public-domain relational database management system able to store very large databases and answer complex queries. Our analysis included totals for gender, age, and fatal vs. nonfatal outcome.

Results
A. FDA Data

Twenty-five cases met study criteria: 22 male and 3 female; 76% of these cases were within the two to four age range. Twelve of these 25 cases were fatal, corresponding to a case-fatality rate of 48%. Of the fatal cases, five involved ingestion of oral fentanyl citrate, in the form of lollipops and lozenges; five involved fentanyl patches, and two fatalities were by oral route from unknown type of fentanyl.

Figure 1



Females represented only one of twelve fatalities; the male:female ratio for all cases was 7.3. (See Figure 1).

B. CDC Wonder Data

The CDC Wonder database was examined to see if CDC data confirmed the age ranges for narcotic poisonings found in the FDA data. The CDC Wonder data tracks narcotic overdoses generally, without specifying specific drugs. CDC Wonder data shows



that most pre-adolescent narcotic poisonings occur in the zero to four age range. Selecting the ICD-10 code "accidental poisoning by and exposure to narcotics and psychodysleptics (hallucinogens)" and deaths for individual ages shows that 160 deaths occurred during 1999-2013 for the zero to four age group and only 69 deaths occurred in the five to twelve age group. By twelve years of age, total narcotic deaths begin to approach the high levels observed in adolescent children.

Discussion

Fentanyl: A popular, powerful narcotic that kills quickly

Fentanyl is widely prescribed, ranking fourth (behind acetominophen-oxycodone, buprenorphine-naloxone, and acetaminopvhen-hydrocodone) among narcotics prescribed in the U.S.[6] It is not widely appreciated that fentanyl is the strongest μ-opioid agonist. In antinociceptive potency per milligram, fentanyl is the most powerful narcotic-ten times as powerful as heroin. As measured by antinociceptive potential in rats, assigning codeine a potency =1, the order of potency is: fentanyl 774.2, heroin 77.4, oxycodone 28.7, methadone 28.2, hydrocodone 18.8, morphine 11.3, and codeine 1.[7] This potency is increased for children, so that even low doses of fentanyl patches, 25 mg in two of the cases above, can lead to a fatal outcome. The package insert for fentanyl patches states that fentanyl "should ONLY be used in patients who are already receiving opioid therapy," and "who have demonstrated opioid tolerance."[8] Opioid tolerance is defined explicitly in the package insert: "those who have been taking, for a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily."

The bioavailability of fentanyl varies according the route of administration. Putting the patch in the mouth and chewing or sucking the patch increases the bioavailable dose significantly beyond that which is obtained from application of the patch to the skin or even eating the patch: "If the entire contents of a 50 mg fentanyl patch were removed and administered transbuccally, this systemic level would be approximately three times that achieved with gastrointestinal absorption (i.e., approximately 5,000 micrograms of fentanyl or 375 milligrams of intravenous morphine."[9] Therefore, an adult sucking on a fentanyl patch, even an adult with opioid tolerance, is at risk for fatal overdose, as in the fatal case of the Rolla babysitter. A baby or toddler lacking opioid tolerance is at higher risk, and may die quickly sucking on a fentanyl patch, lozenge or lollipop. The one-year-old girl in Case 3 was found dead only two hours after ingestion of a 25 microg/hr patch.[3]

The FDA recommends disposal of fentanyl patches by "folding them in half with the sticky sides together, and then flushing them down a toilet."[10] The FDA reported 32 cases of accidental exposure to fentanyl ingestion, with 12 deaths, from 1997- April, 2012, mostly "involving children younger than 2 years old."[10] One more year of

AERS data ending in April 2013 in our analysis yielded seven new cases of accidental fentanyl ingestion: six cases in two-year-olds, and one in a 10-year-old child.

Our report shows that fentanyl accidents continue unabated, with most childhood cases occurring in boys, with most childhood victims either two or four years of age. All of the accidental patch exposures occurred in four-year-old boys. All fatal accidental ingestions of oral lollipop or lozenge forms occurred in one- or two-year-old children, all but one of whom were boys.

Why are two-to-four-year-old boys at risk?

Two-year-olds are particularly predisposed to putting things in their mouths. Greater abilities possessed by four-year-olds, who can better observe where adults put things that are of potential interest and are agile enough to successfully access trash containers and storage areas, may account for patch ingestion in the older children. Data presented here suggest that males, 22 of 25 reported cases, are particularly susceptible to accidental ingestion of improperly disposed fentanyl. The reason for this male preponderance is unknown. Greater risk-taking by males could account for this gender disparity.[11]

Our study of fentanyl primary suspects in accidental exposures reported to the FDA 2004-2013 showed that nearly 50% (12 of 25) cases were fatal. We also examined reports where fentanyl was a secondary suspect. For this situation, 28% (112 of 375) cases were fatal. In contrast, only 0.4% exposures of methadone involving children reported to the FDA were fatal.[4] The high potency of fentanyl, the high levels of absorption from mucosal surfaces, and the power of fentanyl to depress respiration completely and rapidly can explain this high case-fatality rate. For all these reasons, accidental exposures of fentanyl in children remains an important public health problem, with highest risk for boy toddlers and preschoolers exploring and putting objects in their mouths .

Conclusion and Recommendations

Tragically, accidental ingestions of fentanyl by children continue. Users of fentanyl should protect children and pets by following FDA recommendations to flush all forms of fentanyl down the toilet. The FDA specifies that "Fentanyl patches should be folded "in half with the sticky sides together."[12] Those persons using fentanyl patches and caregivers for those using fentanyl patches should always dispose of patches immediately in the recommended manner. Any other method of disposal places any child in the area at risk for a fatal accident.

Limitations

AERS cases are submitted voluntarily; therefore data provide only a subset of all exposures. AERS "route of administration" distinguishes transdermal patches from oral forms of fentanyl. We have inferred final exposure by ingestion in most cases, as ingestion was the circumstance for most of the case reports with fatal outcome.

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Disclosure

None reported.

MM

Acute Ischemic Stroke: Current Status and Future Directions

by Brandi R. French, MD, Raja S. Boddepalli, MD & Raghav Govindarajan, MD

Stroke is defined as a sudden onset of the neurological deficit caused by an acute focal injury to the central nervous system due to a vascular cause.



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Abstract

The evolving knowledge on stroke in conjunction with advances in the field of imaging, treatment approaches using recombinant tissue plasminogen activator (rtPA) or thrombectomy devices in recanalization, and efficient emergency stroke workflow processes have opened new frontiers in managing patients with an acute ischemic stroke. These frontiers have been reformed and overcome in overcoming the decades-long watch and wait approach towards patients with ischemic stroke. In this article, we focus on the current strategies for managing ischemic stroke and conclude by providing a brief overview of anticipating developments that can transform future stroke treatments.

Introduction

Stroke is defined as a sudden onset of a neurological deficit caused by an acute focal injury to the central nervous system due to a vascular cause.[1] The incidence of strokes occurring every year worldwide is about 17 million and it is the second leading cause of death after coronary artery disease.[2] It is the fifth leading cause of death in the United States, i.e., killing more than 130,000 Americans each year[3] and affecting 795,000 people annually.[4] It is the third most common cause of disability and reduces mobility in more than half of stroke survivors in ages 65 and over.[4,5] Furthermore, the economic burden of stroke on the nation through health care services, medications, rehabilitation and loss of productivity is around $33 billion annually.[4] By 2020 in developed countries, it is predicted that stroke will be accountable for 6.2% of the total burden of illness.[6] These data put forward the need for controlling risk factors, knowledge of identifying the signs of stroke, timely reperfusion therapies and measures to improve delivery of the aforementioned resources for the best possible outcome.

Ischemic strokes are the most common (≈85%), the rest being hemorrhagic that include cerebral and subarachnoid (≈15%).[7] The Trial of Org10172 (TOAST) is the most commonly used classification that identifies five subtypes in acute ischemic stroke: 1) large artery atherosclerosis 2) cardio-embolism 3) small vessel occlusion 4) stroke of other determined etiology 5) stroke of undetermined etiology.[8]

The events resulting from any subtype of ischemic stroke result in the loss of blood supply, oxygen, nutrients and elimination of metabolic wastes. These resulting changes obstruct normal neuronal functioning.[9] This ultimately results in neuronal death/necrosis from occlusion of the vessel. The brain tissue is exquisitely sensitive to these changes, and the therapeutic window that is needed to prevent reversible ischemia from becoming irreversible infarction[10] is narrow and stresses the phrase "time is brain". This concept is especially important to minimizing evolving insult and controlling the propagation of ischemic penumbra.[11,12,13] Furthermore

from a therapeutic point of view, this crucial time provides a "window of opportunity" in reversing the neurological symptoms either partly or completely through acute interventional approaches, either invasively or non-invasive.[14]

Over the last two decades, a lot of stroke specific structured education, intervention trials, and diagnostic approaches have targeted this time period, resulting in better clinical outcomes with decreased associated mortality and morbidity. The modern stroke field is a fast advancing with an emphasis on endovascular stroke therapy/ interventional mechanical devices, and their combined use with thrombolytic agents for better clinical benefits.[15]

In the next few sections, we will discuss management updates in acute ischemic stroke ranging from stroke education to therapeutic strategies, and conclude by providing a brief overview of the advances that are on the horizon.

Table 1
Imaging Studies in Management of Acute Ischemic Stroke

Modality	Level of Evidence[32]	Use
NIHSS[33,34,35].	Level1 /Class1.	1) For easy communication between health care personnel. 2) Initial NIHSS predicts an eventual functional outcome. (NIHSS≥16 higher probability for severe disability or death and ≤ 6 good recovery. 3) Monitors on progression or worsening of the patient during a hospital stay. 4) NIHSS ≥12 likely for a presence of larger vessel occlusion.
NCCT[36,37].	Level1/Class1. Level2/ Class2.	1) Ruling out ICH and Mass Lesions. 2) To detect infarct core volume during first few hours of stroke onset.
CT Angiogram[38,39]	Level1/Class 1	1) To detect large vessel occlusion.
DW MRI[40,41,42].	Level1 /Class1	1) Early detection of Infarct core and 100 % sensitive in diagnosing acute stroke.

∗ ICH=Intra Cerebral hemorrhage; ∗NCCT=Non-contrast CT; ∗DW=Diffusion weighted.

Table 2
Initial Evaluation and Management of Acute Ischemic Stroke

Initial Evaluation and Management
1) Establishing for **C**irculation, **A**irway and **B**reathing. (**C-A-B**).
2) I.V Fluids=0.9% Normal Saline
3) If needed rapid sequence intubation
4) Blood pressure Management:(See Below)
5) Screening for Dysphagia
6) DVT prophylaxis with Mechanical devices
7) G.I prophylaxis with either H2 blockers or proton pump inhibitors
8) Maintenance of core body temperature to <32.7° C either with a use of acetaminophen or ibuprofen or external cooling devices in refractory cases.
9) Target of blood Glucose between 140-180 mg/dl

Stroke Education - Literacy, Behavior, and Proficiency

The frequency in administration of tPA to patients with an acute ischemic stroke within three hours of symptom onset has nearly doubled (4% to 7%) from 2003 to 2011.[15] Still the percent of ischemic stroke patients reaching the hospital within three hours of symptom onset is between 15% to 32%.[15,16,17] The percent of ischemic stroke patient receiving intravenous tPA therapy is in between 2% to 3%,[18] and patients who arrive at the hospital in time for stroke revascularization therapies is between 1% to 7%.[19] The central key for an effective treatment delivery and management of an ischemic stroke patient rely upon 1)Stroke Literacy, 2) Stroke Behavior, and 3) Stroke Proficiency.

1) Stroke Literacy

- Recognition of modifiable (Hypertension, Hyperlipidemia, Diabetes Mellitus) and non-modifiable stroke risk factors (age, gender and ethnicity).[20,21,22]
- Demonstrated stroke symptom awareness. [23,24,25,26]
- Correctly identifying the brain as where a stroke occurs.

2) Stroke Behavior

It is a response to use EMS/911 service[27,28,29] when stroke symptoms occur. EMS services, by contacting nearby stroke centers, bypass non-stroke centers and prepare the emergency staff and neurologist at the receiving hospital. This approach facilitates the rapid transportation for receiving reperfusion therapies within the window period.

3) Stroke Proficiency

Stroke proficiency is described as for having both stroke literacy and stroke behavior.[26]

The public initiatives (media, support groups, and annual stroke awareness day) have promoted stroke literacy, stroke behavior, and stroke proficiency among the communities. Likewise, tele-health stroke education has proven effective in educating remote and rural areas.[30]

The development of validated stroke assessments tools, neuroimaging and stroke teams have helped in early detection and increasing the eligibility for treatment. On arrival to the ED, an initial clinic assessment (history, medications, and comorbidities), time of symptom onset, NIHSS (National Institutes of Health Stroke Scale), "code stroke" order set (complete blood count, coagulation studies, EKG, emergent head CT) will help in determining eligibility for thrombolytic therapy and in ruling out the stroke mimics. After initial physical examination, the only tests that should

lead to decide their eligibility for rtPA are non-contrast CT (NCCT) head and serum glucose level, as hypoglycemia mimics an acute ischemic stroke. However, other tests including blood counts, metabolic panel, coagulation panel, cardiac enzymes and, electrocardiogram, are important but should, in general, not delay in the initiation of treatment.

The level/class of evidence and role of NIHSS and various neuroimaging modalities used in evaluating an acute ischemic stroke as shown in Table 1.

The perfusion studies (CTP and MRP) are Level 3/ Class IIb and may aid in providing further information in diagnosis, management, and prognostic assessment, but their use still remains limited to special situations.[31,32,33.] The initial evaluation with NIHSS followed by CT or CT followed by NIHSS are both accepted protocols that are practiced by different institutions. The CTA has proven beneficial in rapidly selecting patients for thrombectomy in anterior circulation large vessel occlusions, it is likely to be inclusive as part of the initial stroke imaging protocols[31,34] at most institutes. The other key measures and evaluations that need to be observed in acute ischemic stroke patients are as summarized in Table 2.[35]

Stroke education is crucial to the creation of stroke awareness, so the endorsement of stroke specific education in communities and primary care settings would benefit influencing the stroke performance outcome measures. Rapid entry into the health care system is required to achieve rapid thrombolysis in eligible patients. rapid thrombolysis in eligible patients.

Blood Pressure Management

Blood pressure management is very critical in patients with acute ischemic stroke. The International Stroke Trial with 17,398 of ischemic stroke has shown high and low blood pressures are independent prognostic factors for a poor outcome. This study even found a U-shaped relationship between baseline systolic blood pressure and death or dependency.[36] In theory, the "permissive hypertension" in acute ischemic stroke patient is to enhance perfusion and prevent hemorrhagic conversion.[37] The recommended systolic and diastolic blood pressure before administration of IV rtPA in eligible patients is <185 mm HG and 110 mm HG respectively.[34,35] After administration of IV rtPA the blood pressure should be controlled below 180/105, besides monitoring for every 15 minutes for 2 hours, then every 30 minutes for 6 hours, and lastly for every 60 minutes for 24 hours.[38,39] Blood pressure management and adherence to guidelines is crucial, as the pressures either too low or high can influence outcomes.

Thrombolytic Therapy

The intravenous recombinant tissue plasminogen activator (rtPA) is the only proven Level of Evidence 1, Class A recommendation approved by Food and Drug Administration for treatment within three hours of symptom onset, in patients with ischemic stroke.[40,41] The initial studies that have used the first generation thrombolytic Streptokinase and Urokinase have proven ineffective for treating patients with ischemic stroke.[42]

The pioneer study, "National Institute of Neurologic Disorders rtPA Stroke Study," showed the efficacy of thrombolytic when administered within three hours of symptom onset, with minimal or no disability three months

Table 3
Checklist for Inclusion and Exclusion Criteria for Thrombolytic Therapy

STROKE TEAM – RAPID EVALUATION

1. TIME PATIENT LAST KNOWN WELL: _____
2. TIME OF PATIENT ARRIVAL TO FACILITY: _____

Pre-Admission Blood Thinners & Plaque Stabilizers:

Antiplatelet therapy:	Aspirin [ ]	Plavix [ ]	
Anticoagulation:	Coumadin [ ]	Lovenox [ ]	Other: _____
Statin:	Yes [ ]	No [ ]	Which: _____

Cerebral Vascular Risk Factors:

Hypertension	Yes [ ]	No [ ]
Hyperlipidemia	Yes [ ]	No [ ]
Smoking	Yes [ ]	No [ ]
Atrial Fibrillation	Yes [ ]	No [ ]
Age >60 years	Yes [ ]	No [ ]
Diabetes	Yes [ ]	No [ ]

Exclusion Criteria for Tissue Plasminogen Activator (tPA)

1.	Evidence of an acute intracranial hemorrhage	Yes [ ]	No [ ]
2.	Major Early CT signs of infarction	Yes [ ]	No [ ]
3.	Another stroke, serious head trauma, intracranial surgery in the past 3 months	Yes [ ]	No [ ]
4.	Intracranial neoplasm, AVM, or an aneurysm	Yes [ ]	No [ ]
5.	Uncontrolled hypertension (systolic >185, diastolic >110)	Yes [ ]	No [ ]
6.	Rapidly improving or minor symptoms	Yes [ ]	No [ ]
7.	Symptoms suggesting subarachnoid hemorrhage	Yes [ ]	No [ ]
8.	History of intracranial bleed	Yes [ ]	No [ ]
9.	Major surgery in the past 14 days	Yes [ ]	No [ ]
10.	Known bleeding disorder	Yes [ ]	No [ ]
11.	GI or GU bleed in the past 3 weeks	Yes [ ]	No [ ]
12.	Arterial puncture at a non-compressible site in the past 7 days	Yes [ ]	No [ ]
13.	Seizure at the onset of stroke	Yes [ ]	No [ ]
14.	Pt >15, INR >1.7	Yes [ ]	No [ ]
15.	Heparin within the past 48 hours and elevated aPTT	Yes [ ]	No [ ]
16.	Use of direct thrombin inhibitors or direct factor Xa inhibitors with elevated sensitive laboratory tests (such as aPTT, INR, platelet count, and ECT; TT or appropriate factor Xa activity assays)	Yes [ ]	No [ ]
17.	Platelet count <100,000	Yes [ ]	No [ ]
18.	Serum Glucose <50mg/dL or >400mg/dL	Yes [ ]	No [ ]
19.	MI in the past 3 months	Yes [ ]	No [ ]

Exclusion Criteria of IV tPA within 3 to 4.5 hours

1.	Age >80 years	Yes [ ]	No [ ]
2.	Severe stroke (NIHSS>25)	Yes [ ]	No [ ]
3.	Taking an oral anticoagulant regardless of INR	Yes [ ]	No [ ]
4.	History of both diabetes and prior ischemic stroke	Yes [ ]	No [ ]

after treatment with a single IV dose of 0.9mg/Kg.[43] This study has shown favorable outcome in patients who were less than 75 years old and those with a NIHSS score less than 20, but patients >75 years still benefit within three hour symptom onset.[34] The more rapid the time to presentation and evaluation, the greater the benefit of thrombolysis:

1) Patients who received treatment within the first 90 minutes had a more favorable outcome at 3 months compared to patients who were treated between 90 and 180 minutes.[41,44]

2) For every 15 minute delay in treatment there is an estimated 4% reduction in the probability of good functional outcome.[45]

3) Every minute delay in treatment from symptom onset would result in loss of 1.8 days of extra healthy life.[46] Inclusion and exclusion criteria for treatment with rtPA are shown in Table 3. These must be reviewed with the patient or patient representative, and consent should be dscussed, all within this time frame.

The extended use of IV tPA in the 3- to 4.5-hour window is a recommendation but not an approved treatment by Food and Drug Administration. Given its off-label use, the consent to treat is generally required obtained from the patient or family member and need to be documented. It is based on the study of European Cooperative Acute Stroke Study III (ECASS III), which showed a favorable outcome in 821 ischemic stroke patients when treated with either rtPA or placebo within this time frame.[47] The analyses of several other clinical trials have failed to show any beneficial effect in administering rtPA within 4.5 to 6 hour symptom onset.[48]

The mild or resolving neurological deficits or with NIHSS score <4 should never be excluded on the basis of score, as several studies suggested poor outcome, progression of symptoms, or residual disability after failing to receive rtPA[49]. In fact, the more common medico-legal issue is failure to administer IV tPA with resulting functional impairment from stroke rather than from complications of tPA.

The other observant symptoms such as aphasia, gait problems, hemianopia, and large vessel occlusions on MRI should not be excluded, from treatment with tPA, as it has proven beneficial.

The doubts over administering rtPA to patients on novel oral anticoagulants (NOAC) dabigatran, rivaroxaban, apixaban, edoxaban, factor Xa inhibitors stems from the difficulty in measuring their effects. The accurate measurement of dabigatran through thrombin time (TT) or ecarin clotting time (ECT) and factor Xa inhibitors is not available in most emergency departments. Currently, there are no well-accepted guidelines on the time of last dose to the safety of rtPA administration, and these cases are approached individually, and often with the consultation of a clinical pharmacist.

The rtPA infusion should be stopped in patients who develop new neurological deficits after initiation of the drug with strong consideration for a STAT CT of the head. Approximately 6% of patients receiving thrombolytic develop symptomatic intracerebral hemorrhage.50 Neurosurgical consultation should be sought for any evident surgical management should hemorrhage be present. The other watchful conditions for acute neurological worsening are cerebral edema, stroke progression, recurrent stroke and seizures. The treatment to reverse coagulation consist of administering platelets (6-8U), cryoprecipitate with factor VIII and consideration of recombinant factor VIIa and fresh frozen plasma (FFP).51 Different institutes have different protocols and there is little evidence-based data to guide treatment.52,34 Other conditions to be considered with acute neurological worsening are cerebral edema, stroke progression, recurrent stroke and seizures.

Several studies that have used third and fourth generation thrombolytics (Tenecteplase, Reteplase, Desmoteplase and Ancrod) have failed to show any benefits in treating patients with acute ischemic stroke.[42]

The rtPA has proven very beneficial, when administered within three hours of symptom onset. In fact a common medico legal issue is, patient not getting IV tPA and having functional impairment from stroke and not from complications of tPA.

The emergence or reporting of newer symptoms and worsening clinical condition should dictate, discontinuation of infusion and reassessment of the patient.

Endovascular Therapies

The benefit of IV rtPA in large proximal vessel occlusions is limited and in some studies up to 57% to 58% patients die or become dependent, regardless of treatment with IV rtPA.[42,53] This has driven the search for more diagnostic and treatment approaches that can achieve higher rates of recanalization in less time with minimal risk to the patient. The 11th commandment in stroke treatment previously was "thou shall reserve endovascular therapy in the most desperate cases." The advancements in neuroimaging (CTA/CTP/MRP) have broadened the investigations and use of various endovascular therapies. The success of intra-arterial thrombolysis (IA) was well established with Prolyse in Acute Cerebral Thromboembolism II (PROACT II) study which showed 66% recanalization and 40% good neurological outcomes.[54] The Recanalization using Combined intravenous Rt-PA

and Neurointerventional ALgorithm for acute Ischemic StrokE (RECANALISE) study of intracranial occlusions showed 52% and 87% of recanalization at 24 hours but no significant difference in a mRS (modified Ranklin scale)at 90 days.[55] However, the use of IA with microcatheter is advantageous in delivering high concentrations of thrombolytics with reduced systemic exposure. Currently, the optimal dose of rtPA for IA treatment is not well established and is not approved by FDA.[56]

Theoretically, mechanical stent-retriever devices expedite recanalization, revascularization of large-artery occlusions with reduced risk of hemorrhage and longer time window for use when compared to thrombolytics.

The successive generations of MERCI (Mechanical Embolus Removal in Cerebral Ischemia) retriever devices that were used in various studies (MERCI pilot, MERCI1 and Multi-MERCI) yielded better recanalization rates which prompted other trials (Intra-arterial Versus Systemic Thrombolysis for Acute Ischemic Stroke [SYNTHESIS], Mechanical Retrieval and Recanalization of Stroke Clots Using Embolectomy [MR RESCUE], Interventional Management of Stroke III [IMS III]), resulting in negative outcome. These trials were heavily criticized for slow recruitment, time to intervention, lack of vascular imaging in selecting appropriate patients and the use of older devices instead of stent retrievers.

The subsequent trials demonstrated better results with stent retrievers, and when using neuroimaging to identifying patients with proximal anterior occlusions. The multi-center MRCLEAN[57] showed independent functional outcome, that was achieved at 90 days with endovascular therapy (33%) and standard care group therapy (19%). Below is the summary of the stent retriever trials that showed recanalization and better clinical outcome with the use of neuroimaging as shown in Table 4.

Endovascular therapies offer a new window of opportunity to treat when last well known is less than 6 hours or in "wake-up" strokes in some special cases. These therapies are only available at a limited number of highly specialized comprehensive stroke centers. These centers provide 24/7 care from a rapid response stroke team, consisting stroke neurologist, neuroendovascular specialistneurosurgeon, neurointensivist, anesthesiologist and nursing. They incorporate well-practiced treatment protocols, inpatient pathways, and provide rapid consultation and transfer services for patients in smaller centers.

Table 4
Summary of Treatment Trials with Endovascular Therapy

Name of trial	No. Of pts.	Mode of Intervention	Time Window (Hour)	Primary endpoint	Imaging selection
MR CLEAN	500	Endovascular treatment (stent retrievers 81.5%) plus usual care (87.1% IVT)	0-6	mRS at 90 days (mRS 0-2)	CT, CTA
ESCAPE	316	Endovascular treatment (stent retrievers 86.1%) plus standard care (72.7% IVT)	0-12	mRS at 90 days (OR for 1 point improvement in mRS)	CT, CTA (good/moderate collaterals), CTA Alberta Stroke Program Early CT score (ASPECTS).
EXTEND-IA	70	Endovascular thrombectomy (Solitaire FR stent retriever) plus IVT < 4.5 h	0-6	Reperfusion 24 h Early neurological improvement	CT, CTA, CT perfusion Core/mismatch-RAPID
SWIFT PRIME	196	Endovascular thrombectomy (Solitaire stent retriever) plus IVT <4.5 h	0-6	mRS shift at 90 days	CT, CTA, CT/MR perfusion, core/ mismatch and ASPECTS.
REVASCAT	206	Endovascular thrombectomy (Solitaire stent retriever) plus usual care (77% IVT)	0-8	mRS shift at 90 days	CT, CTA, ASPECTS.

*IVT=intravenous thrombolysis; mRs=Modified Ranklin scale; FR=Flow restoration

Management of Acute Ischemic Stroke in Ineligible Patients for Thrombolytic Therapy

Complications in Acute Ischemic Stroke Patients

Medical complications in patients with acute ischemic stroke effect clinical outcome and with an extended length of hospital stay.[63] Ingeman et al., study demonstrated that 25% of patients with stroke suffer from medical complications including[64] urinary tract infection (15.4%, pneumonia (9%), and constipation (6.8%). Depression is a disturbing and serious complication that is noted in 30% of patients, either early or in the later stages of stroke[65]. Unfortunately, it is under-recognized. Other complications that need to be remembered are fever, hyper/hypo glycemia and deep vein thrombosis. Patients with large strokes, even those not amenable to thrombolysis or mechanical intervention, are often monitored in an ICU setting as these patients may be at higher risk for intracerebral edema and resultant deterioration caused by mass effect.

Antiplatelet Therapy

Patients who are ineligible for thrombolysis should be administered aspirin immediately (81-325mg).[58] The administration of aspirin within 48 hours of ischemic stroke onset has been shown to reduce death and disability.[59, 60] The combination of clopidogrel and aspirin in selected patients showed better protection from subsequent strokes than aspirin alone in first 90 days without an increased risk for hemorrhage.[61] The long-term use of combination of clopidogrel and aspirin beyond 90 days is not recommended for secondary prevention as it may increase risk for hemorrhage with little therapeutic benefit.[58,62] Clopidogrel is slightly more effective than low dose aspirin in prevention of secondary stroke.

Anticoagulants

The use of anticoagulants and antithrombotic in acute ischemic stroke patients is declining as the studies on the use of heparin and other anticoagulants remain inconclusive.[66,67] Although newer anticoagulants such as direct thrombin inhibitors-dabigatran, and Factor Xa inhibitors-apixaban and rivaroxaban are equally or more effective than warfarin, data of their use in acute ischemic settings limited. Atrial fibrillation is still the most common indication and adds an overall risk of stroke of 5% per year.[68] The treatment with oral coagulants in these patients can often be started within one to two weeks after acute ischemic stroke.[69]

Rehabilitation in Acute Ischemic Stroke

The rehabilitation measures incorporating goal-targeted therapies hasten the recovery with considerable benefits, when compared to the natural recovery. Previous studies endorse early mobilization and intense neuro-rehabilitation for better functional outcomes.[70] The common impairments resulting from ischemic stroke are motor impairment, speech and language, swallowing, vision, sensation and cognition. The rehabilitation in these patients is a step wise and a progressive goal oriented process with an aim to reach their optimal physical, cognitive, emotional, communicative or social functional level.[71]

The last decade witnessed significant increases in the number of clinical trials with anticipated interventions that can enhance stroke rehabilitation phase. The advances in Brain–Computer Interface (BCI) devices, enabled their use into various clinical trials and have demonstrated gain in functional outcomes.[72] The potential of other therapies including motor imagery (MI),[73,74] virtual reality (VI),[75] robotic assisted training (RAT),[76] and drug augmentation of exercise training with amphetamines[77] in improving functional outcomes are on the horizon. Continued research is anticipated and needed.

These rehabilitation measures need to be established, optimized, and quantified for which they are being intervened and with cyclical reassessments to achieving the targeted functional outcomes.

Stem Cell-Based Therapies for Acute Ischemic Stroke

Stem cell-based therapies are an emerging new direction as potential regenerative or protective treatments for ischemic stroke. The Stem Cell Therapies as an Emerging Paradigm in Stoke (STEPS) committee suggests and establishes guidelines for preclinical and clinical trials. Studies in preclinical ischemic stroke models, have shown promising functional improvement with therapies that used embryonic stem cells (ESC), pluripotent stem cells (iPSC), neural stem cells (NSC), mesenchymal stem cells (MSC), and mononuclear cells (MNC) cell types.[78,79] The advances and understanding from basic researches empowered the translation of using various stem cell therapies in patients with ischemic stroke. However, the clinical trials in patients have shown limited benefit, needing more studies to establish the safety and efficacy of these cell therapies. So far MSCs are considered the only treatment to improve neurological function in stroke patients.[80] There are several ongoing clinical trials using adult stem cells to treat patients with ischemic stroke. See http://clinicaltrials.gov.

Conclusion

The telestroke has proven instrumental and effective in supporting awareness in rural and remote areas, and has increased the use of rtPA in rural areas by a factor of 2-6. Telemedicine has opened new frontiers in aiding community hospitals in triaging and providing treatment to complex acute ischemic stroke patients. Additionally, EMS and mobile stroke units have furthered accessibility to high-quality care in time for the better outcome. The designations for primary and comprehensive stroke centers with 24/7 dedicated stroke teams, advanced in providing complex medical care in acute settings, have expanded.

The current use of neuroprotectants, such as IV magnesium, was shown to be safe to use in mobile stroke units, with hope for advancement on near the horizon. The advancement of neuroimaging as a diagnostic tool is a significant factor in the development of endovascular therapeutics and expanded and judicious use of perfusion imaging may expand future stroke therapies.

The development of newer thrombolytics targeted towards fibrin specificity, rapid onset of action, and shorter half-life can be safe and effective in treating patients with AIS. The development of reversal agents for the newer oral anticoagulants can improve safety of these agents when used in an extended care setting.

Additionally, stem cell based therapies are emerging as a new therapeutic approach and as a potential restorative therapy. Technological advances are transforming neurorehabilitation interventions through BCI, MI, VR and RAT and may offer more promising outcomes.

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Disclosure

None reported.

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Understanding Patient Perceptions of Hypertension for Optimal Management in a Student-Run Free Clinic

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The status of hypertension management in this inner-city, student-run free clinic reflects how evidence-based practice does not fully translate into improved patient understanding and adherence to blood pressure control.



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Abstract

The burden of hypertension (HTN) is disproportionately high among adults with low socio-economic status. Our objective was to examine the knowledge, attitudes and barriers related to HTN among this cohort. Using a mixed-methods approach, we interviewed twenty adults at a student-run safety-net health clinic. Most patients recognized HTN-related risks, but themes of denial, financial burden and misinformation emerged when addressing treatment adherence. Our findings highlight an urgent need to address patient-centric approaches in HTN management.

Introduction

Hypertension (HTN) is a documented, modifiable cardiovascular risk factor with an estimated annual prevalence of 80 million and an attributable cost of 46 billion dollars in the United States.[1] However, in spite of the well-recognized importance of optimal blood pressure (BP) control, on average only one in three Americans with diagnosed HTN has well-controlled BP levels.[1-3] Among the subgroups considered at high risk for HTN, individuals who are of poor socio-economic status face an especially high burden with multiple comorbid conditions and other unique challenges that affect adherence to evidence-based recommendations.[1,4-10]Therefore, to achieve a favorable shift in BP control, it is imperative for health care professionals to better understand the patients' perspective of HTN-related burden and the perceived barriers for engagement and self-management.[11]

In the United States, medical schools have increasingly supported the establishment of student-run clinics to provide service-learning opportunities to medical students and to address the unmet health care needs in low-resource and underserved communities.[12,13] While the importance of these safety-net clinics is underscored in existing literature, [12,14] data on the quality of care delivered are sparse.[13, 15, 16] One published study examined the management of HTN but did not include a qualitative assessment of patient perceptions.[13] Our objective, therefore, was to examine the knowledge, attitudes and perceived barriers related to HTN among adults receiving care at our university-supported, student-run Sojourner Free Health Clinic (SFHC). SFHC was established in October 2004 and students provide weekly free outpatient medical care and medications to the homeless and underprivileged population in downtown Kansas City, Missouri, under faculty supervision.

Methods

Study Sample

The SFHC clinic staff identified potentially eligible, English speaking patients, age 18 years or older, with

previously established diagnosis or new diagnosis of essential HTN (systolic BP ≥ 140 mmHg or diastolic BP ≥90 mmHg)[17] and referred them to one of the authors (V.G.) for further screening and consent. Patients were excluded if they had a history of severe/persistent mental illness or were prescribed antipsychotic medications.

Data Collection

In this study, we collected both quantitative and qualitative data (mixed-method approach). One of the authors (V.G.) abstracted data from the medical charts and conducted participant interviews that were audiotaped. Data were obtained on participant socio-demographics and behavioral and clinical factors including HTN-related data. During the interview, participant responses were elicited on the following topics: 1) awareness and understanding about elevated BP and predisposing factors; 2) attitude toward the elevated BP and prescribed management options; and 3) perceived barriers related to adherence to recommended management strategies. Additionally, educational materials made available to HTN patients were reviewed for content.

Data Analysis

Quantitative data were summarized using descriptive statistics. Qualitative data were collected during patient interviews using audio-recordings and were subsequently transcribed verbatim. Two examiners (V.G., L.V) independently coded these data and conducted thematic analysis to determine emerging patterns and domains. Where discrepancies were identified in the thematic analysis between the two examiners, a third examiner (K.W.) adjudicated and verified them though an audit trail. Qualitative data were summarized using thick description provided by participants. The study was approved by the University of Missouri in Kansas City Adult Health Sciences Institutional Review Board.

Table 1: Profile of participants (N=20)

Age, years	**Percent**
30-39	5
40-49	40
50-59	35
60-69	15
70 or greater	5
Race	
White	10
Black	85
Other	5
Body mass index, kg/sq.m	
18.5-24.99	12
25.0-29.99	25
30.0 and above	63
Smoking and Alcohol use	
No Smoking, no Alcohol	21
Only Smoking	21
Only Alcohol	26
Smoking, Alcohol	32
Past Medical History	
Pulmonary	10
Heart	20
Surgery	50
Other	25
Systolic blood pressure at interview visit, mmHg	
<120	5
120-<140	50
140-<160	35
>=160	10
Diastolic blood pressure at interview visit, mmHg	
<80	5
80-<90	35
90-<100	45
>=100	15

Results

Between 8/25/2013 and 1/19/2014, 20 adults with diagnosed HTN were enrolled in the study; 18 participants were returning patients while two were new. The profiles of these participants are summarized in Table 1. Briefly, majority of participants were older than 50 years (55%), male (70%) and African- American (85%). Seventeen (85%) participants reported a family history of cardiovascular disease and sixteen (80%) reported either currently smoking or drinking alcohol.

Hypertension burden and patient perceived outcomes: Most participants with documented HTN reported that they received their diagnosis more than two years prior to this visit (n=16). Fourteen participants had elevated BP levels on the day of the interview. All twenty were prescribed antihypertensive medications and sixteen of them identified the SFHC as the primary source for these medications. Of the fourteen participants who were found to have high BP during the clinic visit, only eight reported that lifestyle modifications were addressed during the visit; five of these participants reported ever receiving any informational handouts on high BP from SFHC but four of them could not recall the content information.

Results of thematic analysis of qualitative data are summarized in Table 2. Several themes pertaining to the perceived knowledge and understanding of HTN emerged, as outlined on next page.

TABLE 2: Themes related to high blood pressure (number of responses)

Focus areas	Exemplar Quotes
What does high blood pressure mean to you?	
Negative Consequences (n=7)	"It means a death sentence"; "Increases the chances of a stroke"; "Could cause heart disease"; "It's lethal".
Physical symptoms, lack of control (n=3)	"Your head hurts a lot sometimes, when it starts, pills don't help, you just have to wait until it goes away."
What happens if blood pressure is not under control?	
Fear of death (n=4)	"If it's not treated, then I could die."
Health complications (n=9)	"High blood pressure affects internal organs, if too high it can …shut them down."
Symptoms (n=11)	"It can cause dizziness."; "it can affect your manhood …because the blood doesn't flow the way it should."
No perceived cardiovascular risk (n=1)	"I do not associate a heart condition that involves the heart with high blood pressure per se."
Why do you think you have high blood pressure?	
Hereditary (n=13)	"It's just hereditary, it runs in my family."; "My family has it in the genes.", "Oh it's genetic alright. They have proven that if your parents had a problem with high blood pressure, there's about a 95% chance you're going to have high blood pressure" "Well like I said, I had family, most of them have died off. I'm pretty sure I might have remaining family members that might have it, like I said it's almost like an epidemic or something of some sort, because a lot people have had it."
Emotions (n=7)	"Stress. I think being in this situation, not really being stable. I do notice that when I'm stressed, my blood pressure seems to go up. I try to stay to myself so I don't have to get upset because that plays a factor too."; "When I lost my job and I lost my home, things just got out of whack."
Lifestyle/Behaviors (n=11)	"Eating…salty foods...Not eating and exercising…days drinking and not taking my medication. Stress. Cigarette, alcohol, drugs."
Denial (n=1)	"I like eating potato chips, but I don't think that gave me high blood pressure."
Do you know of any lifestyle changes that need to be made to control high blood pressure?	
Stress (n=6)	"My mother had high blood pressure, she was keeping her grandson and every time she had him, her blood pressure was high. The doctors tell her the stress is coming from taking care of her grandson. So she sent the grandson back to live with his mama and the blood pressure became normal."
Diet (n=10)	"Stay away from spices, or sugar, food that's high in negative things."
Alcohol (n=2)	"I imagine drinking affects it too."
Physical Activity (n=5)	"You have to …. walk for 40 minutes per day, that's a good thing."
Workload (n=1)	"Basically I have other problems... diabetes .. my weight... so much goes not maintaining your high blood pressure and diabetes... trying to diet and exercise."

What does high blood pressure mean to the participant?

Several participants (7) associated elevated BP with negative outcomes including death, stroke or heart disease. A few mentioned that it manifested as physical symptoms and sometimes they did not have control over their symptoms.

What happens if blood pressure is not under control?

Eleven participants reported symptoms such as dizziness, headaches, vision changes, etc., which occurred as a result of uncontrolled high blood pressure. Nine participants stated that uncontrolled blood pressure could lead to health complications like "internal organs being shut down". Some were worried about mortality associated with high blood pressure.

Why do participants think they have elevated BP?

A majority of the participants (n=13) reported that hereditary factors contributed to their high BP. Eleven participants attributed it to lifestyle and behavioral factors. Seven recognized that emotional stressors caused their blood pressure to rise.

Does the participant know of any lifestyle changes that need to be made to control elevated BP?

Half of the participants knew that dietary changes such as cutting out salt can help control blood pressure. Some said reducing levels of stress (n=6) and increasing physical activity (n=5) could also help reduce blood pressure.

Themes that emerged from the analysis of participant perspectives on adherence to recommended lifestyle and behavioral changes are reported in Table 3. As seen by the exemplar quotes, while concerns about the complications related to uncontrolled HTN appeared to motivate some participants to follow recommended lifestyle changes, financial barriers and an underlying denial of risks associated with unhealthy behavioral factors emerged as potential deterrents.

Discussion

In this mixed-methods study, we report on patient-perceived outcomes related to hypertension among adults receiving care at a student-run free clinic. HTN is a chronic medical condition and a significant risk factor for heart disease and stroke.[1] In the United States, despite the appreciable increase in rates of controlled BP, the prevalence of HTN has remained at 29% since 1999 with a disproportionately greater burden seen across non-white adults and those of lower SES status.[1,3,4] As such, elevated BP poses a major challenge to the public health and healthcare system. In our sample of patients diagnosed with elevated BP, we observed variations in patients' understanding of the burden associated with elevated BP, their knowledge about importance of optimal control of BP levels, and their attitudes towards adherence to recommended treatment strategies. These findings potentially highlight the barriers to achieving optimal BP control especially among high-risk cohorts.

HTN is typically described as a "silent" disease with symptoms appearing only at markedly elevated levels.[18] However, several patients in the study associated the condition with physical symptoms such as dizziness and blurred vision. This is concerning as patients may be unaware of the continuous and incremental risk across the BP continuum and may not seek timely medical attention.

It is noteworthy that all of the participants in the study had some knowledge of behavioral modifications required to control HTN. They could correlate HTN to increased salt in their diet and lack of physical activity. However, they did not recognize that smoking cessation, limiting alcohol consumption, and other healthier food options could help with blood pressure control. The majority of patient participants who received lifestyle materials could not recall the information. Previous studies have shown that patients with HTN often do not receive counseling about behavior modification, and when they do, the information is often vague and difficult to understand.[7, 19,20] Our findings support this pattern and highlight an important opportunity for improvement in the delivery of patient education in a clinic setting.

Our data also highlight some of the social and economic barriers associated with lifestyle changes in this high-risk and vulnerable cohort. Participants were either unwilling to change their life-long practices or cited the high cost of healthier options. The majority of our participants were homeless and were limited in their access to nutritious food options as they relied on shelters for meals. Taken together, our findings have implications for the practice of evidence—based medicine in these resource-poor settings. While it is

TABLE 3: Domains related to adherence with prescribed practices for hypertension management

Domain	Exemplar Quotes
Misinformation	"I do not feel I need to need to check it. I believe all I need to do is keep taking the pills and if I keep taking my pills, then my blood pressure should be regulated."
Financial burden	"I don't follow it to the book, I work on certain things. When I'm hungry I eat, and it isn't always healthy; I don't shop for special foods or anything. I mean, you know certain foods that are good for you are potentially higher priced than food I might eat every day within my budget."
Denial	"When I'm ready to quit smoking, I'll stop. It doesn't affect me. I'm not coughing, I'm not wheezing, I'm not out of breath. I've been smoking for multiple years, like two and half decades, three decades."
Self-efficacy	"Watch my sodium intake…do a little cardio….trying to watch my soda pop intake…cut back on the alcohol. I've never done drugs, so I don't have that problem."
Personal preference	"…food just don't taste right without salt."
Accountability	"I'm in a situation and I know what causes my situation and you either do something about it or you just fall off and die."
Avoid bad outcomes	"Yes, I don't want to get on dialysis."

important that health care professionals address lifestyle modifications at every clinic visit, it is especially important that these recommendations account for the patient-specific characteristics and needs. Furthermore, interactions with patients should include teach-back methods to ensure proper communication and increase retention of critical information. Partnering with area shelters to offer heart-healthy diets may also be necessary to improve cardiovascular outcomes in this population.

Student-run free clinics occupy an important place in the training of health care professionals and provide first-hand real world experience in the care of underserved and high-risk populations. Indeed, organizations like the Institute of Medicine[21] and the Sullivan Alliance [22] have emphasized the need to strengthen our health care workforce to deliver culturally competent care to effectively address the needs of the underserved population. Student involvement in such safety-net clinics helps to promote that vision and is associated with a perceived improvement in the ability and interest in serving socio-economically disadvantaged communities.[14, 23] However, there remain opportunities for improvement. A survey of 209 student respondents revealed the challenges faced by them when addressing coordination of care among safety-net patients and the need for additional training on these issues in preparation for service in these settings. [24] It is imperative that academic and medical communities respond in a timely manner to better equip the next generation of health care professionals to deliver effective, efficient and patient-centered care. Furthermore, training in strategies of motivational interviewing like Elicit-Provide-Elicit (Asking, Listening, Informing) should allow for effective delivery of evidence-based recommendations and engagement of patients.[25] Finally, given the unacceptably high prevalence of modifiable lifestyle risk factors and the low impact of our current educational materials, we have identified a need to design a treatment plan that places a greater emphasis on lifestyle modifications and takes into consideration the social context of our patients. Future quality improvement efforts at the clinic are planned to implement and evaluate the effectiveness of such an algorithm in our clinic setting.

Our findings must be viewed in the context of the following limitations. The study was conducted among a convenience sample of adults receiving care at a single student-run free clinic, and as such, is limited in its generalizability. The scope of our study was limited in that the data were collected from a single interview of participants and we did not examine long-term outcomes including hospitalizations and cardiovascular events. Nonetheless, the burden of HTN reported in this study is similar to those reported in previous studies, [7, 20, 23] and fills a gap in the existing literature on patient-perceived outcomes in the management of hypertension in student-run free clinics.

Conclusion

The status of HTN management in this inner-city, student-run free clinic reflects how evidence-based practice does not fully translate into improved patient understanding and adherence to BP control. Our findings highlight an urgent need to address patient-centric measures in evidence-based HTN management among high-risk patients in low-resource settings.

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Disclosure

None reported. **MM**

Advertisers

Children's Hospital Medical Center ..... CV3 Jan/Feb, July/Aug,112, 165, 346, 441
Doctors Company..... 107, CV3 May/June, 337, 470
Missouri State University 345
MSM Foundation..CV2 Jan/Feb, Mar/Apr, May/June, July/Aug, Sept/Oct, Nov/Dec
MMPAC.....330, 428
Moneta Group 31
MSMA Insurance Agency ..... CV4 Jan/Feb, Mar/Apr, May/June, July/Aug, Sept/Oct, Nov/Dec
MSMA Member Get a Member.....343, 445
MU Orthopedic..... CV3 Mar/Apr, 169
PNC Bank ..... 148, CV3 Sept/Oct
PPIA.....27, 164, 447
ProAssurance 92, 251, 358
PSIC.....91
St. John's/Mercy 29, 147, 155, 257, 408, 443

Advocacy

Legislative Forecast by Kenny Jackson 426
Physician of the Day.....428

Alliance

Alliance Presidential Biography by Jana Wolfe.....217
Holiday Sharing Card..... CV3 Nov/Dec

American Medical Association

AMA Report
by Missouri Delegation 267, 430

Annual Convention

Attendance 240
Biography MSMA President by Ravi S. Johar 216
Council Minutes Summary 227
Credentials & Appointments 226
Delegate Handbook Reports 232
Elections.....239
50-Year Physician Pin.....222
Preliminary Program.....35, 468
Guest Speakers 34, 469
Presidential Address by John O. Stanley.....218
Presidential Inaugural Address by Ravi S. Johar 220
Resolutions/Actions 223
Service Awards.....225
Sponsors and Exhibitors 226

As I See It

Is Health Care Reform a Gathering Storm for Doctors?
by John B. Holds, MD 104
Life After Medicine: A Time to Smell the Roses
by Douglas B. Bogart, MD 176
Medical Errors, Hysteria, and Death
by Gerald Gianoli, MD.....274

Authors

Syed Akbar, MD.....72
Philip O. Alderson, MD 113
Rama Bandlamudi Atluri, MD.....127
Kevin T. Bauerle, MD 378
Zachary W. Bear, MD.....68
Matthew Benage, BS 48
Bhaskar Bhardwaj, MD 395
Jim Blaine, MD.....474
Raja S. Boddepalli, MD.....480
Robert Bondurant, RN, LCSW 16
Barbara Boshard, RN 72
Mitchell Botney, MD.....471
Sarah Bou Malham, MD.....361
Victoria E. Bouhairie, MD.....390
Breton Barrier, MD 182
Kathleen Brady, MD.....19
Daniel M. I. Britt 207
Emily C. Broxterman, MD.....187
Samer Cabbabe, MD.....202, 436
Wayne O. Carter, DVM, PhD 13
Rebecca Chitima-Matsiga, MPH 72
Kelly Cochran, Pharm D 72
Justin G. Cole, BS 476
Amelia G. Cooper.....347, 351
Blake A. Cooper, MD.....347
Kasey Cornell, MD 72
Danielle A. Cunningham, MSIV 415
Austin M. Dalrymple, DO.....118
John S. Daniels, MD 270
Geetha Davis, MD 58
Gregory S. Day, MD 207
Patrice "Patrick" Delafontaine, MD 36
Chitra Dinakar, MD 314, 409
James J. DiNicolantonio, PharmD 93, 272
Brett Donegan, MD 415
Betty M. Drees, MD 352
Dike Drummond, MD.....252, 332, 450
Bruce Dubin, DO 170
Craig Eck, MD.....40
Joel C. Eissenberg PhD 98
Stefanie Ellison, MD 310
Eden M. Esguerra, MD 256
Moss J. Fenberg, MD 44
Allysia Finley.....447
Rebbecca Fenton, MHA.....79
Frederick W. Fraunfelder, MD.....39
Brandi R. French, MD 480
Arthur H. Gale, MD 7, 244,328, 438
Benjamin Z. Galper, MD.....401
Margaret Gibson, MD 284, 305
Drew Glover, MD 305
Scott Gottlieb, MD 407, 444
Raghav Govindarajan, MD.....480
R. Stephen Griffith, MD 288
Jennifer Groner, DO.....284
Constance Guille, MD 19
Vritti Gupta, MD 487
John C. Hagan, III, MD 4, 152, 242, 247
Marc B. Hahn, DO 463
Dean P. Hainsworth, MD 44
Kenneth J. Hainsworth 44
Amneet Hans, MD.....179
Zoë Harcombe, PhD 93, 272
Charles Harris, MD 378
Linda Headrick, MD.....36
Randall Heller, MD.....415
Laura Hempstead, DO 284
Cynthia J. Herrick, MD 361
Jackie Herzberg, MD 182
Brandon Hetzler, MS 191
Emily Hillman, MD 310
Alexander R. Hover, MD 159
Miranda Huffman MD 487
Denise A. Hug, MD 187
Lisa H. Hutchison, MD.....415
Ravi S. Johar, MD 342, 429
Deborah Juhnke, IGP, CRM 34, 264
Bokkwan Jun, MD 63
Steven Keithahn, MD.....72
Jerry D. Kennett, MD.....401
Daniel Kim, MD 72
James P. Koller, MD 72

John Krystal, MD 19
Kathy Lentz, MD 53
Marina Litvin, MD 384
Megan Litzau, MD 310
David E. Madsen, BS 476
Brian Mahaffey, MD 191
Angellar Manguvo, PhD 310
Denise L. Mayfield, JD 463
Janet B. McGill, MD 390
Dustin McKnight, MD 40
Jeet Mehta, MD 179
Anthony A. Mikulec, MD 68
Mark Milton, Esq 22
Terry L. Moore, MD 117, 118
Nancy Morton, BS 16
David Moxley, MLIS 79
Brian D. Muegge, MD 367
Helen Murphy, BHS 409
Breck Nichols, MD 19
John H. Niemeyer, MD 420
Patricia J. Norton, MD 141
Schola Nwachukwu, MD 384
Michael L. O'Dell, MD 162, 279, 301
Frederick T. O'Donnell, MD 196
Evan L. O'Keefe, MS 395
James H. O'Keefe, MD 93, 249, 272, 395
Evan A. Olson, MD 53
Munir Patel, MD 415
Rebecca R. Pauly, MD 179, 487
David W. Parke II, MD 448
Peri Hickman Pepmueller, MD 136
Mihail Popescu, PhD 79
Patrick K. Price, MD 10
Rithwick Rajagopal, MD 372
Hariharan Regunath, MD 72
Jyotsna Reddy, MD 72
Frank Rieger, III, MD 40, 44
Beth Rosemergey, DO 280
Jon Schultz, MD 305
Teri Scott, DNP 280
Clay F. Semenkovich, MD 359
Srijan Sen, MD 19
Todd Shaffer, MD 284, 293
James Shortridge, DO 72
Peter Sloan, JD 264
Debra J. Sprague, MA 182
John O. Stanley, MD 26
William V. Stoecker, MD 476
Meryl Sundy, MD 40
BobbieJean Sweitzer, MD 320
Reema Syed, MD 131
Stanford C. Taylor, MD 372
Katherine K. Temprano, MD 123
Derek Thompson, MA 166
Garry S. Tobin, MD 367
Kathrene D. Valentine, BS, MS 141
Lakshmi Venkitachalam, PhD 487
Daniel C. Vinson, MD 182
David A. Voran, MD 280
Charles Van Way, III, MD 88, 260, 336, 434
Barbara Warady, RD 314
Haider Javed Warraich, MD 104
Weldon Webb, MA 36
W. Abraham White, MD 258
William L. White, MD 258
Karen B. Williams, PhD 487
Jamie Wolverton, BHS 409
Zachary Woolsey 476
Shumei Yun, MD 352
Zhuo Zhao, MS 19

Dean's Report

MU School of Medicine: Understanding the Importance of Inclusion, Diversity, and Civility in Education
by Patrice "Patrick" Delafontaine, MD 36
State of the School of Medicine
by Philip O. Alderson, MD 113
A Symbol of Commitment: MU School of Medicine Expansion Reflects Medical School's Mission
by Linda Headrick, MD, Weldon Webb, MA & Derek Thompson, MA 166
Innovative Curriculum Prepares Medical Students for a Lifetime of Learning and Patient Care
by Bruce Dubin, DO 170

Editorials

Making "Someday" Happen- The Years of Living Dangerously
by John C. Hagan, III, MD 4
Burning Down the Docs
by Charles Van Way, III, MD 88
"We Get By With a ~~Little~~ Lot of Help From Our Friends" Honoring Missouri Medicine's Editorial Board & Editors
by John C. Hagan, III, MD 152
Drug Company Compensated Physicians Role in Causing America's Deadly Opioid Epidemic: When Will We Learn?
by Arthur H. Gale, MD 244
Kansas City Center for Practical Bioethics at Epicenter of Congressional Concerns about Conflicts of Interest with Pain Pill Industry
by John C. Hagan III, MD 247
Obama Evaluates Obama Care Positively - Some Analysts Disagree With His Conclusions
by Arthur H. Gale, MD 328
Belonging to MSMA and Advocating for Medicine: Why It Matters for All Physicians
by John C. Hagan, III, MD 242
Fifty Years of Trauma
by Charles Van Way, III, MD 434

Medical-Legal

How to Improve Data Security in 2015
by Deborah Juhnke, IGP, CRM 34
Protecting Against Tax ID Theft and Avoiding Other Fraudulent Tax Schemes
by Mark Milton, Esq 22
Tax Identity Theft Scams Physicians
MSMA Staff 106, 418
Secure Disposal of Medical Practice Records
by Peter Sloan, JD & Deborah H. Juhnke, JD 264
Medical Patents and How New Instruments or Medications Might Be Patented
by Denise L. Mayfield, JD 463

Medical School Perspective

Missouri's First New Medical School in Nearly 50 Years Comes to Joplin
by Marc B. Hahn, DO 463

Military Medicine

War and Trauma: A History of Military Medicine
by Charles Van Way, III, MD 260
War and Trauma: A History of Military Medicine, Part II
by Charles Van Way, III, MD 336

Missouri Medicine Departments

1 Picture = 1,000 Words 12, 91
Book Review 108, 195
Contact Guide 3, 87, 11, 243, 327, 423
Correspondence 108, 275, 345, 467
Editorial Board 2, 86, 150, 242, 326, 422
Get to Know Your Physician Lawmakers 331, 425
Index for Missouri Medicine 493

In Memoriam 467
Membership Benefits 3, 87, 11, 243, 327, 423
Missouri Medicine In the News....30, 109, 178, 278, 344, 466
Statement of Ownership, Management and Circulation 357

Missouri Physicians Health Program

Implementing Change to Reduce Depression, Suicide, and Burnout Among Physicians-in-Training
by Robert Bondurant, RN, LCSW & Nancy Morton, BS....16
Web-Based Cognitive Behavioral Therapy Intervention for the Prevention of Suicidal Ideation in Medical Interns: A Randomized Clinical Trial
by Constance Guille, MD, Zhuo Zhao, MS, John Krystal, MD, Breck Nichols, MD, Kathleen Brady, MD, Srijan Sen, MD....19
Missouri Physicians Health Program Contributor Report....20

Perspective

The Measles Outbreak Coming Near You
by Haider Javed Warraich, MD 104
What You Don't Know About Vaccines Can Hurt You
The Hospital as a Factory and the Physician as an Assembly Line Worker
by Arthur H. Gale, MD 7
Sustainable Growth Rate Repeal: Why the "Why" Matters
by Patrick K. Price, MD 10
Growing the Life Sciences in Missouri & Kansas into a Global Epicenter – Path to 2025
by Wayne O. Carter, DVM, PhD....13
Problems with the 2015 Dietary Guidelines for Americans: An Alternative
by James J. DiNicolantonio, PharmD, Zoë Harcombe, PhD & James H. O'Keefe, MD 93
More than Meets the Eye: Eye Color and Alcoholism
by Joel C. Eissenberg PhD....98
John Wennberg, MD: The Influential Doctor Who Blames Physicians and Fee-For-Service Medicine for the High Cost of Health Care
by Arthur Gale, MD....156
The "Devil in the Details"
by Alexander R. Hover, MD....159
Lessons Learned During a Military Career
by Michael L. O'Dell, MD....162
Rising Mortality from Substance Abuse Among Middle-Aged White Americans
by James H. O'Keefe, MD....249
Burnout Basics – Symptoms, Effects, Prevalence and the Five Main Causes
by Dike Drummond, MD 252
Heartland Virus: A New Virus Discovered in Missouri
by Eden M. Esguerra, MD 256
Successfully Incorporating Trainees in Medical Missions
by W. Abraham White, MD & William L. White, MD....258
Prevent Physician Burnout: 8 Ways to Lower Stress and Get Home Sooner
by Dike Drummond, MD 332
The Burden and Benefits of Teenage Life with Type 1 Diabetes
by Amelia G. Cooper & Blake A. Cooper, MD 347
Sixteen-Year-Old Diabetic High School Student Conducts & Presents National Research
by Amelia G. Cooper 351
Reducing the Burden of Diabetes Mellitus in the State of Missouri: A Call to Action
by Betty M. Drees, MD & Shumei Yun, MD 352
Should Nurse Practitioners Be Allowed to Practice Independently?
by Samer Cabbabe, MD 436
Physicians Present Opposing Views of Hospitalists
by Arthur Gale, MD....438
Research of Note: Physician-Owned Surgical Hospitals Outperform Other Hospitals in Medicare Value-Based Purchasing Program
Journal of the American College of Surgeons....442
Sidebar: Inspector General: Medicare Spends Hundreds of Millions on Medically Unnecessary Chiropractic Services
Wall Street Journal....443
How Obama's FDA Keeps Generic Drugs Off the Market
by Scott Gottlieb, MD....444
A Brave New Weed
by Allysia Finley 447
Measuring and Mattering
by David W. Parke II, MD 448
The Joint Commission Deserves Some Blame for the Opioid Crisis
by Skeptical Scalpel, MD....449
Prevent Physician Burnout: 4 Work-Life Balance Tools
by Dike Drummond, MD 450

Point/Counterpoint

Problems with the 2015 Dietary Guidelines for Americans: A Rebuttal
by John S. Daniels, MD....270
A Response to a Rebuttal
by James J. DiNicolantonio, PharmD, Zoe Harcombe, PhD & James H. O'Keefe, MD....272

President's Forum

A Call for Fairness in Drug Prices
by John O. Stanley, MD....26
E-Cigarettes: Safer Than Tobacco?
by Ravi S. Johar, MD....342
Advocating for What Is Important to Medicine
by Ravi S. Johar, MD....429

Scientific Articles by Issue Release Date & Theme

Ophthalmology
by University of Missouri School of Medicine

MU Ophthalmology Charts a Future of Growth
by Frederick W. Fraunfelder, MD 39
Visual Acuity Outcomes of Toric Lens Implantation in Patients Undergoing Cataract Surgery at a Residency Training Program
by Meryl Sundy, MD, Dustin McKnight, MD, Craig Eck, MD & Frank Rieger, III, MD....40
Vitrectomy as a Risk Factor for Complicated Cataract Surgery
by Moss J. Fenberg, MD, Kenneth J. Hainsworth, Frank G.Rieger III, MD & Dean P. Hainsworth, MD....44
Vaccine-Associated Uveitis
by Matthew Benage, BS & Frederick W. Fraunfelder, MD 48
Central Retinal Artery Occlusion: A Literature Review and the Rationale for Hyperbaric Oxygen Therapy
by Evan A. Olson, MD & Kathy Lentz, MD....53
The Evolution of Cataract Surgery
by Geetha Davis, MD....58
Diagnostic Considerations in Patients Presenting with Transient Vision Loss
by Bokkwan Jun, MD....63

Rheumatology
Saint Louis University School of Medicine

Rheumatology Update: 2016
by Terry L. Moore, MD 117
Laboratory Studies in Autoimmune Diseases
by Terry L. Moore, MD & Austin M. Dalrymple, DO....118
A Review of Raynaud's Disease
by Katherine K. Temprano, MD 123
Inflammatory Myopathies
by Rama Bandlamudi Atluri, MD 127
Evaluating the Limping Child: A Rheumatology Perspective
by Reema Syed, MD 131
Undifferentiated Connective Tissue Disease, Mixed Connective Tissue Disease, and Overlap Syndromes in Rheumatology
by Peri Hickman Pepmueller, MD 136

Community and Family Medicine
University of Missouri - Kansas City School of Medicine

UMKC Community & Family Medicine: A Heritage of Service Since 1851
by Michael O'Dell, MD....279
The "Magic Triangle" Foundation to Effective Use of Information Technology in the Exam Room
by David A. Voran, MD, Beth Rosemergey, DO & Teri Scott, DNP 280
Clinical Competency Committee: Tools for Developing Tomorrow's Physician Leaders
by Laura Hempstead, DO, Margaret Gibson, MD, Todd Shaffer, MD & Jennifer Groner, DO 284

A Triad of Dermatologic Dilemmas
by R. Stephen Griffith, MD....288
Primary Care Physician Supply for Missouri
by Todd Shaffer, MD....293
What is a Patient-Centered Medical Home?
by Michael L. O'Dell, MD....301
To Supplement or Not
by Margaret E. Gibson, MD, Jon Schultz, MD & Drew Glover, MD....305

Diabetes
Washington University School of Medicine

Diabetes Update 2016:
What Bartleby the Scrivener Can Teach Us About Diabetes Care
by Clay F. Semenkovich, MD....359
New Pharmacologic Agents for Diabetes Treatment
by Sarah Bou Malham, MD & Cynthia J. Herrick, MD....361
Improving Diabetes Care with Technology and Information Management
by Brian D. Muegge, MD & Garry S. Tobin, MD....367
Modern Strategies to Save Sight in Diabetes
by Stanford C. Taylor, MD & Rithwick Rajagopal, MD....372
Glucocorticoids and Diabetes
by Kevin T. Bauerle, MD & Charles Harris, MD....378
Cystic Fibrosis Related Diabetes: a Unique Challenge in Diabetes Care
by Marina Litvin, MD & Schola Nwachukwu, MD....384
Diabetic Kidney Disease
by Victoria E. Bouhairie, MD & Janet B. McGill, MD....390
Death by Carbs: Added Sugars and Refined Carbohydrates Cause Diabetes and Cardiovascular Disease in Asian Indians
by Bhaskar Bhardwaj, MD, Evan L. O'Keefe, MS & James H. O'Keefe, MD....395

Join Missouri Medicine's Index of Authors



Instructions for Authors
www.msma.org/missouri-medicine

Scientific & Clinical Manuscripts
Departments, Perspectives & Opinions

- Medical-Legal - Legal topics that range from professional liability to ethics.
- Socio-Economic - Articles on legislation, policy, insurance, management, etc.
- Public Health - Reports that cover topical and important public health issues.
- Perspectives - Topics presented by health care professionals with different areas of expertise.
- As I See It - A forum of general interest.
- In the News - Summaries of MSMA business and highlights of members.
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Additional Scientific

Tur n on the Music: Cochlear Implants
by Zachary W. Bear, MD & Anthony A. Mikulec, MD....68
Is It Painful to Manage Chronic Pain? A Cross-Sectional Study of Physicians In-Training in a University Program
by Hariharan Regunath, MD, Kelly Cochran, Pharm D, Kasey Cornell, MD, James Shortridge, DO, Daniel Kim, MD, Syed Akbar, MD, Barbara Boshard, RN, Rebecca Chitima-Matsiga, MPH, Jyotsna Reddy, MD, Steven Keithahn, MD & James P. Koller, MD....72
Hospital Personnel Attitude Toward Utilization of Depth Imaging Technology in Hospital Rooms
by Rebbecca Fenton, MHA, Mihail Popescu, PhD & David Moxley, MLIS....79
A Retrospective Study on Infant Bed-sharing in a Clinical Practice Located in an Urban Cluster
by Patricia J. Norton, MD & Kathrene D. Valentine, BS, MS....141
Septic Shock Secondary to a Urinary Tract Infection with Pediococcus Pentosaceus
by Amneet Hans, MD, Jeet Mehta, MD & Rebecca R. Pauly, MD....179
Substance Use in Women of Reproductive Age
by Jackie Herzberg, MD, Breton Barrier, MD, Debra J. Sprague, MA & Daniel C. Vinson, MD....182
Retinopathy of Prematurity: A Review of Current Screening Guidelines and Treatment Optionsv
by Emily C. Broxterman, MD & Denise A. Hug, MD....187
Melior Via: A Better Way to Integrate and Restore Movement into Orthopedic Rehabilitation
by Brandon Hetzler, MS & Brian Mahaffey, MD....191
Preoperative Evaluation of the Surgical Patient
by Frederick T. O'Donnell, MD....196
Plastic Surgery after Massive Weight Loss
by Samer W. Cabbabe, MD....202
Over-Prescribed Medications, Under-Appreciated Risks: A Review of the Cognitive Effects of Anticholinergic Medications in Older Adults
by Daniel M. I. Britt & Gregory S. Day, MD....207
Emergency Medicine Interest Group Procedural Simulation Conference: An Experience for Multiple Learner Levels
by Megan Litzau, MD, Emily Hillman, MD, Stefanie Ellison, MD & Angellar Manguvo, PhD....310
Food Allergy Care: "It Takes a Team"
by Chitra Dinakar, MD & Barbara Warady, RD....314
Perioperative Evaluation and Optimization of Patients at Risk of Cardiac Complications for Non-Cardiac Surgery
by BobbieJean Sweitzer, MD....320
Calcific Aortic Stenosis:New Approaches to an Old Disease
by Jerry D. Kennett, MD & Benjamin Z. Galper, MD....401
Warning: Medicare May Be Bad for Your Heart
by Scott Gottlieb, MD....407
Building a Targeted Asthma Education and Management Program
by Helen Murphy, BHS, Jamie Wolverton, BHS & Chitra Dinakar, MD....409
Bridging the Radiology-Pediatrics Interaction Gap by Incorporating a PGY4 Radiology Resident into the General Pediatrics Team
by Munir Patel, MD, Randall Heller, MD, Danielle A. Cunningham, MSIV, Brett Donegan, MD & Lisa H. Hutchison, MD....415
When Did You Last Speak A Radiologist or Visit the Radiology Department?
by John H. Niemeyer, MD....420
The Evolution of a Regional Lung Cancer Screening Program
by Mitchell Botney, MD....471
Low Dose CT for Lung Cancer Screening Could Provide Substantial Benefit
by Jim Blaine, MD....474
Boys at Risk: Fatal Accidental Fentanyl Ingestions in Children
by William V. Stoecker, MD, David E. Madsen, BS, Justin G. Cole, BS & Zachary Woolsey....476
Acute Ischemic Stroke: Current Status and Future Directions
by Brandi R. French, MD, Raja S. Boddepalli, MD & Raghav Govindarajan, MD....480
Understanding Patient Perceptions of Hypertension for Optimal Management in a Student-Run Free Clinic
by Vritti Gupta, MD, Karen B. Williams, PhD, Miranda Huffman MD, Rebecca R. Pauly, MD & Lakshmi Venkitachalam, PhD....487

Volume 113:6:1-496 November/December 2016 **MM**

Missouri State Medical Association Alliance

Holiday Sharing Card

From the following who most generously gave to the Missouri State Medical Foundation, to its Alliance Scholarship Fund, and to the American Medical Association Foundation.

We bring you tidings of good cheer, & wish you a happy, healthy & peaceful New Year.

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Erol Amon, MD, JD & Sally Amon
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In honor of Richard C. Aiken, MD, PhD
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