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The Journal of the Missouri State Medical Association www.msma.org/missouri-medicine November/December 2017



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MSMA Missouri State Medical Association

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Missouri Medicine, a non-profit continuous publication since 1904, is owned by the Missouri State Medical Association. It is the most important health publication in Missouri and Kansas, and also draws readers from contiguous states Illinois, Iowa, Nebraska, Oklahoma, and Arkansas. It has a national footprint, with our papers reported in the national medical and public media, and are regularly cited in high impact factor journals. We reach both national and international subscribers. By working closely with nine Missouri schools of medicine, we present state of the art reviews and are a platform for cooperation and advocacy for medical education. We are a primary source for clinical education for most of the state's physicians, especially in rural Missouri and Kansas. Previous issues are archived and available at www.msma.org/missouri-medicine-library.

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Saying Good-Bye to a Good Man Doing a Great Job: Tom Holloway

by John C. Hagan, III, MD

As the Missouri State Medical Association bids its former expert lobbyist and present Executive Vice President farewell, I find this editorial especially difficult to write on both a personal and organizational level. If MSMA had a Hall of Fame, Tom Holloway would be a shoo in for first round enshrinement. Our profession, our organization, our medical schools, our practices, and our patients are so much the better for the Herculean efforts of Tom over his 30-year tenure at MSMA. Tom makes so many things look easy you have to wonder if the man ever breaks a sweat or blows his cool. Competence and sangfroid Tom has in abundance.

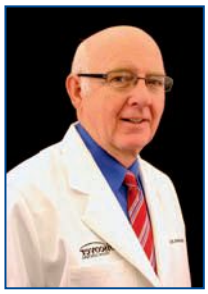
I met Tom Holloway in my leadership position in the Missouri Society of Eye Physicians and Surgeons. No question in my mind that without Holloway's heroics that Missouri's aggressive optometrists would have legislated full medical and surgical parity with physician ophthalmologists. I've never heard a senator, representative, or governor of either political stripe say anything other than "You are fortunate to have such a capable and persuasive advocate for your cause."

One expertise of Tom's is getting all the disparate prancing legislative horses pulling in the same direction before and during the law-making circus. Thus ring-master Holloway is extremely proficient at working with medical and surgical state organizations to co-ordinate legislative efforts, provide guidance and insight, work with other lobbyists to fight the good fight on many issues but perennially and ineffably scope-of-practice. Tom knows everyone and everything that happens in Jefferson City. I have suggested he write a "tell-all" book but he feels 'What happens in Jefferson City stays in Jefferson City." Ever the professional!

Seven years ago stepping out of the musty halls of the capitol and into the executive directorship of MSMA, Tom has fashioned during his tenure one of the most effective, least expensive, and best managed state associations in the entire country. His tenure has been all the more difficult given perturbatious national trends such as the dramatic decline of physicians in private practice and into employment by hospitals; the decreased participation in organized medicine by newly minted physicians and the ever-escalating pressure to inappropriately expand scope of practice as a solution to physician shortages. Tom has directed MSMA's many rousing successes with inimitable aplomb. Often, notably twice with tort reform, Tom has assembled an ineluctable consortium of organizations to pass key legislation or slay pernicious bills.

So reluctantly, forever in his debt, we exclaim gratitude to Tom Holloway for all he has done for MSMA. We wish him and his wife Leslie every personal and professional success, good health, and much happiness. On behalf of *Missouri Medicine*, the editors and editorial board, we thank Tom for his constant and engaged stewardship of our Journal.

Lastly and personally - drawing from the deep and thoroughly fermented well of Irish wisdom: may the hinges of our friendship never grow rusty. Sláinte! Salute! Shalom! Bon voyage! Bottoms up! Happy trails!



John C. Hagan, III, MD, FACS, FAAO, MSMA member since 1975, is a Kansas City, Missouri, ophthalmologist and *Missouri Medicine* Editor since 2000. He is a multi-year Super Diamond Contributor to MMPAC.
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Tom Holloway- an Enigma

by Jerry Kennett, MD
MSMA member since 1980

One of Webster's definitions of enigma is, "inscrutable or mysterious." To me this defines Tom Holloway. As Chairman of the MSMA legislative affairs committee for fifteen years I worked with Tom while he was our lobbyist and also Executive Vice President. I do not think many people know some of his talents. How many know he spends many of his vacations on archaeological excavations? Tom is reserved and does not like the limelight but excelled as our lobbyist, I think primarily because of his high integrity and extreme honesty. Legislators could always rely on what he told them. Tom also has a tremendous vocabulary and literary talent. For years I kept pestering Tom that he should write a regular column for a newspaper or journal or now of course a blog. Tom provided great leadership for our MSMA, we will miss him, and Tom I am still waiting to read your columns.

Guiding MSMA with a Steady Hand

by David O. Barbe, MD
American Medical Association President
MSMA member since 1985

Although strong physician leadership is important to MSMA, a strong, effective executive vice-president with a cool head and steady hand who can guide MSMA year in and year out is critical to MSMA's success. Tom Holloway has provided our MSMA with that strong and steady guidance, first as a ultra-competent lobbyist and more recently at the highest level of organization leadership. Tom's experience in long service to MSMA, his expertise in association management and advocacy, and his understanding of the needs of Missouri physicians and patients and how MSMA can meet those needs have made him an extraordinary EVP. As importantly, Tom has been a mentor for me as well as dozens of MSMA officers, Councilors and other students, resident physicians and practicing physicians over the years. MSMA and Missouri medicine is much better because of Tom's leadership. Thank you!

Fare Well, MSMA

by Tom Holloway
Below is Tom's farewell address to the MSMA Council in October 2017.

If fate smiles on you, and your feet land at MSMA, and if good fortune lets them linger, many great things will befall you.

You will have the privilege to carry this organization's majestic banner onto political battlefields in the great marbled hallways of governance.

You will argue and fight, bargain and cajole; you will run roughshod, and be run over roughshod –all for the glorious cause.

You will be yelled at by a governor, and threatened angrily by another; but you also will stand at governors' sides as they sign into law some words you wrote and fought tooth and nail to win.

You will tangle with the IRS, and battle the Department of Labor; you will fight against and partner with government regulators of every conceivable sort.

You will sign affidavits and be served a federal subpoena; you will testify in civil court, and you will testify in criminal court.

You will be applauded when you don't deserve it, and you will dodge criticism when you do.

If fate smiles on you and your feet land at MSMA, you will get to be part of the most marvelous surrounding of teammates. Family, really – remarkably talented and dedicated, if occasionally eccentric and exasperating.

You will celebrate their birthdays, and revel at their weddings.

You will see their children born, and you will see those children's children born.

You will take them to the emergency room, you will visit them in their convalescence. You will drive them to work in the morning, and take them to their treatment in the evening.

You will share bread and drink; you will share joy and heartache.

You will pray against their illness, and you will bear the unbearable weight of a casket.

Above all else, you will have the singular honor to work for and with the very brightest and the best of mankind's most noble calling. A chance to soar with the eagles (even though you've never seen a weasel get sucked into a jet engine).

If fate smiles on you and your feet land at MSMA, you will not get rich. But you will be forever and immeasurably enriched.

And from the very core of me, I thank you for that – for letting me be a part of this extraordinary family for thirty extraordinary years.



I am an incompetent wordsmith to adequately bid you a fair farewell, so let me borrow a few words from Bob Dylan, who said:

"May God bless and keep you always,
May your wishes all come true,
May you always do for others
And let others do for you.
May you build a ladder to the stars
And climb on every rung,
May you stay forever young."

Thank you so very much.

2017: A Signal Year's Review at *Missouri Medicine*

by John C. Hagan, III, MD

This was an outstanding year for your 114-year-old *Missouri Medicine* medical journal. We continued our long-standing format of themed issues developed by state medical schools. For the first time an osteopathic medical school produced an entire theme with September/October's "Building on Our Osteopathic Foundation" by Kansas City University of Medicine & Biosciences (KCUMB). In a propitious reprise, looking ahead the January/February 2018 issue will be produced by A.T. Still University-Kirksville College of Osteopathic Medicine. MSMA and *Missouri Medicine* remains committed and the 'big tent' for advocacy, representation, and publication of all medical schools in the Show-Me state.

New editorial board members this year include: Susan Berdy, MD (Allergy/Immunology), Kan N. Huang, MD (Hematology/Oncology), and John B. Holds, MD (Ophthalmology). I want to thank my good friend Chuck Lederer, MD, for his service and counsel as our long-time ophthalmology expert.

The second book based on a series of articles in our Journal was published: *The Science of Near-Death Experiences.* (Missouri University Press, 2017 John C. Hagan III, MD Editor and is available from MSMA or Amazon.com). The book has had favorable international exposure and review in both professional and lay publications. Your Editor has been invited to give Grand Rounds on the book in Audrain County, KCUMB, North Kansas City Hospital and next year Santa Barbara Cottage General Hospital. A first literature report appeared in September/October, "Uveitis Following Treatment of Verruca Vulgaris with Intralesional Candida Antigen" by Doctors Crowley, Hagan, Dyer and Brundige.

One of the most important reasons for *Missouri Medicine*'s national reputation and ability to attract quality manuscripts and have academic departments eagerly commit to producing our signature theme issues is our content goes to internet-search availability via our indexing services including MEDLINE, PubMed and EBSCO host data bases. Approved and encouraged by the Publication Committee/Contributing Editors, about three years ago we began a long, rigorous qualifying procedures to have all our content linked at PubMed Central. Except for the *New England Journal of Medicine,* this is unprecedented by a state medical journal. *Missouri Medicine* was approved and set to 'go live' in early Fall. We then learned that MEDLINE was going to a new publication method and they were requiring re-certification of all publications approved prior to 1988. *Missouri Medicine* has been indexed by MEDLINE for over 40 years. Moreover, PubMed Central requires journals to be included in MEDLINE as a condition for their acceptance. So, we had to stand down from linking with PubMed Central while we reapplied to MEDLINE. This all boils down to over a hundred hours of work by *Missouri Medicine* most notably Liz Fleenor, our consummate managing editor and one-woman production staff, your Editor, the Publication Committee and MSMA staff. We eagerly anticipate MEDLINE approval in several months of our very strong re-application and retrospective uploading all 2017 content plus all future publications to PubMed Central.

All of us at *Missouri Medicine* thank MSMA and its members for 114 years of encouragement, participation, and support. **MM**

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Forecast for 2018 Legislative Session

by Jeff Howell, JD

Prescription Drug Monitoring, Tort Reform, Insurance, Scope of Practice... *the List Goes On*

Missouri's 99th General Assembly will reconvene on January 3, 2018, to begin their second session of legislative work. They will work until May 18, 2018, when the state constitution mandates their adjournment. In between those dates, your MSMA lobbyists will be advancing a pro-physician agenda, while simultaneously heading off attempts to interfere with your profession. Following is a list of some of the issues we anticipate dealing with during the first five months of the new year.

Prescription Drug Monitoring Program

Last year's effort to establish a statewide Prescription Drug Monitoring Program (PDMP) died in the last days of session when some legislators disapproved of supplanting the St. Louis County PDMP with a lesser state-run version. Since the end of the 2017 session, the St. Louis County program has only strengthened as counties and municipalities have become frustrated at the lack of a comprehensive state PDMP. At the time of this writing, 49 cities and counties have joined the St. Louis County program. This local PDMP now covers almost 80% of the state's patients and 90% of its prescribers. In July, the Governor issued an executive order that allows that Department of Health and Senior Services to data mine prescription information from Express Scripts in a curious effort to identify over-prescribers. This new government surveillance program has not yet been launched due to push back by the General Assembly. We anticipate the introduction of a comprehensive statewide PDMP bill this year. We will oppose efforts to mandate physician utilization of the PDMP. As things progress, we may come to realize the best way to implement a statewide PDMP is to allow the state to assume the St. Louis County program, thereby giving the state an operational head start.



Jeff Howell, JD, is MSMA's General Counsel and Director of Governmental Relations.
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Tort Reform

The state's tort reform coalition (of which, MSMA is a member) had a very impressive 2017. Among other tort issues the coalition managed to pass were physician friendly changes to the collateral source rule and expert witness standards. We foresee fewer tort issues this year that would have a direct impact on physicians, but we will continue to pursue some of the coalition's objectives, including an overhaul of the state's venue laws. In addition, there are two cases pending before the state Supreme Court which ask the court to either significantly weaken or declare unconstitutional the state's affidavit of merit law. We will keep a close eye on the Court's eventual decisions, as well as continue to monitor efforts to assail the noneconomic damages cap in medical malpractice cases.

Insurance

It appears that much of our time during the upcoming session will be dedicated to fighting a growing number of disastrous policies unilaterally implemented by insurance companies in the past year. The most well-documented of these issues is Anthem's new policy in which they retroactively deny payment for certain emergency room services. We will be introducing legislation to ensure that whether or not the prudent layperson standard is met is ultimately determined by the patient's symptoms, not the insurance company. We will attempt to limit insurer's ability to unilaterally amend contracts, especially those which opt physicians into new networks. Redefining "clinical peer," as it relates to adverse determination appeals, to ensure that



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they are actively practicing and board certified will be on our agenda. We will also take a close look at changing payment recoupment practices, banning claims payment by virtual credit cards, and some anti-retaliation provisions. It appears that we will have a close working relationship with our insurance industry counterparts this coming spring.

APRNs

For a number of years we have battled the advance practice registered nurses over their scope of practice and their attempts to desecrate the collaborative practice act. We are anticipating that their advocates will once again introduce legislation to remove collaborative practice and the necessary patient protections that accompany it. Last year, we agreed to make some of the changes the APRNs had pursued for years. Once we had done so, they demanded even more, and their efforts eventually died. We may see a repeat of that compromise language in 2018. In addition, we will likely seek to allow a stand alone APRN license for those accomplished nurses under the authority of the Board of Registration for the Healing Arts. That board already oversees licensure for assistant physicians and PAs, two groups with nearly identical scopes of practice as APRNs. They will likely oppose this effort, but we think it commonsense, and will perhaps open further avenues for compromise in the future.

Tanning Bed Prohibition

Forty-four states have some type of restriction on indoor tanning use by minors. In 2014, MSMA was instrumental in passing a law that required parental consent for minors who utilize tanning beds. Frequent exposure to ultraviolet rays by young people greatly increases their risk of developing melanoma. This year, we will make an effort to completely ban the use of tanning beds by people under 17 years of age. If successful, Missouri will join 16 other states in this prohibition. MSMA will be part of a large coalition of organizations that will lead this effort, including the cancer society, dermatology associations, and children's hospitals.

Fund Sweep

From time to time, the General Assembly finds itself in a financial pinch so seemingly dire that they try to sweep the professional licensure fees collected by the Board of Registration for the Healing Arts. That was case last year when the legislature sought additional funds to close a gap in expected in-home care funding. With a week remaining in the 2017 session, we found ourselves protecting the Board's funds. The Board of Healing Arts receives no public funding; its operating expenses are borne entirely from fees. Therefore, any skimming of those funds for other state purposes would, in effect, be a tax on physicians. We will watch for this financial sleight-of-hand as the session progresses.

Grab Bag

As is the case every legislative session, we are sure to contend with some issues we dealt with last year that failed to cross the finish line. Expect to see us contend with the annual effort to repeal the motorcycle helmet law. It is highly likely we will lock horns at some point with the chiropractors, athletic trainers, radiology technicians, physical therapists, and maybe the professional counselors as well. We will keep a watchful eye on the activities of the statewide MO HealthNet managed care companies, and fight for increased physician reimbursement and funding for public health initiatives. It's bound to be another busy year for organized medicine.

If you wish, there are a number of things you can do to assist us in these endeavors. First, please consider volunteering as the MSMA Physician of the Day in the Capitol. This rewarding program gives participants insight into MSMA's physician advocacy, and can initiate or further a relationship between MSMA members and their legislators. Plus…it's a lot of fun. You can find available dates on the MSMA Advocacy webpage. Second, keep in mind that 2018 is an election year. Get to know who is running in your area. See if they're friendly to our efforts, and share that information with us. This data is incredibly helpful to the Missouri Medical PAC as election day draws near. Speaking of the PAC, there's no better way for you to support candidates that support organized medicine than through a PAC donation. Please consider giving. Finally, as a member, don't hesitate to reach out to the MSMA lobbyists when you have a question or concern. Advocacy on your and your patients behalf is one of your many MSMA member benefits.

Follow our adventures during the 2018 legislative session in MSMA's weekly *Legislative Report*. The first edition will head out the door on January 4, 2018, and members will continue receiving it each Thursday throughout session.

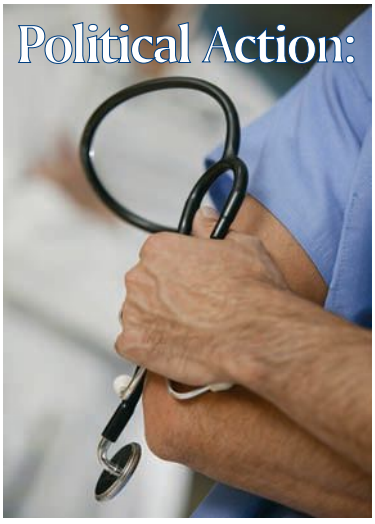
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10 Reasons to Volunteer as MSMA Physician of the Day



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PERSPECTIVE

Stay Out of the Emergency Room – Or Else

by Jonathan Patterson, MD

Treating patients in a busy, crowded emergency room (ER) for an ailment that could be handled in a less expensive and intensive venue is an all too familiar problem for ER physicians and nurses. Often those less costly options are not available to patients in an acceptable time frame. Other times, minor problems that could be addressed in an outpatient setting make their way to ground zero of our healthcare system – the emergency room.

One insurance company has decided to take action against such putative abuse of the insurance policies they sell. Anthem Blue Cross Blue Shield has devised a cost-shifting scheme to deny coverage, after the fact, for care that they deem retrospectively to have been non-emergent. This judgement is made in hindsight after review of tests and examinations done in the ER. "Save the ER for emergencies – or you'll be responsible for the cost," they ominously informed their patients by mail.

This policy will no doubt create numerous scenarios where a patient who reasonably sought emergency care will be left with an enormous bill if Anthem, many months after the hospital visit, decides the ER visit was not "truly emergent." For example, if a patient presented to the ER for a cough and fever, concerned about a possible pneumonia, and was found to have only a viral cold, Anthem could refuse to pay as they deem the patient's use of the emergency room unnecessary. "Sorry, next time have a real pneumonia," they might say in a denial letter. Such a policy, which seems to violate state and federal laws, could be financially ruinous for many of Missouri's families. The reason people purchase health insurance is to protect against the enormous costs associated with hospital care. As anyone who has ever looked at their hospital bill knows, those charges begin as soon as they snap on that paper bracelet.



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While this cost-shifting scheme may deter some from seeking non-emergent care in the ER, it will likely have dangerous and possibly deadly unintended consequences. That is because it will increase the number of patients who choose not to seek emergency care because they are afraid of being entirely responsible for an astronomical ER bill.

Sometimes a headache is a headache. Sometimes a headache is meningitis. Anthem's scheme unreasonably places the burden on the patient to diagnose themselves, make the right decision without the benefit of medical knowledge, labs or x-rays, or possibly face huge life-changing financial repercussions. This violates the federal Prudent Layperson standard, which aims to ensure that insurance coverage is not based on the ultimate diagnosis, but on whether a prudent person, defined as someone with average knowledge of health and medicine, might anticipate serious impairment to his or her health in an emergency situation. So far, Anthem says they have only penalized 1% of claims in this manner. However, they do not say how many people chose not to seek care for real emergencies—because that is a number they cannot know.

Insurance companies have a legitimate reason to be alarmed by the costs of insuring those who misuse the emergency room. Perhaps a more appropriate first step for Anthem would be to seek out its most frequent ER users and identify the reason they are utilizing ERs so often and address those needs and educate that sub-group. Oftentimes the reasons are quite evident. Alternative options for care will require incentivizing primary care networks to improve access. In our healthcare system, where patients are becoming sicker and technology can do more and more, the opportunities for constructive systemic change must be explored. Unfortunately, Anthem Blue Cross Blue Shield's policy of penalizing patients after the fact is self-serving for the company and will be catastrophic financially for some of their subscribers.

All of the players in this system – patients, doctors, nurses, and insurance companies - have a responsibility to make good use of healthcare resources. However, this scheme is dangerous and could potentially lead to serious illness and even death due to patients choosing to forgo seeking care for financial reasons. Missouri's patients – the customers paying those ever-increasing premiums – deserve better. **MM**


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Physician Advocacy: The AMA Interim Meeting 2017

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

The Interim Meeting of the American Medical Association considered matters of policy, including legislative priorities, November 11-14, in Honolulu, Hawaii.

David Barbe, MD, Mountain Grove, Mo., continues to serve as the President of the American Medical Association. Dr Barbe spoke to the House of Delegates (HOD), emphasizing AMA leadership in several activities: easing requirements of MACRA-MIPS, increasing public awareness of the opioid crisis, controlling chronic diseases, fostering innovations in physician practice, and supporting changes in medical education. James Madara, MD, AMA CEO, discussed the role of the AMA in improving medical education, facilitating innovation in medical technology, and promoting a new data model to facilitate sharing of data.

Other members of the delegation had leadership roles. Edmond Cabbabe, MD, St. Louis, serves on the Council for Long Range Planning and Development. Charles Van Way, MD, Kansas City, serves on the Steering Committee of OSMAP (see below).

OSMAP, the Organization of State Medical Association Presidents, meets the day before AMA meetings, and is known for its programs presenting current and controversial topics. This year, the presentations concerned the proposed American Health Care Act, monitored injection centers, electronic participation in medical association decision-making, and the ever-unpopular maintenance of certification. Dr Barbe discussed "arcs of focus" of the AMA: improving health outcomes, facilitating physician practice, and accelerating change in medical education. He also addressed on the APRN compact, a new attempt to promote independent practice of advanced practice nurses. This issue was also discussed in the HOD. There was a presentation on Delaware's use of blockchain technology to facilitate pre-authorization. Colorado reported on their virtual House of Delegates.

The AMA is highly concerned about the increasing number of deaths secondary to opioid overdose, which has reached 60,000 in the last year. A number of resolutions addressed this "epidemic," which now takes more lives than motor vehicle crashes and gun violence combined. But no one has easy answers. Resolutions suggested better controls, prescribing smaller amounts, better treatment in correctional facilities, and other actions which may help. One resolution advocated the increased availability of naloxone, the opioid antagonist. Over-reliance on patient surveys may be pushing physicians to prescribe more opioids. Everyone, including the AMA, points fingers at the medical profession. But physicians cannot stop patients from wanting drugs, nor do they have any control over the companies who make the drugs. Physicians should be part of the effort to slow opioid abuse, but we cannot solve the problem by ourselves.

The current health crisis in Puerto Rico and the US Virgin Islands was addressed. The AMA has provided assistance to physician clinics on the islands. The AMA will encourage Medicare and Medicaid funding waivers to maintain access to health care. In general, the AMA continues to strongly support Medicaid by opposing work requirements, caps on Federal spending, and in general supporting Medicaid expansion.

There was continuing concern over electronic prescribing of drugs. Inadequate EHR systems, federal regulations, and state laws all set up barriers to adopting this new technology. The full promise of electronic prescribing has never been achieved. The AMA continues to lobby Congress and Federal agencies to remove such



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Attedning the AMA Interim Meeting, from left: Drs. Rebecca Hierholzer, Joe Corrado, Jim Conant, Charles Van Way, David Barbe, William Huffaker, Medical Student Shannon Tai, Drs. Edmond Cabbabe, Warren Lovinger, and Medical Students Ariel Carpenter and Jared Lammert.

barriers as requiring a physician's handwritten attestation and signature for certain drugs, like opioids.

Each meeting, the Board of Trustees (BOT) and several councils report on significant matters, usually in response to resolutions from previous meetings. This year, there were significant reports on peer review, physician competence and self-assessment, and mergers of secular and religiously-affiliated hospitals. Several of these were sent back to the BOT for a re-do, including physician competence and mergers. There was a report on fees charged by open access journals. It turns out that one AMA journal may charge up to $5,000 for open access publication. Nonetheless, the AMA will work with the Federal Trade Commission to control so-called "predatory publishers." All of these reports, and others, are available on the AMA web site.

There were two resolutions concerning freedom of speech by physicians. Resolutions in previous years addressed legislative limits on physician speech. But these centered on lawsuits against physician leaders and retaliation by health systems and hospitals. A BOT report on media relations also addressed this issue, and was returned to the BOT for revisions. Unfortunately, free speech is under serious attack from activists on both ends of the political spectrum. This issue will persist.

Immigration was discussed in two resolutions. The AMA remains supportive of immigration in general, especially of physicians, scientists, and other health workers. A resolution adopted by the HOD opposed allowing immigration enforcement (ICE) agents in hospitals. There have been some unpleasant incidents recently of patients seized while in their hospital beds.

Physician burnout, a concern at the last meeting, was only addressed superficially. One resolution suggested that hospitals and systems should institute physician wellness programs, to include emotional and psychological wellness. Another suggested changing "burnout" to "demoralization," as if changing the name might make it easier to deal with the problem.

Resolutions supported state maternal mortality reviews, improving treatment of maternal depression, and promoting methadone treatment for opioid abuse in breastfeeding mothers. A resolution addressed concerns about the adverse effects of electronic and/or social media on mental and physical health. Another advocated limiting "screen time" for children. A resolution concerned modifications of prescriptions by pharmacists, including

generic or therapeutic substitution of medications and regulating the quantity of medicine allowed. Your AMA will continue to work with all stakeholders to improve this situation.

A great deal of attention was paid to education. The Council on medical Education issued a report on the "crowding-out" of students in US schools by students from off-shore schools. Caribbean schools do not have teaching hospitals, but they can afford to pay hospitals large amounts to host their students. There has been legislation passed in Texas to control crowding-out. There are only so many hospitals which can host medical student education, currently about 15% of US hospitals. If they begin to sell educational slots to offshore schools, US medical education may be adversely affected. This is related to the problem of too few resident positions. Our model of medical education, both undergraduate and graduate, appears to be reaching its limits. Yet, we still project a physician shortage, and there is still great market demand for physicians. We must expand our capacity, for both undergraduate and graduate. A bill is in Congress authorizing a 15% increase in the cap on resident positions which was set 20 years ago. It's a start.



Missouri Physicians Health Program Executive Director Bob Bondurant (left), presented a program on physician health and well-being during the AMA Meeting. Center is Missouri physician and AMA President David Barbe, and right, co-presenter Warren Pendergast, MD, Federation of State Physician Health Programs.

That said, a resolution proposing a "house physician" category was not well-received. This is being considered in Florida, allowing MD and DO graduates to work as hospital physicians under supervision. Missouri has such a program already, and other states are considering such. But allowing state legislatures or Congress to manipulate medical education further than they already do has significant risks. The HOD has consistently voted against such interventions.

A resolution addressed the use of remotely scored computer-generated video interviews in order to evaluate interpersonal skills. The Association of American Medical Colleges (AAMC) presently requires this interview of all applicants to Emergency Medicine programs, and intends to expand this to all residency applicants. There is no evidence that these interviews improve resident selection. Of course, it generates income for the AAMC. Testing interpersonal skills by requiring the applicant to talk to a computer seems like an idea whose time should never come. The HOD overwhelmingly supported delaying and, if possible, stopping this practice.

The AMA remains very concerned about the cost of medications. Pricing of drugs must become more transparent. The AMA will work with the federal government and with pharmaceutical manufacturers, pharmacies, and pharmacy managers to control the cost of medications. Drug costs are only a part of total health care spending, but they are increasing more rapidly than any other component.

A Council on Science and Public Health issued reports on drug shortages, organ donation, neuropathic pain, respiratory inhalers, and cannabis use. There was general approval for retaining AMA policy on marijuana. The AMA opposes legalization both of medical uses of marijuana and of recreational use, but supports allowing research into medical uses of marijuana. A bill currently in Congress would relax some of the restrictions on cannabis research.

One resolution advocated pay for all physicians required to take call for emergency services and/or trauma. This was the subject of brisk debate, but such on-call pay has become more and more common in an increasing number of specialties.

On a delegation update, William Huffaker, MD, will be retiring from the group. Your AMA delegation continues to support your interests at the national level. Keep those e-mails coming! And be thinking of new resolutions for the MSMA Annual Convention next spring. **MM**

Reframing the Relevance: Engaging Residents and Fellows in Organized Medicine

by Joanne Loethen, MD

Is Organized Medicine Relevant?

This was a question posed in a recent Medscape article by writer Leigh Page.[1] The digital age, growth of specialty societies, and an increasing number of employed physicians are a few issues posed as challenges to modern day organizing bodies. But does this reflect a lack of relevance?

In a subsequent article, Missouri physicians and AMA President, David Barbe, MD, highlighted efforts of the American Medical Association (AMA) and state societies which help shape the healthcare system, illustrating that the relevance of organized medicine has never been more evident.[2] The AMA and state societies are closely connected and working diligently to advocate in an ever-challenging healthcare and political environment – from shaping Medicare payment and delivery, optimizing access to healthcare for all, arming physicians with tools to address the opioid epidemic, and enhancing resources to ensure the personal well-being of physicians.

The relevance of organized medicine is clear. Therefore, it is not so much a lack of relevance that presents a challenge to organized medicine. Rather, what may be necessary is a "reframing" of the relevance as it relates to today's physician - specifically as it relates to residents, fellows, and early-career physicians. This group will drive the future of organized medicine and sustain its relevance for generations to come. With this in mind, how can organized medicine better portray its relevance to trainees and early-career physicians?



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Reframe the Investment

As the time crunch of post-graduate training descends on residents and fellows, the return on investment from both a time and financial perspective must be worthwhile. Specialty societies excel on this front. Members obtain networking within their specialty as well as opportunities for research publication - all of which enhance their profile for fellowship applications. Providing comparable programing may help trainees justify their participation in organized medicine. Such programming might include resources to prevent resident burn-out, financial strategies for early-career physicians, opportunities for leadership development, and advice for contract negotiations. Board review resources and related product discounts also add value that attracts training physicians.

Start with Why

Despite the relevance of current policy to future practice, residents often do not correlate the gravity of policy decisions with their current role. Residency and fellowship provide a buffer from the legal, financial, and reimbursement issues faced by active physicians. In his book Start With Why, marketing consultant Simon Sinek emphasizes how individuals will not truly buy into a product, service, movement, or idea until they understand the 'why' behind it.[3] It's not what we do, it's why we do it. Reshaping the message to better communicate organized medicine's 'why' will aid in engaging more trainees. Highlighting issues that weigh heavily on this group, such as easing student loan debt and preserving loan forgiveness programs, will further illustrate organized medicine's vested interest in trainees and early-career physicians.

Mentorship

Ask any active participant of a medical society such as the Missouri State Medical Association (MSMA) or AMA how she or he first became involved in organized medicine. The most common answer? Mentorship. A faculty member, colleague, or other acquaintance invited the individual to a meeting or encouraged him or her to draft a resolution. The



MSMA Resident and Fellow Section officers at the MSMA House of Delegates. From left: Secretary: Adam Grumke, MD, Vice Chair: Daniel Young, MD, Chair: Joanne Loethen, MD, Vice-Councilor: Mihir Brahmbhatt, MD, Councilor: Nathan Nolan, MD.

rest is history. Word of mouth recruitment from a trusted individual is invaluable. The MSMA is fostering mentorship programs at the medical student level, but a similar program may serve residents and fellows as well.

High-Yield Digital

Digital communications are important. But as physicians and trainees are flooded with digital messaging on a daily basis, the quality of this communication has become crucial. Only that which contains high-quality, user-friendly content stands out. Creating high-yield digital communications that simplify the complexities of health care policy will help to draw in millennial physicians.

Summary

The challenge of engaging trainees in organized medicine is multi-factorial and extends beyond the issues listed above. Both the AMA and MSMA are taking steps to encourage resident involvement, but we have a long way to go. Enhancing resident and fellow engagement in organized medicine will certainly require a dynamic approach - one that must continue to adapt and "reframe the relevance" for this group of potential members. The future of organized medicine and our next generation of leaders depend on it.

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Resident members shall be limited to those members of the Resident and Fellow Section (RFS) who are serving a full-time postgraduate training program approved by the American Medical Association or the American Osteopathic Association and shall enjoy all of the privileges of active membership.

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Thoughts on Medical Education

by Charles W. Van Way, III, MD

One of the things we all have in common is our exposure to the medical education system. Now, we've had different experiences. Some of us are MDs, some DOs. Some have been educated in foreign schools, either in their home countries, or in international venues. And we all have opinions about our own education, and how we should be educating our successors. In my case, I've spent all of my career in teaching hospitals, with both residents and students. I've had a lot to do with medical education. Being part of the system has been something of a mixed experience.

It has been more than 100 years since the Flexner report in 1910 condemned the general quality of medical education. The report held up as an ideal the Johns Hopkins model of university-based post-graduate physician education. Since then, this model has become almost universal in the United States and Canada, with some variations between MD and DO schools. Medicine has become totally integrated into higher education, with all that implies for quality of medical education. All students mix classroom education with "hands-on" work in hospitals. While the level of responsibility allowed to students has decreased steadily over the past 30-40 years, students still see patients, and participate in their care.

But the model is beginning to show its age. Most obviously, it's failed to meet society's demand for physicians. Granted, US schools have been expanding recently, but we're still not keeping up. We have widespread shortages in nearly all specialties.

One side effect of the shortage has been the development of some 31 "offshore" schools in the Caribbean.[1] These schools are closer to the 19th-century proprietary schools than they are to the Hopkins model.



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Academic classwork is in the school, instruction is in English, and clinical training usually takes place in US hospitals with considerably less direct supervision than is common in MD and DO schools in the US. Whatever one may think about the quality of these schools, they are fully subscribed. Collectively, they turn out several thousand physicians per year.

The medical education system doesn't serve students particularly well. The cost is astronomical. The average student graduates with $200,000 of educational debt. Imagine the burden on students who marry one another. And of course, we underpay residents so badly that the debt simply accumulates. To get through the process, a student must undergo at least three high-stakes selection processes. Undergraduate college, medical school, and then residency. And maybe one or two more for fellowships. Plus, an ever-increasing number of national examinations. Small wonder that the smart kids are going into engineering or computer science.

From the student's standpoint, the system wastes a lot of time. Four to six years of undergraduate, four years of medical school and then three to ten years of residency and/fellowship training. The biggest change since 1910 has, of course, been resident education. Making medicine a four-year post-graduate school was a great idea in 1910. Today, we're piling on the years. The age of finishing resident education is up to the mid- or late-thirties. The sheer amount of knowledge required of today's physician makes it difficult to cut much time out of medical school. University of Missouri - Kansas City manages to cut college plus medical school down to six years, so it can be done. But only one other school in the country is doing that. While other types of accelerated programs are enjoying a small surge of popularity, past surges have died out.

To add insult to injury, we're busily adding medical school capacity to a system without adding residency positions. Right now, there aren't enough positions for all graduates. Currently, 6% of US medical school graduates go unmatched, as do 50% of foreign graduates. Including American graduates of Caribbean schools. Now, only about 600 of the 5,000 acute care hospitals have residency programs. And only about 300 have multiple programs. There are many hospitals that could support residency

training, but have chosen not to. Why? There are a lot of barriers. Many physicians, perhaps most, are unwilling to commit to the time and effort required to train residents. Patients often have mixed feelings about being cared for by residents. Most new medical schools are being established around hospitals which already have residency programs, so a new school does not mean new residency slots. Hospitals find it expensive, even with Federal subsidies for residency training. The Federal subsidy is capped. Although there is some room for new programs, it is very hard to expand existing programs. Lastly, accreditation for new programs is fairly difficult, as it should be.

Let's see. Medical students are poorly served. Residents are overworked and underpaid. There aren't enough residency slots. Does the system work well for anyone? Well, medical school faculty do well enough. I've had a great career as a faculty physician. They're often overworked, but that's true for all doctors. They tend to be underpaid relative to other physicians in the same specialty, so that's sort of a minus. Job security is pretty good, unless you move up to a chair. Deans do very well, often making nearly as much as hospital executives. But their turnover makes mayflies look long-lived, so there's a lot of insecurity.

Teaching hospitals are clear winners. We have built some of the world's best hospitals and health systems around our major teaching hospitals. Locally, imagine Kansas City without Kansas University Medical Center or Truman Medical Center. Whatever we do to fix the system, we should preserve these institutions. Indeed, while the teaching hospital model is too expensive for all hospitals, we would be well-advised to incorporate that model into more of our non-teaching hospitals.

We do not, let me say, need a 21st century Flexner report. Our medical education system continues to produce bright and well-trained young physicians. Residency programs do a very good job of training both generalists and specialists. We're doing something right. No, we're doing a great deal right. But we need to improve How?

We should reduce barriers to medical education. Early commitment to medical school would help. Shortening both undergraduate and medical school would be positive. Further, it is vital to increase the number of residency positions available. Right now, we have 28,000 positions and 42,000 applicants, or 1½ applicants for each position.[2] There's a long way to go. Creating more residency slots is absolutely vital. The increased number of medical school graduates isn't going to do any good if they cannot get trained.

As noted above, the teaching hospital model is extremely strong. But it is also expensive and difficult. Many hospitals simply cannot afford to have residents, and many physicians cannot afford to incorporate teaching activities into their practices. So as we are making up our wish list, we need to address how we can incorporate teaching into more hospitals and more practices.

We should remove harassments. Right now, we require four separate tests of students, three of which are before graduation. The silliest of these is Step 2CS, which requires students to pay $1,000, travel to one of six centers, and talk with "simulated" patients to test whether they can take a history and physical.[3] Really? Our schools are so bad that we need to test the medical equivalent of reading and writing? The pass rate is 96% for US graduates, so it's not as if the test serves any real purpose. Of course, somebody benefits. The USMLE collects in the neighborhood of $20 million a year from students taking the exam.

We should do something about debt. The national need for physicians is a serious matter. Perhaps we should underwrite medical education, to a much greater degree than at present. Universities tend to view medical schools as cash cows, and medical students as captives. Of course, the problem isn't just medical schools. Cost inflation in higher education is about twice as high as health care cost inflation, which itself is twice as high as everything else. Somehow, we need to get educational costs under control. If education is a national priority, as all politicians say it is, then why do we keep making it more expensive?

What can we do to make residency training more bearable? We've cut down somewhat on the workload, but it's still very high. Pay is pretty much capped because Medicare pays for most residency training. And of course, no hospital will pay residents more than they get from the Feds. It's cheap labor, after all. Supply and demand doesn't work here. It's a controlled market. But residents still should be paid better. Paying subsistence wages to a 35-year-old professional is not going to motivate young people to follow us into medicine.

The system isn't broke. But it's creaking. It's time to fix it before it DOES break.

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Data Integration and e-Commerce Threats Challenging Providers

by Christopher A. Budke & John A. Ferguson

The explosive growth of data integration and e-commerce has resulted in new and emerging threats to every service provider, including healthcare professionals. As more procedures and services are integrated with technology, these threats will continue to become more sophisticated and common. Healthcare professionals appear especially vulnerable to these risks as fraudsters presume they have higher incomes, are more focused on patient care than data and e-commerce risks, and have access to large amounts of confidential data. This article provides guidance to healthcare professionals on identifying, avoiding and reacting to these challenges.

Internet Frauds

The 2016 Internet Crime Report published by the FBI's Internet Crime Complaint Center (IC3) reported the receipt of 298,728 internet crime complaints, with reported losses in excess of $1.3 billion. While these numbers are staggering, the report estimates that only 15 percent of the nation's fraud victims report their crimes.[1] While internet crimes vary widely – including non-payment/non-delivery and lottery/sweepstakes schemes, investment frauds, government impersonations, "hacktivist" activities and ransomware – there are certain internet-based frauds that frequently target healthcare professions.





This article was written by former FBI Special Agent and firm special investigator Christopher A. Budke, (left), in the Kansas City office and associate John A. Ferguson, (right), in the Dallas office of Husch Blackwell. The information contained in this article should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general information purposes only, and readers are urged to consult their own attorney concerning their specific situation and specific legal questions.
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Phishing/Vishing/Smishing/Pharming

Cyber criminals, who run the gamut from individual mischief-makers to sophisticated state-sponsored entities, most commonly break into networks to gain access to sensitive data, or, in some cases, data on a victim's computer is locked, typically by encryption, and payment is demanded before the ransomed data is decrypted and access returned to the victim. Professional service providers, including healthcare organizations, are increasingly targeted as hackers attempt to exploit providers' fiduciary responsibility to protect sensitive data and the consequences for failing to do so.

Phishing

This is defined as the fraudulent practice of sending emails purportedly from reputable companies to induce the receiver to reveal protected and/or private information. According to Alan Paller, director of research at the SANS Institute, 95 percent of all attacks on enterprise networks gained entry through "spear phishing,"[2] sophisticated phishing attacks that are carefully targeted to give the appearance of being sent by an acquaintance. Because the fraudster must understand the departmental and leadership structures of victim companies, these attacks may indicate an existing compromise of a company email account.

Spear phishing attacks are difficult to detect because the fraudulent email appears to be from a trusted sender and is designed to induce the receiver to respond in an otherwise appropriate way. Phishing attacks commonly attempt to induce the receiver to click on a hyperlink that, if clicked, downloads a Trojan virus designed to bypass security software and allow access into networks. They may also seek to induce the recipients to provide passwords or other sensitive information, or to induce the transfer of funds. These sorts of attacks often lead to ransomware or extortion demands.

Vishing

Similar to phishing, vishing involves the fraudulent practice of making phone calls or leaving voicemail messages purporting to be from reputable companies in an effort to induce individuals to reveal protected information or take other actions compromising the security of their personal

"There are only two types of companies: those that have been hacked and those that will be."
– Robert Mueller, former FBI director

information and accounts. Instead of exploiting a victim's lack of data security awareness, these fraudsters will utilize social engineering techniques to gain the trust of victims to induce their desired actions.

Smishing

Also known as SMS phishing, this type of attack targets mobile phone text messaging. Like email phishing attacks, these text messages often contain hyperlinks designed to download a Trojan virus that can bypass mobile phone security settings.

Pharming

This is defined as the fraudulent practice of directing internet users to illicit websites that mimic the appearance of legitimate websites in order to obtain protected and private information. Healthcare professionals must be vigilant to ensure they are using legitimate third-party websites before transferring confidential and protected information.

Data Breaches

The question is not if your medical practice will experience a data breach as a result of cyber-criminal activities, but when. Thus, it is crucial that your practice be alert to possible intrusions and prepared when they inevitably occur.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that healthcare providers, and their business associates, secure Protected Health Information (PHI) from unauthorized use and disclosure by implementing reasonable and appropriate physical, technical, and administrative safeguards. In today's digital world, this is challenging. In 2016, more than 16.4 million patient records were exposed in the 329 healthcare data breaches of 500 or more records reported to the Department of Health and Human Services' Office for Civil Rights (OCR).[3] In contrast, 18 breaches and 134,773 compromised records were reported in 2009, when OCR first began collecting data.

Human error, primarily carelessness, on the part of office employees and other insiders is estimated to be responsible for nearly 60 percent of breaches. Laptop computers containing patient information are left in cars and stolen; documents are sent to the wrong recipients. Employees also commonly unlock the data-security door by clicking on phishing emails.

Traditionally, hackers sought to steal personal patient data that could be sold to identity thieves. This data was used to file fraudulent medical claims and prescriptions, or used to create spear phishing attacks. However, the criminal activity has evolved due to a severe decrease in the monetary value of medical records on the black market. In 2012, the World Privacy Forum estimated the value of a single medical record on the black market to be near $50. In its most recent healthcare cyber breach report, TrapX Security estimated the current value of a medical record to be as low as $10.[4] Ironically, this decrease in value is thought to be due to an increase in availability of medical records since the 2012 study. As personal identifying data has become widely available on the "dark web," hackers have changed their focus from stealing individual identities to targeting businesses to exploit the fiduciary duty of healthcare entities to protect patients' health information. After gaining access to a computer server, the hackers use intrusive ransomware designed to seize control of data and encrypt it, denying access to the rightful users. Alternatively, the hackers download files and threaten to publish the data unless a ransom is paid, usually in untraceable bitcoin.

Be Prepared

The best defense against data breaches is a good offense. There is nothing to gain – and much to lose – by ignoring the risks until after a breach is detected.

It is important to realize that data security is not purely an IT function, and that data breaches do not necessarily result from attacks stemming from outside the organization. Because employee ignorance and negligence are a primary cause of breaches, education is critical in safeguarding your data.

Employees should be trained to be suspicious of phishing emails, to always ask questions, and to be aware of the hazards involved in using, storing and transferring sensitive data. Additionally, employees should be advised that the use of social media can cause complications and lead to accidental disclosure of PHI. Employee social media policies should be reviewed, revised and clearly posted to avoid having employees accidentally disclose PHI, and other sensitive data, through photos and live streams (i.e., Facebook Live and Periscope). Corporate compliance

programs must include regular data risk assessments from hardware, software, employees and backup services; proactive data security education of employees; behavior monitoring systems; and data breach response plans.

If your practice doesn't already have a data security policy in place, enlist aid to draft one. Review and update the policy frequently, and encourage team members to refer to it often.

It is also important to assess existing security risks. Start by evaluating your computer system. It may be vulnerable to hacker "bots" that roam the internet, looking for servers that are running with outdated software or on unregistered operating systems that do not receive security updates. Because it is inexpensive to add digital storage, organizations may add new storage without disconnecting older insecure servers, allowing hackers to access data still stored there. Other areas of vulnerability include unused websites and patient portals, unencrypted mobile devices and the data disposal process.

What Qualifies as a Breach?

Physicians are required to report data breaches to state and federal authorities. However, not every inadvertent disclosure of PHI is legally a data breach. Under HIPAA, a breach is, generally, an impermissible use or disclosure that compromises the security or privacy of the PHI. An impermissible use or disclosure of PHI is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment of at least the following factors:

1. The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
2. The unauthorized person who used the PHI or to whom the disclosure was made;
3. Whether the PHI was actually acquired or viewed; and
4. The extent to which the risk to the PHI has been mitigated.[5]

Covered entities and business associates, where applicable, have discretion to provide the required breach notifications following an impermissible use or disclosure without performing a risk assessment to determine the probability that the protected health information has been compromised.

Although any ransomware attack is presumed to be a reportable breach, other incidents may not be so clear-cut. If an employee accidentally sends an email to the wrong person, a forensic investigation may determine the file was never opened or copied; hence, no breach occurred.

The definition of data breach varies by state. Missouri law describes a breach as the unauthorized access to personal information maintained in electronic form that compromises the security and integrity of the data.[6] Determining whether your incident satisfies this test is a decision best made with the assistance of legal counsel, as the penalties for a misstep can be severe.

Missouri law specifically forbids a private right of action;[7] however, hefty fines may be leveled by the OCR and by state governments for improper breach response. These fines may add up to hundreds of thousands of dollars.[8] Additionally, the Secretary of Health and Human Services is required to post a listing of breaches that affect 500 or more individuals on its website,[9] and the resulting media reports can lead to uncomplimentary PR. Irate patients and the cost of supplying free credit monitoring to those whose information has been compromised are other possible negative impacts of a reported breach.

It should be noted that although HIPAA and Missouri data breach laws do not provide a private right of action, using HIPAA as the standard of care in a negligence claim and private causes of action under state consumer protection laws have been successfully used to sue offending entities. For example, the Supreme Court of Connecticut has ruled that a patient may sue a provider for negligence using HIPAA as the standard of care. The court asserted that "neither HIPAA nor its implementing regulations were intended to preempt tort actions under state law arising out of the unauthorized release of a plaintiff's medical records."[10]

Similarly, two federal District Courts in Missouri have held that HIPAA may be used to establish a standard of care against which to judge a defendant's actions and a legal duty of care in a Missouri "negligence per se" claim. In both instances, the District Court was determining whether the federal or state courts had jurisdiction because, if the cases were tried in federal court, HIPAA's lack of a private right of action would take precedence.[11] Similar claims have been brought to state courts in Indiana, North Carolina, Utah and West Virginia. Healthcare entities should review state case law and court decisions to see whether there is precedent in their jurisdiction for allowing HIPAA to be used as a standard of care in tort and negligence cases where PHI is involved.

Furthermore, audit controls are absolutely mandatory. The lack of these controls can set a covered entity back millions of dollars.[12]

There's Been a Breach … Now What?

When PHI is compromised or lost, the response must be immediate and synchronized to minimize the confusion and cost that can occur in rapidly unfolding data breaches.

Compliant incident response should include:

Incident Investigation

Forensics experts look for digital "fingerprints" in computer hardware and software. The collection and preservation of forensic evidence must comply with evidentiary standards and regulatory and contractual mandates.

Coordination with Law Enforcement

Although initial reactions to a breach include outrage and a desire to see justice served, notifying law enforcement may not be in the organization's best interests. Healthcare entities must consider what an FBI investigation could mean for their practice. Some hackers threaten to retaliate if the breach is reported to third parties. Whether, when and how to report the breach to law enforcement is a business decision that must be made with care with the advice of counsel.

Collaboration with Public Relations Professionals

A PR plan can help contain damage to an organization's reputation that may result from large breaches.

Assessment of Liabilities

Service providers, vendors and other business partners may bear partial responsibility for the breach. Their roles must be analyzed and quantified.

Insurance Coverage

Traditional insurance policies are unlikely to cover data breaches. When they are in place, cyber liability policies may carry multiple exclusions and stipulations, so should be reviewed carefully for adequate and necessary coverage.

Breach Notifications

Federal and state regulations mandate that affected patients and government agencies be notified if information has been compromised. Depending on the number of individuals involved, this can be an onerous and expensive task. Generally, Missouri requires that each affected individual be provided with a written account of the nature of the event, the type of information that is at risk, a telephone number for further information, and contact information for consumer reporting agencies.[13]

Litigation Defense

In the wake of a breach, healthcare providers may be hit with subpoenas and investigatory demands, or, depending on the geographic reach of your practice, out-of-state class action or individual lawsuits. Such claims can strain the resources of a practice of any size.

The best time to think about your organization's response to a data breach is before the breach occurs, not after. A compliance audit can be invaluable in helping establish security controls that help prevent breaches, as well as determining your legal obligations and next steps when a breach occurs.

E-commerce

Healthcare professionals can become targets of credit card fraud, as either credit card account holders or when accepting credit cards as payment for services provided. The risks associated with credit and debit cards vary, depending on whether you are the account holder or the merchant.

Liabilities for Credit and Debit Card Account Holders

Generally, federal laws and individual bank policies limit an account holder's liability for unauthorized charges. However, these limitations vary depending on the type of card used, whether the card was stolen, whether the account number was used by phone or internet, and the timeliness of notification to the card issuer.

Credit Cards - Federal law limits the liability of holders of credit cards to not more than $50 for unauthorized use only if; a) the card is an accepted credit card, b) the issuer gives adequate notice of the cardholder of the potential liability, c) the card issuer has provided the cardholder with a description of a means by which the card issuer may be notified of loss or theft of the card, d) the unauthorized use occurs before the card issuer has been notified that an unauthorized use of the credit card has occurred or may occur, and e) the card issuer has provided a method whereby the user of such card can be identified as the person authorized to use it. This limit of liability requires the account holder to notify, or at least attempt to notify, the card issuer of the loss or theft of the card once the holder becomes aware of the loss or theft. If your credit card account number is used fraudulently by phone or internet, you have no liability[14] Often banks and card issuers have policies and agreements under which this $50 liability risk is waived. It is important to understand the card agreement and comply with the issuer's conditions.

Debit Cards – With ATM and debit cards, you must act quickly to avoid full liability for unauthorized charges when your card is lost or stolen. The Electronic Fund Transfer Act limits your liability to $0 if you report the loss or theft of the card immediately and the card has not been used. Your liability can increase to $50 if you notify the bank within two business days after you realize the card is missing. Failure to notify the bank within two business days increases your liability to $500. Failure to notify the bank within 60 days after your bank statement is mailed to you will eliminate any cap on your liability.[15] Again, individual bank policies and agreements may eliminate some or all of these liabilities, but it is important to comply with the established conditions.

Merchant Liability for Credit and Debit Card Fraud

October 1, 2015, and the nationwide adoption of EMV (Europay, Mastercard and Visa) chip cards and the accompanying processing technology introduced a major shift in who must shoulder the cost of credit and debit card fraud. Liabilities for unauthorized transactions have generally shifted to whomever has the lowest level of security. Merchant liability largely depends on whether an unauthorized transaction was tied to the use of an EMV chip card or non-EMV chip card, if the card number was used online, or if an EMV chip card was swiped by a merchant not EMV compliant. If all parties involved have upgraded security, then the card issuer would likely reimburse the consumer and the merchant would shoulder no liability. It is perhaps best explained using specific scenarios.

Stolen or lost EMV chip card is fraudulently used at a merchant not EMV chip compliant – In this scenario, the merchant would likely be determined the party with the lowest level of security and would shoulder the liability for fraudulent use.

Magnetic strip data is copied from an EMV chip card onto a counterfeit card and used at a merchant not EMV chip compliant – Again, in this scenario the merchant would likely be determined to have the lowest level of security and would likely shoulder the liability for fraudulent use.

Stolen or lost EMV chip card is fraudulently used at a merchant EMV chip compliant – The card issuer is likely to shoulder the liability for the fraudulent use.

Stolen or lost EMV chip card or magnetic strip card is fraudulently used by phone or internet – The card issuer is likely to shoulder the liability for the fraudulent use.

As with credit and debit card account holders, merchants should review and understand the agreements they have with their payment processing company to ensure they understand their liability risks.

Conclusion

As complex technology plays a more vital role in healthcare facility operations, a data breach becomes increasingly likely, either through user error or third-party cyber attacks. These attacks against hospitals and medical organizations are still driven by the potential monetary rewards through the sale of the medical records or imposing a ransom on locked data. It is vitally important for healthcare organizations, no matter their size and complexity, to take a proactive approach to data security. This includes the implementation of technological, physical and administrative safeguards. Most importantly, all employees and contractors should go through data security training appropriate to their individual role, with refresher courses taking place on an annual basis. Technology can be beneficial to the efficiency of an organization, but it can also create certain risks. It is crucial that these risks are identified and prepared for as early as possible.

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MM

PERSPECTIVE

Innovative Assistant Physician Program Enhances Patient Care: The Nevada Medical Clinic Experience

by Jennifer Conley, MD

Nevada Medical Clinic ("the clinic") has recently recruited an 'assistant physician' (AP) position for our busy Missouri practice. The innovative legislation for this license passed in 2014 but regrettably licenses were not available until 2017.

Our clinic became aware of this unique healthcare practitioner and began investigating it in early 2017. It has been increasingly difficult to recruit physicians to our charming but isolated small town. There are many other locales in this nation that have similar needs and attributes. We are a privately-owned clinic with six physicians and three nurse practitioners. We find it challenging to compete with higher guaranteed salaries from large corporations and hospital systems. Many new graduates, most carrying huge educational debt, are skeptical that they can succeed in private practice. Consequently, few are willing to consider private practice especially in rural locations. Our clinic concluded that we could utilize an assistant physician; we hoped it would also be an opportunity for permanent recruitment.

We listed the position on the website www.residentswap.org. There were no other similar positions listed. We were inundated with responses from potential candidates and quickly requested our posting be removed. We later learned that numerous medical school graduates move to Missouri and apply for an assistant physician license. To date we are not aware of other practices using assistant physicians. We were delayed in our implementation date by logistical challenges. Our liability carriers and insurance providers were not aware of this new limited-practice license and needed time to adapt policies and premiums for it. The first physician assistant license was issued July 31, 2017. We quickly obtained the National Provider Identifier and began the insurance credentialing process. Missouri Medicaid representatives had not heard of APs and needed to review copies of the legislation. Some of the Medicaid carriers are not credentialing APs individually so we are billing charges "incident-to" the collaborating physician's services. Our local hospital is still adapting the by-laws to include APs job description and privileges before granting credentials. We based the AP's salary offer on those representative of a first-year resident's income in the Midwest.



From left, Amanda Turner, MD, who is the primary collaborating physician for Dr. Mukherjee, Jennifer Conley MD, who is the author of the article, and Elizabeth Mukherjee, MD.

Missouri is one of only a few states to offer a position of this nature. Arkansas passed similar legislation in 2015.[1] Kansas limits AP opportunities only to graduates of the University of Kansas School of Medicine.[2] The number of unmatched residency applicants in 2017 was greater than 8,000.[3] This disturbingly large number has been growing. Unfortunately, there are limited ways for these highly trained women and men to use their medical degrees without a residency. The American Association of Medical Colleges reported in October 2016 that the average 2015 medical school graduate had more than $180,000 in debt. This debt was incurred and these loans made with the understanding that successful medical school graduates will be able to progress through post-graduate residencies and then have excellent employment prospects. The reality of such a large disparity between medical school graduates and available residencies is



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that the competition for post-graduate training has become ultra-intense. Of note, 1,000 US allopathic medical school graduates did not successfully match last year.[3]

The assistant physician license has met with some criticism that it might encourage graduate physicians to circumvent further training. Allegedly this might lead to a sub-class of physician providing inferior care. The current standards have strict eligibility requirements including US residency, English language proficiency, medical school graduation within the past three years and successful completion of the first two steps of the US Medical Licensing Exam within the past two years.[4] The law's intent, and our expectation, is that the AP will use the unique supervised medical work experience positively for enhanced application to the following year's residency match program and completion of residency/fellowship training.

The AP must collaborate closely with the supervising physician and not provide care independently. APs are considered learners. The experiences of each AP depend to a great extent upon the supervision and teaching skills of participating collaborating physicians. The AP is a unique physician extender and should enhance both the quality and quantity of care fully trained physicians can provide.

Ideally the number of available residency positions will increase to meet the demand from medical school graduates and to supply communities across the nation desperately trying to recruit new physicians. There has been an effort to advance legislation of this nature through the federal government as resident salaries are historically covered by Centers for Medicare and Medicaid Services. Medical school enrollments have increased. In the past two years Missouri has seen an increase at University of Missouri-Columbia from 96 to 128 by utilizing a satellite campus in Springfield and also at Kansas City University of Medicine and Biosciences which opened a new campus in Joplin for an estimated 150 more students annually. Residency positions have not kept pace. Employing APs may give unmatched individuals the opportunity to learn and begin supervised medical practice until they can complete their training.

Our assistant physician is Elizabeth Mukherjee, MD, and is a 2017 graduate of Ross University School of Medicine in Dominica, West Indies. She earned a Bachelor of Science in Molecular Biosciences and a graduate certificate in Autism Spectrum Disorders from the University of Kansas. She is a graduate of Blue Valley Northwest High School in Overland Park, Kansas. She was born in Kolkata, India. She later moved to Reading, England at age six and Overland Park at age 10. She volunteered in Moshi, Tanzania, for two months and Ngeruka, Rwanda, for one year as a health volunteer. She is interested in family medicine with obstetrics. Elizabeth has been able to participate and further those interests at Nevada Medical Clinic.

Within the first month the physicians and staff have developed rapport, familiarity, and respect towards our AP. We hope that Dr. Mukherjee will be matched into a residency program and come back to join us as a partner after her graduation. We are considering hiring another AP next year and might expand the number and responsibilities. We will be monitoring the financial impact of this AP employee and determine the feasibility of continuing the program.

From our perspective the AP is a win/win for the non-matched physician, our fully trained physicians and staff and most importantly the health and well-being of our patients.

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MM



AS I SEE IT

One Common Hope: To Be Healed

by Akash Jani

There's no need to be modest. We all have stereotypical opinions of India. Many think of poverty, wild animals in the streets, and how we frequently use India as an example for some of the diseases in our microbiology class. While most of these are indeed prevalent, I knew that there was something more. Curious in international medicine and poverty alleviation, I began my hunt for what I hoped to be a different India. After 10 years since my last visit, I took my fall semester finals, packed my bags, and headed to Ahmedabad, Gujarat. There I will be able to see my sister become a bride and simultaneously begin my hunt to find the progress in India that I had hoped to find.

Hospital One: Sol Hospital

I first visited Sol Hospital in Ahmedabad. It was introduced to me as a residential living building, which was converted into a private hospital. I was able to get a tour of the hospital after visiting a family member who was sick. After the doctor made his rounds to my uncle and shut the door behind him, I quickly did what any spoiled American medical student would do. I scoured through every drawer and cabinet and was left distraught and appalled. I turned to my dad and told him in Gujarati:

"Dad, ah room ma gloves nati."

Translation: "Dad, there are no gloves in this room."

My dad heartbrokenly smiled at me as he was used to growing up in this standard of care in Indian hospitals. I kept searching for something that would make me believe in the progress I had been hunting for but to my dismay, no hand sanitizer, no antibacterial sprays; nothing. I quickly went to my cousin and asked him if there was another healthcare facility that he thinks I should see. He recommended a private practice that was much different than anything I had ever seen before.



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Orthopedic Surgery Private Practice

This private practice was an experience in medical practice that is targeted for the population living in poverty. That is how I met Dr. Deepak Bhatia. As our car pulled up to his private practice, it was side-by-side with sandwich shops, jewelry stores, and other local street vendors. We walked into a crowded waiting area filled with dozens of people all with the common hope: to be healed.

Among the crowd were villagers who had traveled to Ahmedabad knowing that this was the only doctor who would be able to provide care that they could afford. I will begin by saying that Dr. Bhatia's practice is not 100% accurate and does not follow the rules and regulation that we are accustomed to in the US. Nevertheless, Dr. Bhatia has implemented practicality and justice to the population of Gujarat. After a short consultation, Dr. Bhatia lines the patients up in his x-ray room and remembers from his consultations where to have his x-ray technicians scan the patient. Then, without printing or writing anything down, he nods and calls the next patient. Afterwards, he calls them into his office and gives the short and easy-to-understand explanations on how they can heal using dietary adjustments found in affordable foods and exercise that can be done without equipment. How often have you seen a doctor prescribe milk? Then, for the patients that can afford it, he prescribes medication as well.

As you can imagine, Dr. Bhatia has come to the realization that it is economically impossible for some patients to afford medication and feed their family at the same time. He does whatever he can to cut costs for the patients and this includes a smaller staff, less housekeeping, basic medical equipment, and not printing the x-rays. He did not wear a white coat or a tie, simply a fleece and jeans. I realized that the true wealth of this clinic was Dr. Bhatia and his heart. I truly believe that Dr. Bhatia's knowledge and fluent English could lead him to become a multimillionaire orthopedic surgeon in the United States, but I knew that this was something that he was well aware of, as he has been in this practice for 20 years.

Dr. Bhatia's Clinic Rates

Type of Visit	Price (rupees)	Dollar Equivalent
First consultation	300	$4.54
Subsequent consultations	200	$3.02

Dr. Bhatia works harder, longer, and cheaper than any doctor I have ever encountered. Although this was not the hunt for progress I was exactly looking for, I began to realize that India might need practicality more than progress.

Hospital Two: Zydus Hospital

In the last facility of my hunt, we found Zydus hospital that opened its doors six months before my visit. I was honored with the opportunity to meet the man who helped design the hospital from scratch and works there as well, Dr. V. N. Shah. As I walked to his office, I was enlightened by the public signs across the hospital directing visitors to not feel obliged to tip the workers as they would in other places in India. In our meeting, I explained to him that after visiting the other hospital and the private clinic, I understood that compared to the United States healthcare system, India must first adjust to practicality before it can enter the laws, guidelines, and standards that American medical schools are teaching. Dr. Shah became noticeably uncomfortable by my comment and fought back "I know the standard of care." He then clarified to me how he implemented every guideline into this new hospital. He wanted this hospital to be different. He then arranged a tour down 15 stories of this high-rise hospital. I was finally at ease as he showed me the hospital floors filled with the newest technologies. The administration team was happy to show me their emergency codes, organization, and communication throughout the hospital. Above all, they believed in the importance of infection control in India. Every corner was armed and ready with gloves and disinfectants. The nurses even scolded the hospital administrators for not using the plastic wrap machines on their feet before entering the ward and sent us back!

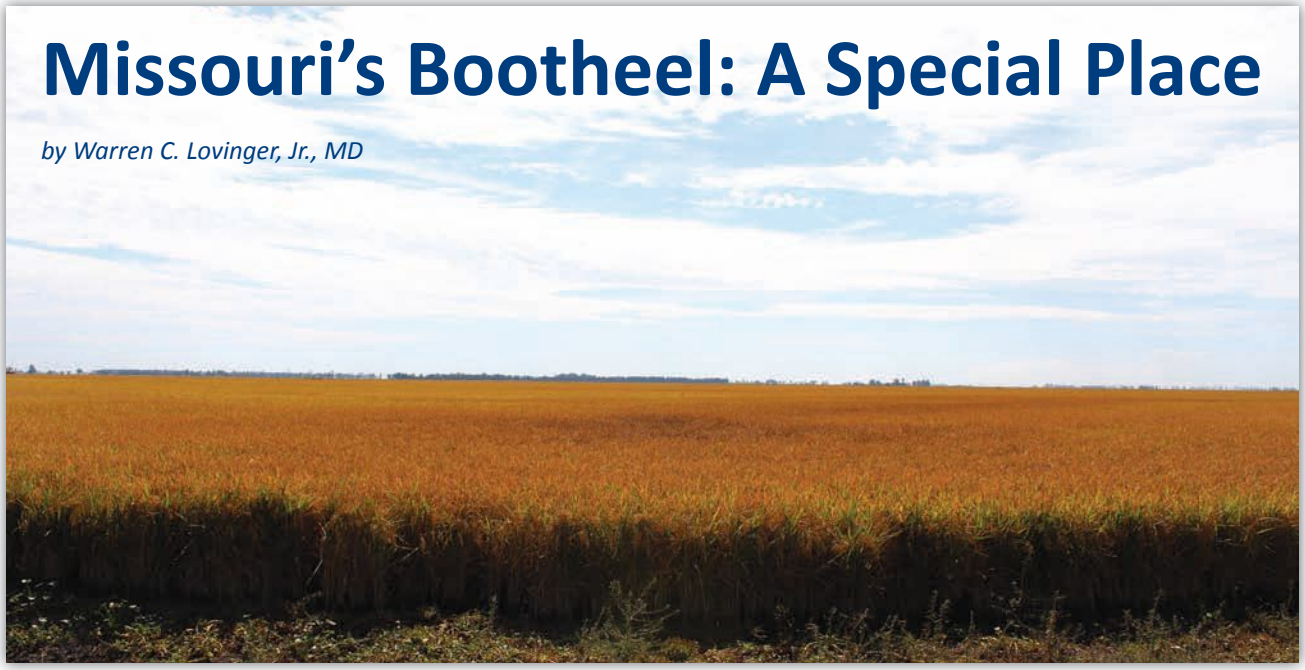




The most important goal the administration wanted for their hospital was a respect for India's culture. As we passed through the floors, I realized that all staff members were trained to bow their heads in greeting as they say the customary "Namaste." Lastly, the administrators of the hospital explained to me that India is different. The family values of India could not be ignored, and they understood the practicality that they must have for visiting family members. At Zydus, every room is equipped with a pullout bed for family members to sleep in during their relative's hospital stay. "If we do not take care of the family members, they will become sick as well." As this last comment was made, I finally found my kill in my hunt for progress in India and her healthcare system. I was blessed to learn that it is culture, professionalism, and education that make a hospital function. The technology and the infrastructure mean nothing unless you have hard-working individuals pushing to change the status quo. **MM**

Missouri's Bootheel: A Special Place

by Warren C. Lovinger, Jr., MD



A ripening filed of rice in Dunklin County. October 2017.

During the first seven months of my tenure as MSMA President, I have enjoyed the adventure of vising all 114 Missouri counties (and the City of St. Louis). My truck's odometer has added 13,000 miles in the process! Usually accompanied by my wife, Marilyn, we have been amazed by the geographic diversity of this state, as well as the uniform friendliness of its people. However, we believe that the most unique region in Missouri is "The Bootheel." This southeastern corner, protruding southward into Arkansas, is comprised of seven counties in the flat floodplain of the Mississippi River. Everything here is distinctive, including the terrain, types of crops, and accents of the people. Huge fields of cotton and rice were being harvested while we were there in October.

Even the medical community seems distinctive. Though the larger hospitals and physician groups are in Poplar Bluff, Cape Girardeau, and Sikeston, smaller communities like Kennett, Caruthersville, East Prairie, and Dexter also have readily accessible health care services. We were impressed by the physicians we visited who had returned to their hometowns to provide many years of compassionate service. An example is Andrew Painter, MD, a family practitioner and longtime MSMA member in Portageville, who has been there over 50 years. He fondly remembers the day when he delivered babies in his office! Citizens of these communities are fortunate.



Matthew Riffle, MD, MSMA member since 2010, Internal Medicine, practicing 29 years, Poplar Bluff, Butler County.

I continue to marvel at the great attitude and service orientation of Missouri's practicing physicians, residents/fellows, and medical students. It makes me proud and thankful to be part of this profession. **MM**



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Stefan Scheidler, MD, MSMA member since 2007, Family Practice, practicing 10 years, Kennett, Dunklin County.



Stevan Douglas, MD, Family Practice, practicing 19 years, East Prairie, Mississippi County.



John Nwora, MD, Internal Medicine, practicing 23 years, Caruthersville, Pemiscott County.



Gordon Jones, MD, MSMA member since 1987, Family Practice, practicing 31 years, Sikeston, Scott County.



Andrew Painter, MD, MSMA member since 1977, Family Practice, practicing 50+ years, Portageville, New Madrid County.



Cheryll Rich, MD, MSMA member since 2017, Family Practice, practicing 18 years, Dexter, Stoddard County.

A Legacy for the Missouri Physicians Health Program

by Robert Bondurant, RN

In the early 1970s, the American Medical Association and the Federation of State Medical Boards created the physician health program concept. One physician, Donald McIntosh, MD, a Kansas City anesthesiologist, brought it to Missouri in the late 1970s. Dr. McIntosh was eventually able to recruit the MSMA to expand his work and make it an official program.

Dr. McIntosh often spoke of his desire to create an endowment fund to ensure that the Missouri Physicians Health Program (MPHP) would be funded for years to come. He saw the need. He personally contributed to the program while he was alive, as well as sought contributions from hospitals and other donors. His family members continue to honor him with annual contributions. Funding is the life blood of the program. You can have a lot of good ideas, make a lot of good efforts, but if you don't have the necessary funding, the program simply won't be there for physicians. We are known as first responders, but to be first responders, you must exist! Funding allows us to be there whenever the need is there. We seek contributions annually from many sources – hospitals, clinics, medical societies, and individuals to take care of our basic operating expenses year to year.

However, we must look to the future. Dr. McIntosh's dream was to have an endowment fund of three to five million dollars, so the program could live off the interest. Obviously, that dream was never realized, and we are very far from that dream. What we have done is create a legacy program through which Missouri physicians may include us in their wills and estates. This allows physicians to join Dr. McIntosh and his family in developing a type of forever program.

We have to worry about finances each year. We probably spend at least 25% of our time with fund raising efforts. Sometimes, it is challenging to meet the needs of referrals and meet the needs for funding. So, an endowment program of the magnitude Dr. McIntosh talked about would give us a cushion that would allow us to focus more on services and less on seeking contributions. With that in mind, a new legacy program has been developed, with the assistance of an attorney, which is now available for anyone that would like to include the MPHP in their estate planning. A copy of the gift policy is available upon request.

Why is this important? Because the problems that physicians have are not going away. In fact, what the AMA and the Federation of State Medical Boards did in the 1970s was very prescient, when they voiced concern with physician suicide and substance abuse. Today, suicide is an even greater problem that it was then. Helping physicians with a substance abuse issue has been much more successful with the development of good treatment approaches and effective monitoring techniques. Our success rate is very high.

However, today, we are looking at new problems that weren't discussed previously–burnout, stress, mental health, and behavior issues. Frankly speaking, these additional issues are much more expensive to deal with than substance abuse issues. In the case of substance abuse, you receive a referral, you do an intervention, refer to treatment, follow through with monitoring and advocate for the physician as needed. It's a clear path. When you have one or more of these other issues, you can spend many hours for many months helping someone before you are even able to develop a monitoring agreement.

As an example, one morning I received a call from a VPMA who said that he had a call from a detective with a law enforcement agency. A physician had come to him early in the morning saying that he was in fear for his life, that someone was trying to kill him. The detective took his time to contact a physician colleague to discuss the situation. The VPMA who knows and respects our program

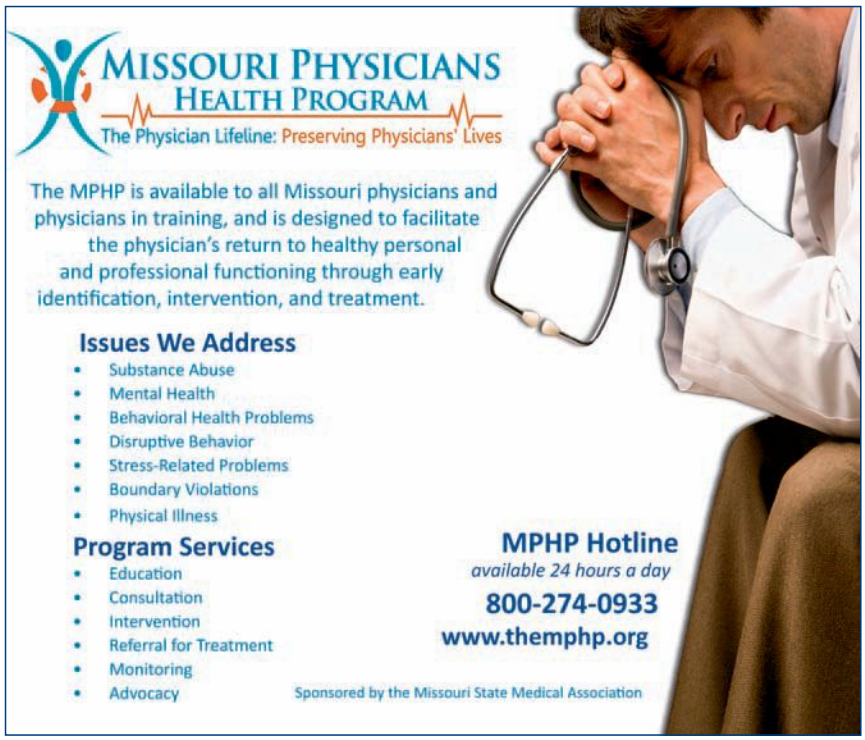


Robert Bondurant, RN, LCSW, is Executive Director of the Missouri Physicians Health Program.
Contact: rbondurant@themphp.org

"What lies behind you and what lies in front of you pales in comparison to what lies inside of you"
-Ralph Waldo Emerson

then called me. He provided me with the detective's contact information, who I called. The detective was generous with his time and quite concerned about this physician. The detective offered to locate the physician and have him call me. The physician was then brought back to the station where we had a lengthy phone call. He agreed to meet with our local Regional Coordinator and spent several hours in that meeting. The coordinator did a thorough evaluation and even contacted the physician's family. This led to a voluntary mental health admission for evaluation and treatment. We continue to assist this troubled physician. We expended hours of service with little hope of reimbursement. That is why contributions become so important. They allow us to provide services without expecting financial reimbursement.

Please be among the compassionate physicians who want to make sure we are there when needed for years into the future. Take a moment to consider this opportunity. During this moment of calm, please consider how you can support our ability to be available in the time of crisis. **MM**



✔ Yes! I want to help physicians through MPHP's Spirit of Compassion Campaign.

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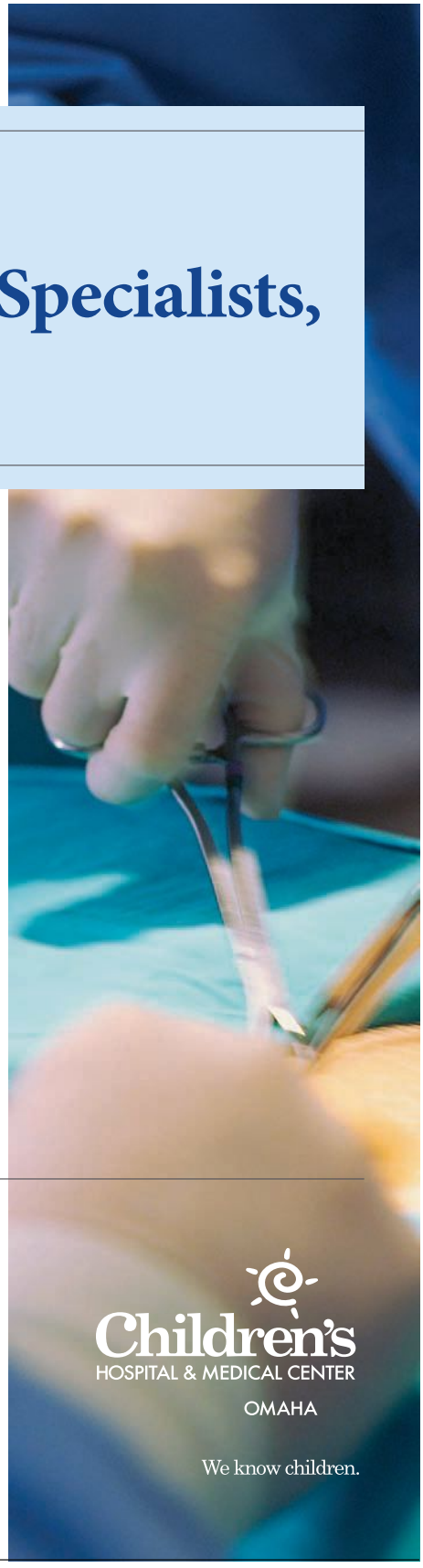
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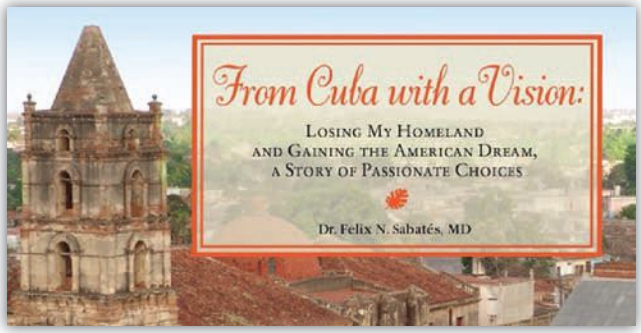
BOOK REVIEW

From Cuba with a Vision

by Dr. Felix N. Sabates, MD

Chandler Lake Books 2017
Hardcover. 246 pp. ISBN-13: 978-1-943338-11-5
Available at www.felixnSabatessr.com or Amazon. $30

Submitted by Arthur Gale, MD



Medical and surgical historical memory is ethereal unless committed to print. Felix N. Sabates, MD, the first fellowship-trained retina surgeon in Missouri and the Founder and Emeritus-Chair UMKC Department of Ophthalmology has thankfully collected in a single appealing book his witness of international, national, state and city history in both ophthalmology and international relations. This book should appeal to most physicians and all ophthalmologists. In detail it outlines how Sabates' mentor Charles Schepens, MD, revolutionized the medical and surgical treatment of blinding retinal detachments and trained the world's first skillful vitreo-retinal surgeons. It should appeal to all Missourians as it chronicles the development of the departments of Ophthalmology at MU-Columbia and UMKC, the latter which Sabates built from the ground up into the internationally respected department it is today. America is a land of immigrants and ultimately our forebears came to the USA in search of freedom, democracy and economic opportunity that were lost or threatened elsewhere. The now prosperous Sabates clan came from Cuba to escape the despotic rule of Communist Fidel Castro. My Irish ancestors came here to escape starvation in the Irish crop famine of the mid-1800's. Yours I'm sure had an equally compelling story.

There are significant insights in this book on the fate of nations and peoples that do not resist the spread of Communism and murderous, authoritarian political regimes and devalue honesty, patriotism, hard work and family values. As such I can recommend it to all freedom loving women and men.

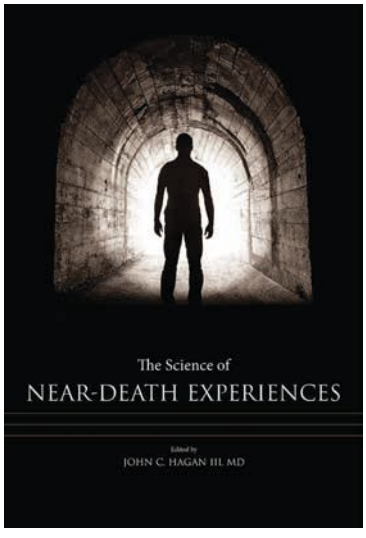
BOOK REVIEW

The Science of Near-Death Experiences

by John C Hagan III, MD, Editor

University of Missouri Press
Hardcover. 169 pp. ISBN 978-0-8262-2103-2
Available on Amazon, University of Missouri Press and msma.org

Submitted by Jim Blaine, MD



Anyone familiar with Missouri Medicine knows that it is a highly respected peer reviewed scientific journal that is the pride of the Missouri State Medical Association. Long time Missouri Medicine editor Dr. John Hagan has a reputation as a critical thinker, and, when I heard that he had edited a book on Near Death Experiences, I was eager to see how he would approach the topic.

I was not disappointed! I expected his careful research concerning the known statistics. Over nine million Americans have experienced an NDE; probably much more as the research reveals that, although the majority of NDEers experience a significant life change following their adventure, many do not share their memories with others. However; it was the stories shared by well known physicians who went through an NDE that intrigued me the most; they were so credible that I found myself rereading their accounts.

The experts on NDE caution physicians that, when our patients confide an NDE, we should be knowledgeable and supportive to avoid causing harm to vulnerable person. After reading this book, I feel prepared for that encounter.

MSMA Members in the News

Did you make the news? Submit your success story and photo to hwansing@msma.org.



MSMA member since 2010, Miriam Borden, MD, hosted a community seminar on Total Care of Rheumatoid Arthritis last month at Lake Regional Hospital.

Congratulations, Advanced Orthopedic Specialists and MSMA members for joining Saint Francis Healthcare System. MSMA appreciates the 70 years of combined membership from physicians in this practice, including Jimmy D. Bowen, MD; Bernard C. Burns, DO; James M. Edwards, MD; Patrick R. Knight, MD; Rickey L. Lents, MD; August Ritter III, MD; Brian C. Schafer, MD; and Andrew C. Trueblood, MD.



A new MSMA member this past year, Michael E. Aberger, MD, has expanded his practice to include patients in both St. Joseph and Fairfax.

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Connie Butler, MD, deserves a round of applause, as she has been instrumental in setting up an on-site Mercy Clinic in Cassville school district for students, teachers, and staff. Dr. Butler joined MSMA in 2008.



Congratulation to Patricia Dix, MD, member since 1989, who was recently nominated for Most Influential Women of 2017 by Springfield's Best.



James Fleming, MD, is expanding his practice to provide psychiatric services in the outpatient clinics of Community Hospital-Fairfax. MSMA appreciates his membership since 2015.



Mike Kozminski, MD, made the news for expanding his practice to see patients in both St. Joseph and Trenton. MSMA appreciates his support as a member since 1990.



Judyann Krenning, MD, valued MSMA member since 1999, helped sponsor the 5th Annual Superhero 5K Walk/Fun Run at Veterans Memorial Park in Rolla.



Raymond Lobins, DO, has expanded his oncology practice to include patients in both Springfield and Monett. MSMA is thankful to have him as a new member this past year.

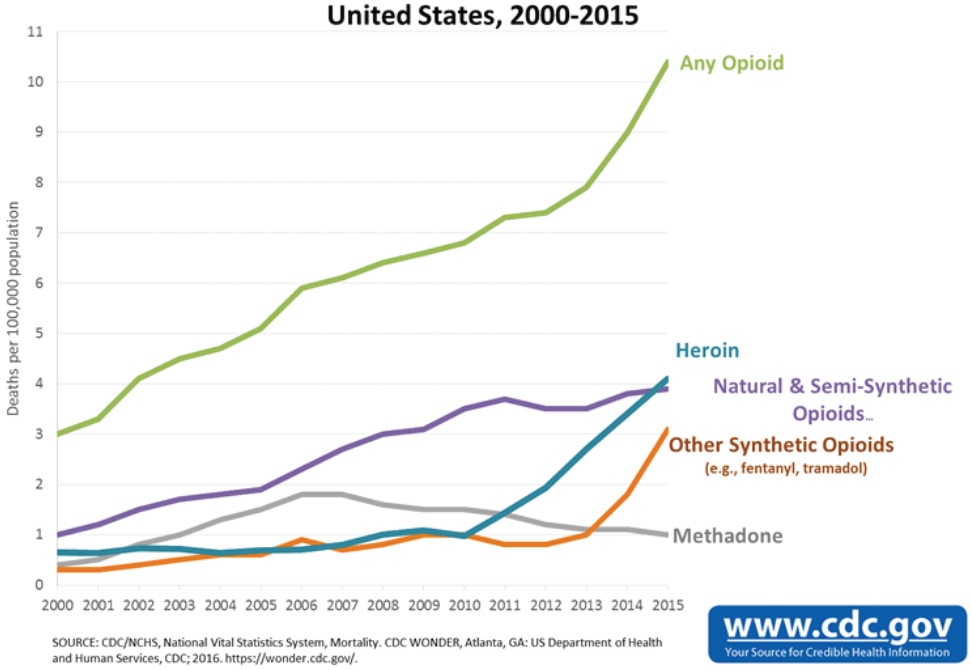


Joseph Sharlow, MD, MSMA member since 1993, is now practicing full-time at Ste. Genevieve County Memorial Hospital.



MSMA members like Richard Weachter, MD, pave the way for patient health. He recently became the first cardiac electrophysiologist in central Missouri to implant the smallest, minimally-invasive cardiac pacemaker available. We are pleased to have him as a member since 2004.

1 Picture = 1,000 Words



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Calendar for Continuing Medical Education

Jan. 20	Hematology and ASH Abstract
Feb. 3	Breast Cancer Update
Feb. 3	Rheumatology Update and Highlights from ACR
Feb. 21-24	Annual Refresher Course and Update in General Surgery
March 23-24	11th Annual Sports Medicine Update
March 24	Nephrology Update
April 7	Melanoma Update
April 13-14	Fetal Cardiac Symposium
April 14	Update on Osteoporosis and Fracture Prevention
April 28	Care of the Hospitalized Patient
May 31	9th International Pediatric Antimicrobial Stewardship
June 2	Cardiology Update

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Missouri State Medical Association
160th Annual Convention
March 23-25, 2018 | Renaissance St. Louis Airport Hotel

www.msma.org/annual-convention

Pre-Convention Meetings

Thursday, March 22

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
6:30 pm	**MSMA Council Reception & Dinner**

Convention Meetings

Friday, March 23

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**
11:00 am	Missouri Physicians Health Luncheon & Meeting
11:30 am	"Spirit of the Alliance" Awards Luncheon
Noon	SLMMS Caucus & Luncheon
Noon	KCMS Caucus & Luncheon
1:30 pm	**MSMA General Session**
3:30 pm	**MSMA General Session**
4:00 pm	Medical Student Section Meeting
4:30 pm	Alliance Past President's Reception
5:00 pm	OMSS Business Meeting
5:30 pm	Medical School Alumni Receptions
7:00 pm	Alliance Foundation Fundraiser/Dinner
7:00 pm	Resident and Medical Student Mixer

Saturday, March 24

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
7:00 am	International Medical Graduate Section Meeting
8:00 am	**MSMA General Session**
8:30 am	Alliance General Assembly - Session II
10:00 am	**MSMA General Session**
10:00 am	MMPAC Meeting
10:30 am	Exhibit Hall Closes
12:30 pm	Alliance Installation Luncheon
1:00 pm	AMA Issues
1:00 pm	Resident and Fellow Section/Young Physicians Section Program
1:30 pm	**MSMA General Session**
2:00 pm	Resident and Fellow Section Meeting
2:00 pm	Young Physician Section Meeting
2:30 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, March 25

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

Program subject to Change. Refer to Convention Official Program for times and meeting locations. All meetings held at the Renaissance St. Louis Airport Hotel 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 $100 per night plus charges and taxes.



Missouri State Medical Association
160th Annual Convention
March 23-25, 2018 | Renaissance St. Louis Airport Hotel

www.msma.org/annual-convention

General Sessions & Events



Friday, March 23 | 1:30 pm

Ten Practical Techniques for Improving Care for Patients with Life-Limiting Illnesses

Patrick White, MD
Chief Medical Officer
BJC Home Care
Washington University
School of Medicine
St. Louis, Missouri



Friday, March 23 | 3:30 pm

Immunotherapy for Disease Management

Richard D. Brasington, MD
Professor of Medicine
Division of Rheumatology
Washington University
School of Medicine
St. Louis, Missouri



Saturday, March 24 | 8:00 am

Hospitalists: What You Need To Know

Hiral Choksi, MD
Section Chief of Hospital Medicine
Saint Louis University Hospital
St. Louis, Missouri

FREE CME TO MEMBERS

CME procedures, sessions available for MOC points, how to obtain CME credit, disclosures, and evaluations will be described in the Official Program. For more information, contact Benita Stennis at 800-869-6762 or email bstennis@msma.org.



Saturday, March 24 | 10:00 am

Advances in Heart Failure Management

Justin Vader, MD
Assistant Professor of Medicine
Division of Cardiovascular Medicine
Washington University
School of Medicine
St. Louis, Missouri



Saturday, March 24 | 1:30 pm

Burning Out or Burning Bright?

Richard Gunderman, MD
Chancellor's Professor
John A. Campbell Professor Radiology
Indiana University
School of Medicine
Indianapolis, Indiana



Saturday, March 24 | 3:30 pm

OMSS PRESENTATION Hospital Medical Staffs 2018: Protect Your Practice & Profession

Elizabeth "Libby" Snelson, Esq.
Legal Counsel to Hospital Medical Staffs
St. Paul, Minnesota

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PERSPECTIVE

Super Bugs and Antimicrobial Stewardship

by Eden M. Esguerra, MD

The discovery of antibiotics and similar drugs together called antimicrobial agents, have revolutionized the modern world. These drugs were very effective in reducing illness and deaths from infectious diseases since the 1940s. Because these drugs have been so widely used and for so long, the infectious organisms they were designed to kill have adapted to them, making the drugs less effective.

Every year in the United States, at least two million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections.[1] Even more alarming, experts believe that worldwide, approximately 700,000 people die each year from antibiotic-resistant infections and the number is expected to surpass 10 million per year by 2050.[2]

In the US 20-50% of all antibiotics prescribed in acute care hospitals are either unnecessary or inappropriate.[3,4,5,6,7,8] Just like any other medications, antibiotics can have serious side effects including adverse drug reactions and *clostridium difficile* infection. Patients who are given antibiotics unnecessarily are placed at risk for serious adverse events with no clinical benefits. The misuse of antibiotics has no doubt contributed to the growing problem of antibiotic resistance, which has become one of the most serious and growing threats to public health.[9]

To understand the importance of antibiotic-resistant pathogens as a global problem, on February 27, 2017, the World Health Organization (WHO) published its first ever list of antibiotic resistant "priority pathogens" – the 12 specific bacteria/bacterial families that pose the greatest threat to human health.



Eden M. Esguerra, MD, MSMA member since 1995 and *Missouri Medicine* Editorial Board Member in Infectious Disease, is in Infectious Diseases, Mercy Hospital, Joplin, MO.
Contact: eden.esguerra@mercy.net

The list is intended to spur governments to put in place policies that incentivize basic science and advanced research and development by both publicly-funded agencies and the private sector investing in new antibiotic discovery. The WHO list is divided into three categories according to the urgency of need for new antibiotics: critical, high and medium priority.

Priority 1: Critical

- *Acinetobacter baumannii*, carbapenem-resistant
- *Pseudomonas aeruginosa*, carbapenem-resistant
- *Enterobacteriaceae*, carbapenem-resistant, ESBL-producing

Priority 2: High

- *Enterococcus faecium*, Vancomycin-resistant
- *Staphylococcus aureus*, methicillin-restistant, Vancomycin-intermediate and resistant.
- *Helicobacter pylori*, clarithromycin-resistant
- *Campylobacter spp*, fluoroquinolone-resistant
- *Salmonellae*, fluoroquinolone-resistant
- *Neisseria gonorrhea*, cephalosporin-resistant, fluoroquinolone-resistant

Priority 3: Medium

- *Streptococcus* pneumonia, penicillin non-susceptible
- *Hemophilus* influenza, ampicillin-resistant
- *Shigella spp*, fluoroquinolone-resistant[10]

In an effort to decrease antimicrobial resistance and inappropriate antibiotic use, different organizations including the Infectious Disease Society of America (IDSA), the Society of Healthcare Epidemiology (SHEA) and even the Joint Commission issued antimicrobial stewardship standards. In a very important decision, in June of 2016, CMS released a proposed rule change to its Condition of Participation which would, among other changes, require hospitals to implement antibiotic stewardship programs in order to participate in Medicare and Medicaid.[11] Thus, Antimicrobial Stewardship (AMS) quickly became the new buzzword in all hospitals across the US who want to continue to participate in CMS programs.

What is antimicrobial stewardship (AMS)? It refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy and route of administration. AMS seeks to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the cost of healthcare for infections, and limit the selection for antimicrobial resistant strains.

- **Leadership Commitment** – Dedicating necessary personnel, financial and information technology resources.
- **Accountability** – Appointing a single leader responsible for program outcomes. Experience with successful programs show that a physician leader is effective.
- **Drug Expertise** – Having a strong pharmacy presence with responsibility to improve antibiotic use.
- **Action** – Implementing at least one recommended action, such as systemic evaluation of ongoing treatment need after a set period of initial treatment. This is known as "antibiotic timeout, eg: after 72 hours when cultures are available to guide antibiotic therapy.
- **Tracking** – Monitoring antibiotic prescribing and resistance patterns on a regular basis.
- **Reporting** – Regular reporting information on antibiotic use and resistance to physician, nurses and other relevant staff.
- **Education** – Education clinicians about resistance and optimal prescribing.[12]

In summary, there is an urgency in the field of infectious diseases because of increasing worldwide incidence of antibiotic-resistant organisms. Antimicrobial resistance is now recognized as a priority global health issue. In this regard, the recognition of antimicrobial resistance problem in 2016 by the United Nations is potentially a landmark event, for it heralds international awareness of the problem.[13]

There is no easy solution to this problem which is now a crisis. The statement made by Jawetz in the 1950s when he stated "the position of antimicrobial agents in medical therapy is highly satisfactory" and that the "majority of bacterial infections can be cured simply, effectively and cheaply"[14] couldn't be farther from the reality that we face today.

Part of the solution can be as simple as good hand washing by everyone, with emphasis on healthcare professionals who are directly involved in patient care. The solution can also be as complex as a partnership between the political establishment and private entities, e.g., the pharmaceutical industry to explore potential solutions to the global problem. It is almost certain that it would involve incentivizing the pharmaceutical industry in the development of new antimicrobial drug development.[15] Antimicrobial stewardship (AMS) which is essentially the appropriate and judicious use of antimicrobials plays and important role in this human struggle against resistant pathogens, which, based on current data that we have, seems to be an external struggle much like the humans' struggle against infectious disease.[16]

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MM



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The Opioid Crisis in Missouri: A Call to Action for Physicians, Legislators, and Society

by Lawrence Lewis, MD, Christopher R. Carpenter, MD, Evan S. Schwarz, MD, Randall S. Jotte, MD, Corey Waller, MD, Rachel Winograd, PhD, Randall Williams, MD, Steven Stenger, Holly Rehder, Shannon Governick & Luis Giuffra, MD



Lawrence Lewis, MD, is Professor; Christopher R. Carpenter, MD, MSc, MSMA member since 2016, Evan S. Schwarz, MD, MSMA member since 2014, and Randall S. Jotte, MD, MSMA member since 2016, are Associate Professors, Division of Emergency Medicine, Washington University School of Medicine, St. Louis. Corey Waller, MD, MS, is Senior Medical Director for Education and Policy, National Center for Complex Health and Social Needs, Camden Coalition of Healthcare Providers in Camden, NJ. Rachel Winograd, PhD, is Research Assistant Professor, Missouri Institute of Mental Health, University of Missouri - St. Louis. Randall Williams, MD, MSMA member since 2017, is Director, Health and Senior Services, Jefferson City, MO. Steven Stenger is a St. Louis County Executive, Clayton, MO. Holly Rehder is Missouri State Representative, 148th District. Shannon Governick is a patient in the study. Luis Giuffra, MD, PhD, is Professor of Clinical Psychiatry, Washington University School of Medicine, St. Louis and Medical Director, Clayton Behavioral, St. Louis, MO.
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Abstract

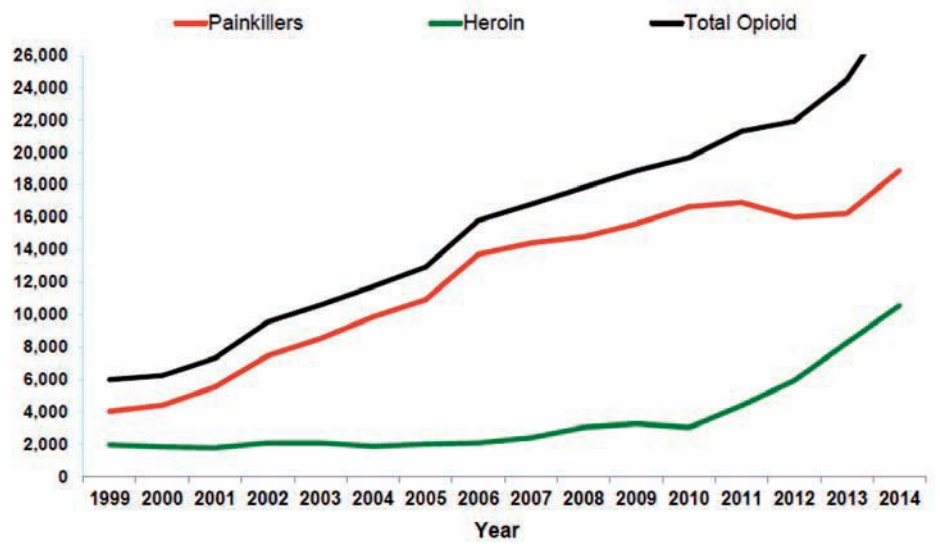
Opioid overdose deaths in the United States increased sharply over the last decade leading the President to declare a national emergency. The neurobiology of opioid addiction is explored in conjunction with the historical events preceding the current epidemic. A patient-centric perspective is provided along with rationale for contemporary Medical Assisted Therapy (MAT) options to safely reduce overdose deaths and other preventable consequences of prescription misuse and heroin abuse. A multidisciplinary medical provider approach is essential, in addition to legislative efforts to reduce current regulatory burdens that reduce access to MAT in many settings. This review introduces a new Missouri Medicine series intended to explore key concepts to simultaneously reduce opioid prescribing, while effectively managing acute and chronic pain across complex healthcare settings.

Understanding the Scope of the Opioid Epidemic

In 2014, an estimated 2.9 million adults in the United States (US) were non-medical users of opioid pain relievers meeting the criteria for opioid use disorder.[1] More than 50,000 people died of drug overdose in the US in 2015, and over 60,000 died from overdoses last year; more than all homicides (https://www.cdc.gov/nchs/fastats/homicide.htm) and motor vehicle crashes combined (https://www.cdc.gov/nchs/fastats/injury.htm). About 60% of these deaths are due to opioid overdoses, which have increased over 400% in the past 15 years (See Figure 1). Drug overdose is now the leading cause of death in the US in those under 50 years of age.[2] According to the Missouri Bureau of Vital Statistics, there were 908 deaths from opioid overdose in Missouri in 2016 (http://health.mo.gov/data/opioids). Although opioid-related deaths are most common in eastern Missouri, people are dying across the state (See Figure 2). Because of the scope of the problem, Washington University in St. Louis recently hosted a health policy symposium on the opioid epidemic (http://emed.wustl.edu/larry-lewis-symposium).

The symposium included nurses, physicians, including several trained in addiction medicine, government officials, researchers, social workers, and a recovering patient to discuss the genesis and pathophysiology of the opioid epidemic, and pragmatic workable solutions. The problem is ubiquitous, touching numerous medical specialties, with published guidelines pertaining to emergency medicine, obstetrics, geriatrics, pain management, surgery, and anesthesiology. This essay will serve as the first in a series of Missouri Medicine reviews exploring widely available approaches from multiple disciplines to reduce the scourge of preventable opioid deaths in Missouri.

Figure 1
Deaths Due to Opioid Overdose, 1999-2014
Reproduced with permission from the Centers for Disease Control National Center for Health Statistics



Genesis of the Problem

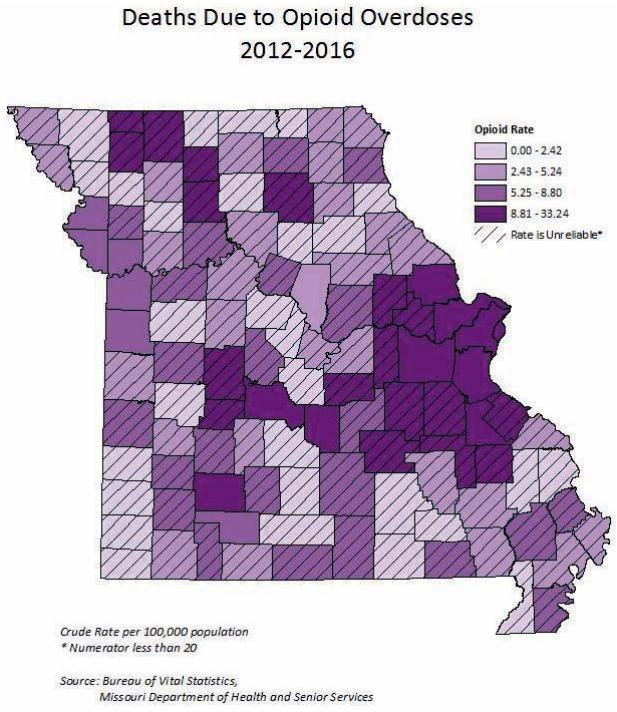
In 1999 the age-adjusted death rate from drug overdose was 6.1 per hundred thousand population, this increased to 16.3 per hundred thousand population in 2015, an average increase of 5.5% per year. The biggest increases were between 1999 and 2006, where the rate of increase was 10% per year. The increase in opioid-related deaths rose at an even steeper rate in Missouri during this period (CDC WONDER Online database, 1999-2014). Heroin use in the 1960's was largely a minority, urban problem and almost always began with heroin as the initial opioid of use.[3] This trend changed considerably near the turn of the millennium, both in the affected population and the initial opioid exposure. In 2005, less than 10% of heroin users had used heroin as their initial opioid; instead, nearly 80% had initiated with a prescription opioid medication.[4] Many of these initial prescription medication exposures had been diverted for non-medical use.[4]

The causes behind the marked increase in prescription opioids being the "gateway" drug to heroin are complex, but many physicians think that a prominent factor was the well-intentioned effort to combat "oligoanalgesia" and relieve suffering.[5,6] In 1995, the American Pain Society began the "Pain as the fifth vital sign" campaign and in 2001 the Joint Commission followed suit.[7] These campaigns, coupled with a growing emphasis on patient satisfaction scores and misleading information regarding addiction potential, led to a 67% increase in prescription narcotics between 1999 and 2006. The epidemiology of heroin addiction continues to evolve. Over the last five years, a third of heroin users initiated their opioid use with that drug, while only a quarter started with prescription opioids.[3] The transition away from narcotic analgesics towards heroin is likely a combination of development of tolerance, decreased access to opioid medication, and heroin that is more available and cheaper on the street.[4] Even with the changing epidemiology of heroin use, the data are clear; we now have over 2 million people with opioid use disorder in the US, the majority of whom were introduced to their opiates either through legitimate or diverted use of a physician's prescription.[4,8]

Neurobiology of Opioid Addiction

Opioids, like most addictive drugs, induce euphoria by increasing the level of the neurotransmitter dopamine (See Figure 3).[9,10] Dopamine is the predominant neurotransmitter for motivation and reward, and opioids produce dopamine levels that are significantly greater and of longer duration than any known natural reward (sex, food when hungry, or water when thirsty). The example given at the symposium that seemed to make the point compared functional MRI (fMRI) studies of "craving" between study subjects who were 1) water deprived, 2) food deprived, and 3) in early withdrawal. The affected parts of the brain differed somewhat depending on the

Figure 2



source of craving, but the images in opiate withdrawal show significantly more activity in many of these areas than does thirst or hunger, suggesting that the magnitude of craving in drug withdrawal far exceeds these natural cravings.[11,12]

Over time, opioids also reduce the brain's intrinsic ability to produce dopamine, leading to decreased motivation, and a constant search for the one thing that now is required just to make them feel normal.[10] The visual representation of the neuroscience underlying addiction, along with poignant comments from a patient with a long history of opioid addiction are telling. She related that when she was in the Emergency Department (ED), after being treated for an overdose, all she could think about was getting back out to the street to get another fix. Then one day, 11 years ago, someone gave her a dose of buprenorphine and she had in her words "a moment of clarity" which allowed her to begin the path to recovery.

Prevention Strategies

Before discussing treatment alternatives and some of the barriers to effective treatment, a pain management expert addressed the importance of primary prevention. Can opioids be used safely for acute pain management? The Agency for Healthcare Research and Quality National Guideline Clearinghouse provided the following current consensus guidelines for opioid use in acute pain (https://www.guideline.gov/summaries/summary/50568/pain-assessment-nonopioid-treatment-approaches-and-opioid-management?q=acute+pain):

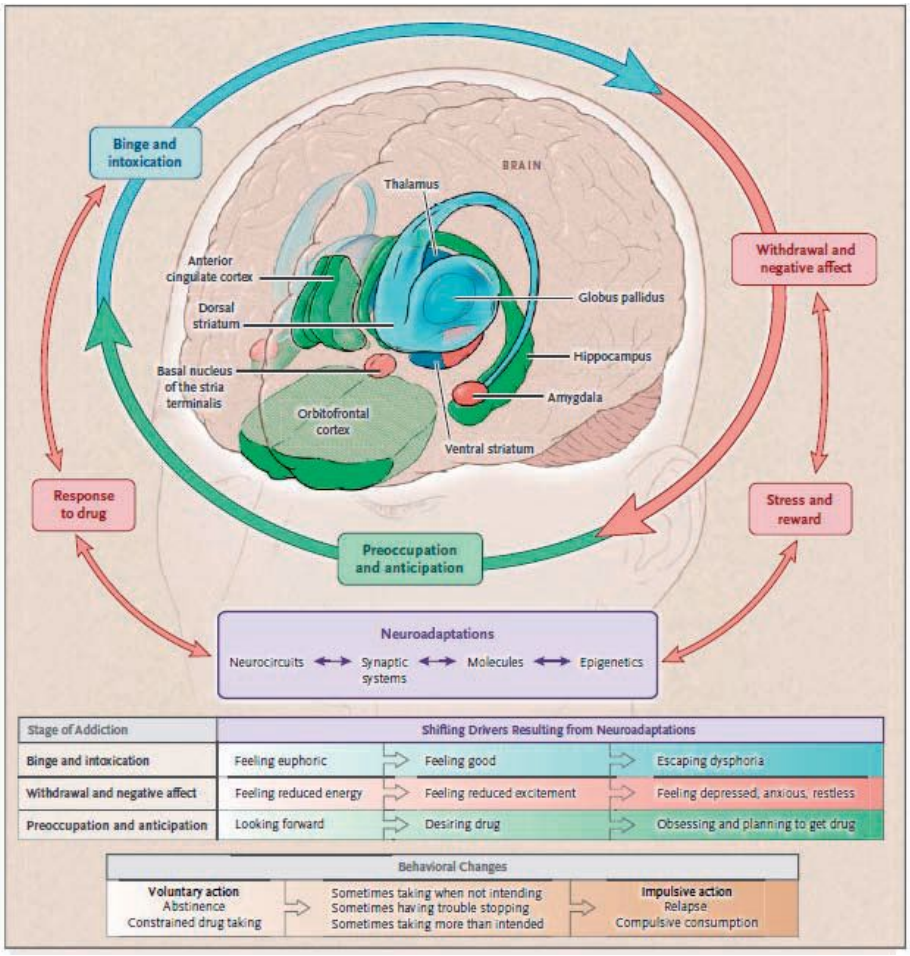
1. Evaluate the patient for potential of abuse (such as prior opioid use disorder) and have an informed risk/benefit discussion
2. If opioids are indicated, the first opioid prescription for acute pain should be no more than 20 low-dose, short-acting opioids or three days of medication, whichever is less.
3. The total dose for acute pain should not exceed 100 morphine milligram equivalents (MME). For patients presenting in acute pain, already on chronic opioids, opioid tolerant or on methadone, use the same pill and dose limits as for opioid-naïve patients.
4. Other considerations, particularly for painful musculoskeletal conditions include use of multi-modalities for pain control (i.e. low-dose non-steroidal analgesics along with low-dose [or no dose] narcotic analgesia) and physical modalities such as ice or heat, physical therapy, and massage. The American College of Emergency Physicians 2012 Clinical Policy on Prescribing Opioids to Adults in the ED cited several studies suggesting narcotic analgesia was not superior to non-narcotics for acute back pain, unless sciatica was present.[13]

Chronic pain is a more complicated issue. Opioid prescribing has markedly increased in the past decade, largely due to the extended treatment of chronic pain conditions.[14] Several professional societies and organizations including the American Society of Anesthesiologists, the American Academy of Family Physicians, and the Commission on Accreditation of Rehabilitation Facilities have addressed the issue of chronic pain. Suffice it to say that patients with chronic pain will require a careful evaluation for risk/benefit and a well-integrated interdisciplinary approach. From the emergency physician's perspective, opioids should be considered for those with chronic pain only if expected benefits (particularly for function) outweigh the potential risks. Recognizing that the majority of these patients will already be on narcotic analgesics, the question of opioid dependence is of concern. Identifying patients who have been on opioids for years may be an effective way we can identify patients with possible opioid use disorder, begin a dialogue regarding chronic pain management, and offer treatment options.

Treatment Strategies: Abstinence vs. Medication Assisted Treatment and the Concept of Harm Reduction

Abstinence programs have been around for centuries. Now known as the Minnesota Model, contemporary programs use the principles first espoused by the support group Alcoholics Anonymous, in 1935. For many years, abstinence programs were the only answer to addiction (whether alcohol or other drugs), and continue to be the most common form of addiction treatment in the United States (http://www.meaning.ca/archives/archive/art_ED_col_may_06_abstinence-addition-treatment_G_Thompson.htm). Medication assisted therapy (MAT) uses various pharmaceuticals to mitigate the neuro-hormonal imbalance which results from opioid use and leads to the cycle of addiction (See Figure 3). Research clearly demonstrates the superiority of most MAT programs over abstinence alone for opioid addiction.[15-17]

Figure 3
Stages of the Addiction Cycle
Reproduced with permission from the New England Journal of Medicine 2016

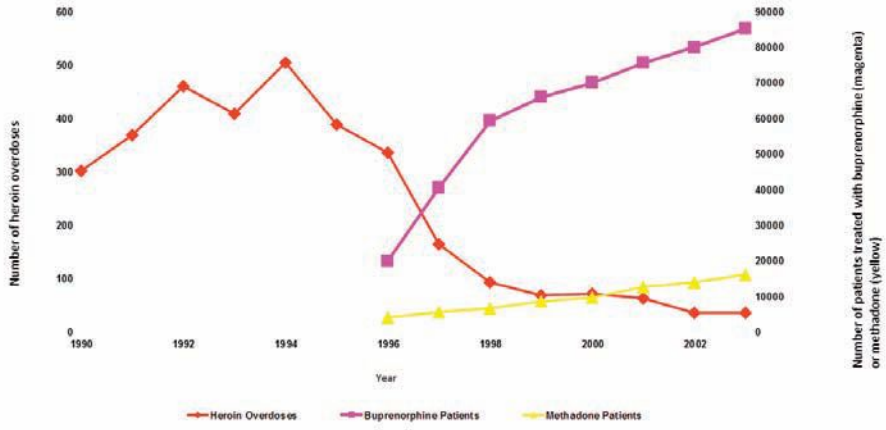


Harm reduction includes interventions that reduce the potential for serious or fatal medical consequences from illicit drug use. Representative harm reduction interventions include providing clean needles (shown to reduce HIV transmission),[18,19] supervised injection sites, and providing naloxone. MAT is also a harm reduction intervention since it not only increases successful remission of addiction, but also reduces rates of new HIV and perhaps hepatitis C infection.[19,20,21] Large population studies in France and Baltimore, Maryland have shown a very significant reduction in overdose deaths with the widespread adoption of MAT, even when used without counseling (See Figure 4).[18,22]

There are several alternative medications in the armamentarium for MAT. The oldest and best studied is methadone. A number of studies have shown that methadone programs have superior rates of remission from drug-use than abstinence programs alone. They also appear to reduce the incidence of HIV and hepatitis C transmission.[23] A major disadvantage is the need for daily outpatient visits for administration, although many practitioners allow patients take-home medication after several months of good compliance. Buprenorphine, a safer partial opioid agonist, has gained popularity in MAT programs over the last decade.[17] Suboxone®, which is a combination drug with buprenorphine and naloxone, has the added benefit of an opioid antagonist to lessen the risk of diversion or overdose when injected intravenously. Naltrexone is an opioid receptor antagonist that requires an initial prolonged abstinent period, ranging from a few days for heroin to as much as two weeks for Suboxone®, but it has no abuse potential and depot formulation (Vivitrol) eliminates the need for daily dosing. Which medication is preferable should be based on a number of patient

factors, including cost and accessibility, and is too broad a topic to be covered in this article. Currently the data favors agonists over antagonists, although no head-to-head trials have been published. No matter which drug is used, the attributes of a successful MAT program include: (a) identifying individuals with opioid use disorder, (b) initiating treatment as soon as possible when the opportunity presents, and (c) to continue MAT until the individual is evaluated and placed on a maintenance program.

Figure 4
Access to Methadone and Buprenorphine with Associated Decline in Overdose Deaths in France, 1990-2003
Reproduced with the permission of the Journal of Clinical Infectious Diseases and courtesy of Dr. Patrizia Carrieri



There are obvious cautionary tales to any MAT program, which may underlie the reason why these programs have not been eagerly adopted. Many addiction experts believe that the social stigma of drug abuse and years of misinformation are the primary factors behind the slow adoption of MAT.[24] A major focus of our symposium was to acknowledge and overcome these issues and review the evidence for MAT outcome benefits or harms. Numerous studies confirm the benefit of MAT in improving rates of recovery, reducing drug overdoses, and reducing risks of infectious disease transmission.[17,20,25] Misuse of MAT drugs does occur with diversion rates varying between 0.2 and 62.4 per 10,000 recipients, depending on the formulation and the particular database.[26] The French allow any physician to prescribe buprenorphine to patients with opioid use disorder with no formal psychosocial counseling or intervention. This French approach resulted in a 79% reduction in overdose deaths and a reduction in new HIV case rates from 25% to 6%, albeit with a misuse rate of 15% and a diversion rate of 39%. In fairness, this diversion rate was over their entire time of MAT, and only 6.2% said they had ever sold the medication. It appears much of the diversion (if not most) is to self-treat withdrawal. The diversion of the combination agonist-antagonist drug Suboxone® is far safer than the diversion of opioid medication, and anecdotal evidence suggests that some, if not most, of the diversion is used to self-treat dependence and reverse opioid overdose. The French and Baltimore MAT experiences can certainly inform subsequent Missouri efforts to reduce deaths and disease that results from opioid addiction, while mitigating against some of the adverse outcomes. Critically, recent evidence suggests that prescription drug monitoring programs not linked to MAT, may actually increase the number of people dying from drug overdose by pushing opioid addicts to heroin and fentanyl.[27]

Barriers to Implementation

There are several barriers to MAT, which range from moral considerations to financial ones. Healthcare providers should be among the first to recognize that social stigma can reduce progress in both studying a disease, and in implementing the findings. With the wide-ranging demographic of the latest opioid epidemic and the emerging science demonstrating the neurobiology associated with addiction, the stigma appears to be waning. Those of us who have a friend or family member that suffers from opioid use disorder realize that this is not "a choice" but rather a disease, based on an imbalance of neurotransmitters, just as depression, mania, and Parkinson's disease are.[10]

Though there is still some lack of awareness regarding effective treatment strategies, the biggest barriers seem to be a lack of trained staff and cumbersome regulations.[28] The recent explosion of coverage in the press, and the Missouri Opioid State Targeted Response Project (Opioid STR: www.missouriopioidstr.org) will serve as an impetus and a resource for healthcare providers to develop and

implement plans for prevention and treatment of opioid use disorder. Longer-term, we must emphasize education on addiction medicine in medical and nursing schools and residency programs. The four medical schools in Massachusetts recently identified ten core competencies for the prevention, identification, and treatment of substance use disorders and worked them into the medical school curriculum (Opioid and Safe Prescribing Training Immersion Program; https://umassmed.edu/opioid/). This model could be integrated in Missouri medical education as well.

Lack of access to treatment is the next hurdle to cross. Opioid STR and its related projects can help provide resources for treatment. MAT training is being offered at multiple locations and times (as well as online). Washington University has embraced the need to train a group of physicians across specialties, in order to be able to initiate therapy along the spectrum of medical care, beginning in the ED, if necessary, and continuing in both the inpatient and outpatient settings.

However, to build an infrastructure that will be ideal for the longitudinal care of these patients over an extended period will require resources and a payment system that can sustain the effort. Many of these patients are uninsured, but the cost of their addiction to our healthcare system greatly exceeds the cost of treatment, not to mention that many of them can re-enter and become productive members of society once on treatment.[29] We need policy changes that recognize that reality and allow for the adequate treatment of all people with opioid use disorder, without regulatory rules that limit care and set up barriers to payment. Finally, we need to develop a more robust and accessible primary care system where conditions associated with chronic pain can be addressed in a more holistic and appropriate way, with the intent of preventing future opioid dependence among the millions of Americans who suffer with chronic pain.

A Personal Message from a Patient

Hello, my name is Shannon, and my story is not unique. I spent a good amount of my life drinking and using drugs. I did not grow up with an un-loving family, in fact I felt very loved. I'm very fortunate to have them all still loving me today! Twasn't pretty... but now, 11 years sober, I'm here to tell you there's hope!

Speaking on my Heroin/Opioid use, pain killers led to Heroin for me. Too much disaster and pain to cover here, so I'm just going to break it down the best I can. This is what worked for me. I confessed to my family and doctor that I was an addict. I found a nonjudgmental/Spiritual Church and was reunited with Jesus. They have an Aftercare Recovery Meeting there I started attending, along with other meetings like CA/AA/NA (Cocaine, Alcohol, Narcotics Anonymous) and began working the 12 Steps of recovery with a Sponsor. I worked closely with my psychiatrist and psychologist, and still do, but the catapult that allowed all of this to happen was when my doctor asked me if I'd be willing to try a medication called Suboxone® (buprenorphine) and my life was forever changed. It was and is still a game changer! I've said it before and will continue to say, "Buprenorphine gave, and still gives me, a fighting chance against Opioids!". I had some struggles before and after starting buprenorphine, but it was Never Again with Heroin/Opioids. Buprenorphine removed all physical and mental withdrawals immediately. I now live a sober lifestyle and others can too! It breaks my heart knowing that many people could achieve what I have, but are not given or being told about all the options they have. Others may not want to take a route similar to mine, but how can you choose if you're never given the choice? I led myself down some bad paths, sometimes knowingly, sometimes unknowingly, and many miracles have happened along the way. I consider buprenorphine to be one of them.

My Sobriety date is December 4, 2006, and I take buprenorphine to this day. One of the hardest things in Sobriety to me is, "One Day at a Time". I have to remind myself that is how it is, and today I just try to do things that help me live a life of hope, joy, and sobriety and I am perfectly fine with that. I hope my experience can help others.

Sincerely,

Shannon G.

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Opioid Crisis Declared a Public Health Emergency

On October 26, 2017, the Trump administration declared the opioid epidemic a "public health emergency." This type of declaration allows the federal government to expend additional funds to appoint specialized personnel to address the epidemic, expand treatment at existing facilities, and provides states with more flexibility when spending federal funds targeting the epidemic. Public health emergencies are limited to 90 days, but can be renewed any number of times. The President's Opioid Commission had previously requested such a declaration.

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Disclosure

None reported. **MM**

Improving Emergency Department Care for Aging Missourians: Guidelines, Accreditation, and Collaboration

by Christopher R. Carpenter, MD, Don Melady, MD, Craig Krausz, MD, Jason Wagner, MD, Brian Froelke, MD, Jennifer Cordia, RN, Derrick Lowery, MD, Brent E. Ruoff, MD, Laurie E. Byrne, MD, Douglas K. Miller, MD & Lawrence Lewis, MD

It is incumbent upon 21st Century providers to wisely invest in system-level resources and educational products that best align patient care experiences with costs and attainable patient-centered outcomes.



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Abstract

Aging baby-boomers present significant challenges to accessible, affordable emergency care in America for patients of all ages. St. Louis physicians served as early innovators in the field of geriatric emergency medicine. This manuscript summarizes a multi-institutional November 2016 symposium reviewing the Missouri history of geriatric emergency care. In addition, this manuscript describes multispecialty organizations' guidelines, healthcare outcomes research, contemporary medical education paradigms, and evolving efforts to disseminate guideline-based geriatric emergency care using a "Boot Camp" approach and implementation science. This manuscript also reviews local adaptations to emergency medical services and palliative care, as well as the perspectives of emergency department leaders exploring the balance between infrastructure and personnel required to promote guideline-based geriatric emergency care with the anticipated benefits. This discussion is framed within the context of the American College of Emergency Physician's planned geriatric emergency department accreditation process scheduled to begin in 2018.

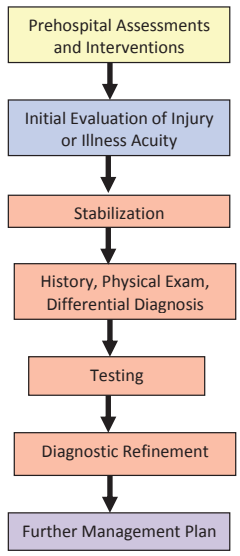
Background

Adults over the age of 65 will have increased from 4% of the population in 1900 to over 20% by 2050, largely reflecting the triumphs of medicine to overcome cancer, cardiovascular disease, and infections that were previously fatal. With medical advances prolonging life, innovative healthcare leaders launched the American Geriatrics Society (AGS) in 1942.[1] Residency and fellowship programs trained generations of primary care and specialty physicians that increasing numbers of elderly Baby Boomers would be able to access geriatricians when frailty ensued. Patient care needs for geriatricians were projected to increase by threefold between 2000 and 2030,[2] but few of the nation's medical schools had a division or department of geriatrics or any geriatric course requirements. Caring for an aging nation would be the responsibility of all physicians, not just geriatricians, but the country was woefully unprepared for the "silver tsunami."

Using John A. Hartford Foundation funding in the 1990's, emergency medicine (EM) answered these geriatric challenges with

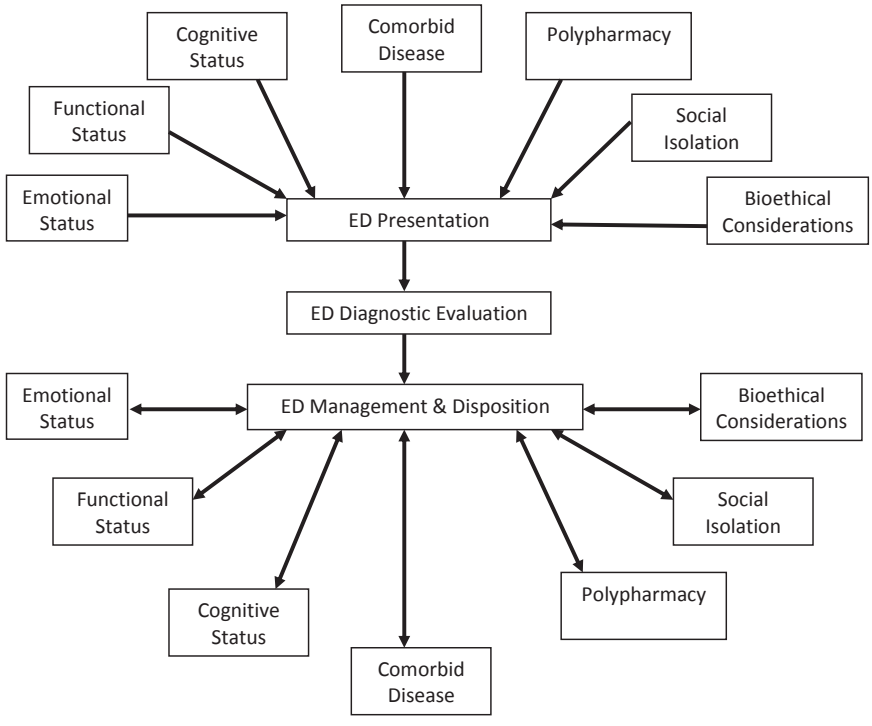
research exploring falls prevention[3] and detection of cognitive impairment,[4] as well as geriatric-focused resident curricula and a series of increasingly detailed textbooks. EM researchers quickly realized that an increasing focus on older patients opened a Pandora's Box of previously unrecognized issues and threats to recovery from acute illness or injury – such as delirium, dementia, depression, frailty, and unmet social needs. The traditional model of EM care is a linear one-problem, one-diagnosis approach (Figure 1a). In contrast, older adults frequently present atypically with both the chief complaint and the likelihood of recovery clouded by multiple other functional, cognitive, medication, and social factors (Figure 1b).[5] Despite quality indicators[6] and EM resident core competencies[7] that emphasize the importance of identifying age-related functional and cognitive frailties, attention to geriatric syndromes such as injurious fall prevention,[8] functional decline, dementia, and delirium[9] was often lacking. Suboptimal emergency care for older adults was associated with patient dissatisfaction,[10] preventable ED returns,[11] and loss of independence after minor injuries. St. Louis physicians were historic innovators in the field of geriatric EM. Cognizant of this history the SLU and Washington University Departments of EM co-hosted a multidisciplinary half-day symposium on November 8, 2016 to highlight ongoing local innovation including opportunities for trans-hospital networking to improve older adult emergency care. This manuscript summarizes that symposium.

Figure 1a
Traditional EM Management Pathway
Source: Adapted from [11] with permission.



Settings Where Processes Occur
Yellow = Home, Clinic, Accident-Scene or Nursing Home Environment
Blue = Waiting Room or Triage station
Red = ED patient room or hallway
Purple = Observation Unit, Inpatient or Outpatient Setting

Figure 1b
Geriatric Emergency Care Model
Source: Adapted from [11] with permission.



St. Louis and the Silver Tsunami

St. Louis was very involved in those early years, exploring some of the unique problems inherent to older adults, and determining if screening and preventative services in seniors being evaluated in the ED might decrease healthcare utilization and improve outcomes. In 1990, Drs. Douglas Miller and

John Morley at St. Louis University (SLU) demonstrated that the use of formal geriatric assessment instruments in outpatient departments significantly improved identification of problems relating to cognition, gait, affect, and nutrition in an outpatient setting.[12]

Drs. Morley and Miller subsequently collaborated with early leaders in the nascent field of geriatric EM.[13] They forged local collaborations between geriatrics and EM at SLU highlighting the need for a formal assessment of functional status in these patients.[4,11] These findings fueled efforts to fund research exploring the unique challenges providing emergency care to elders. This funding supported the development of leaders in the nascent field of geriatric EM via the Jahnigen Scholarship[14] and promoted best practices. A geriatric specific curriculum in EM and the publication of the first comprehensive textbook on geriatric emergency care followed.[15]

Momentum slowed locally and during much of the first decade of the new millennium, Missouri was less involved in innovative geriatric EM, even as national efforts accelerated. Early geriatric EM leaders and those attempting to implement best practices today have identified three essential lessons:

- Targeting the right patients (as opposed to targeting all patients);
- Extending care - effective geriatric interventions almost always need sustained care to achieve best outcomes;
- Delivering required care – mandates that referring providers retain significant influence over the care delivered because referrals without control generally do not work.

Another lesson learned pertains to the required resources for implementing "best practices." The learning phase typically involves decreases in efficiency that characteristically revert to equal or superior levels of throughput with the added benefit of improved care and better outcomes once the intended intervention becomes standard care. When appropriately implemented the investment is worth the time and effort. These investments imply the crucial need for long-term committed collaboration across domains of care (pre-hospital, ED, inpatient, and outpatient including home health services). Long-term success requires getting all stakeholders to the table to adapt healthcare delivery in a patient-centered, cost-effective way.[16]

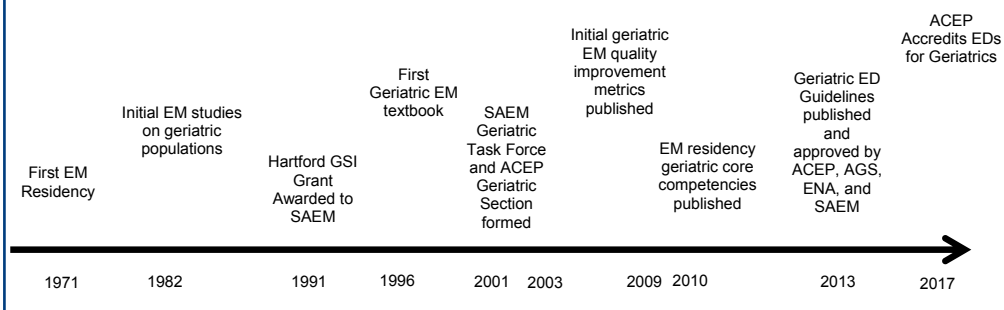
Overcoming Inertia: The Evolution of Geriatric Emergency Medicine

The "diffusion of innovation" across the country was slow despite opinion leaders' endorsements to refine pre-hospital, ED, and post-acute care. The pace of adaptation quickened when the first self-defined "Geriatric Emergency Department" opened in 2008 followed in rapid succession by 29 more by 2014.[17] The American College of Emergency Physicians (ACEP), Society for Academic Emergency Medicine (SAEM), Emergency Nurses Association (ENA), and AGS worked collaboratively to develop "Geriatric Emergency Department Guidelines"[18] that provide evidence- and consensus-based recommendations about the education, staffing, protocols, quality improvement metrics, and infrastructure modifications that are most likely to improve the experience of care and outcomes for older adults. In January 2017, ACEP established a three-tiered accreditation program for EDs based upon these guidelines (Figure 2).[19]

Educating Clinicians – Relevant Geriatric Free Online Access Medical Education (FOAMed)

Historically EM training has prioritized the "guts and glory" of ED work – trauma, procedural resuscitation, and acute critical illness – while reinforcing the "one patient-one problem" approach. In contrast, current ED practice involves predominantly assessment and care of frail adults

Figure 2
Historical Timeline of Geriatric Emergency Medicine



Abbreviations: EM (emergency medicine), GSI (geriatrics for specialty initiative), SAEM (Society for Academic Emergency Medicine), ACEP (American College of Emergency Physicians), ED (emergency department), AGS (American Geriatrics Society), ENA (Emergency Nurses Association)

with multiple co-morbidities transitioning through a complex health care system.

EM educators strive to fill this education gap. Six months prior to the citywide symposium, symposium organizers encouraged SLU and Washington University EM residents to complete six online modules (www.geri-EM.com). This FOAMed resource is a peer-reviewed and accredited resource that provides free CME and an interactive case-based approach with the opportunity for self-assessment in each of the core competency domains of Geriatric EM: cognitive impairment; trauma and falls; medication management; atypical presentations; functional assessment; and end-of-life care.[7]

Implementing Palliative Care in the ED

Patients seeking care solely to alleviate distress often find the ED ill equipped. Discrepancies between patient goals and those of the ED (rapid assessment and initiation of interventions targeting life threatening conditions) are common.[20] Families identify a focus on disease modifying interventions rather than distress modifying actions for patients approaching end of life as a source of preventable distress. Incorporating palliative care into an ED requires assessing physical, emotional, spiritual, and social domains. A simple ED screen to assess palliative care appropriateness is the clinician query "Would I be surprised if this patient were to die in the next year?"[21]

Overcoming these barriers does not require extensive financial or time commitments from an institution. Identifying an ED palliative care champion dramatically increases access to palliative care for ED patients. Obstacles to ED palliative care include:

- inadequate palliative care education[22]
- insufficient protocols to identify palliative care patients
- poorly developed ED-palliative care hospital collaborations
- inappropriate privacy and space for discussions about goals of care in the ED
- lack of access to advanced care planning documents that have been completed, or lack of access to forms available for patients to complete.

Figure 3
CHAP team member evaluates a patient at home including vital signs and signs/symptoms of congestive heart failure decompensation in the immediate post-ED period.



Adapting Emergency Medical Services for Geriatric Care

The Community Health Access Program (CHAP) coordinates transitions of care (Figure 3) focusing on patients using emergency medical services (EMS) for non-emergency or chronic care. CHAP works one-on-one with patients to identify individual medical, social and mental health needs. CHAP staffing includes three community paramedics and an "access coordinator" working with inpatient and outpatient providers and resources. Individuals with more than two ED visits within a 20-day period trigger an alert. Since 2015 CHAP decreased ED visits by 56% and inpatient admissions by 65% for these "High Utilizers". The current EMS financial structure does not reimburse for these non-traditional efforts, so hospital finances, charitable donations, and grants currently fund this program.

CHAP is collaborating with Memory Care Home Solutions to train paramedics to provide non-pharmacological interventions that improve outcomes in older adults with cognitive impairment. The goal of the partnership is to decrease preventable ED and EMS utilization for patients with dementia, while helping these patients to remain in their homes. Providers from both agencies are able to identify patients who might benefit from the others' services in order to link families to appropriate resources.

ED Leadership Perspectives on Engaging Hospital Administrators with Geriatrics

In 2009 the ED was the site for 75% of non-elective hospital admissions in those 85 years old and above.[23] Age is an independent predictor of hospital admission so an aging America will directly impact access to ED and hospital care for patients of all ages for several decades.[24] Medical centers already struggle to provide timely and cost-effective healthcare for the increasing number of patients over age 65. Aging "baby boomers" will add three million new seniors to the US population annually for another decade, and with greater longevity, the number of patients over age 85 is rapidly expanding. EDs will become more busy with complex older patients, some of whom will be injured but most of whom will visit with acute complaints associated with chronic medical issues.[25,26] Without an appropriate focus on feasible and efficient geriatric emergency care quality, timely access to emergency care could be negatively influenced for every age group in every ED.[27] As hospitals continue to improve the quality of care through core measures and evidence-based practice, creative solutions and innovations will be necessary to ensure cost-effective, accessible emergency care for older adults. In comparison with the investments already made in pre-hospital care, ED operations, interventional resources, and post-hospitalization rehabilitation for cardiac, stroke, sepsis, and trauma care, investments to "geriatricize" the general ED for an aging population have been trivial. Hospital administrators require the advice and assistance of ED leaders to determine how to best care for this population in a fiscal environment that is providing less reimbursement layered with penalties for both poor patient satisfaction and preventable return visits.[16,28,29] ACEP's recent decision to begin accrediting EDs on a three-tiered platform similar to trauma centers may resonate with key decision-makers and payers to provide the financial stability required to foster disruptive innovation and sustained progress.[19,30,31] Early research exploring the value of the "Geriatric ED" have been inconclusive.[32,33] However, these results are not justification to stop innovating since these findings may reflect inadequate or incomplete implementation strategies [34,35] or assessment of the wrong outcomes.[36]

The financial resources required to better align the ED physical environment with aging populations are relatively modest, but require expertise.[30,37] The most valuable resource for the busy ED is a content expert in geriatric care to lead revisions of the physical plant, structuring of patient protocols, and general staff education. Additional resources helpful to avoid preventable ED returns include trained geriatric emergency nurses, home health caregivers, social workers and case managers, as well as access to transportation, prescription assistance, and physiotherapy.[38,39]

The GED Boot Camp Implementing System-Level Change and Collaborative Learning

As previously noted, despite the existence of published and professional society endorsed geriatric EM quality indicators[6] and resident core competencies[7] for a decade, older adults in the ED usually do not receive guideline-directed fall prevention[8] or cognitive assessment.[9] These deficiencies are associated with patient dissatisfaction,[10] preventable ED returns,[11] and functional decline. How is this gap between published guidelines and bedside healthcare delivery possible? The Institute of Medicine estimates a 17-year delay for just 14% of practice-ready healthcare research and guidelines to reach the bedside.[40] As a pertinent example of an implementation science intervention designed to accelerate knowledge uptake in medicine, organizers introduced symposium attendees to the "GED Boot Camp" initiative, which links innovators with healthcare systems primed to adapt effective interventions into multidisciplinary local practice. The Boot Camp promotes and accelerates knowledge transfer by incorporating prior sites' local leaders' lessons learned into regular teleconferences with other past and future Boot Camp sites so that avoidable mistakes or barriers can be more efficiently anticipated and overcome. The "GED Boot Camp" preparations include several months of preparatory teleconferences between the Boot Camp organizers and the local sites, as well as quarterly teleconferences with prior sites for at least a year to assist with the implementation and assessment of quality improvement projects.

Conclusions

Innovation and expertise likely exist in every community for reformulating the longitudinal processes of geriatric emergency care from the pre-hospital setting, through the ED to the inpatient services, and post-hospitalization recovery. Geriatrics is a team sport and requires multidisciplinary engagement as well as support of hospital administration, payers, and home health services. Medical advances in the 20th Century rendered previously unimaginable relief of suffering and

early mortality. Now it is incumbent upon 21st Century providers to wisely invest in system-level resources and educational products that best align patient care experiences with costs and attainable patient-centered outcomes for geriatric patients.

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Disclosure

None reported.

MM

Sleep and Epilepsy: A Complex Interplay

by Sean Lanigar, MD & Susanta Bandyopadhyay, MD

Certain epilepsies are associated with sleep, especially in childhood, with epilepsies in adults activated by both sleep and sleep deprivation.





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Abstract

In this review we look to provide an overview of the complex interactions between sleep and epilepsy, and how knowledge of the interplay between the two can help in guiding management of disorders in both areas.

Introduction

Going as far back to ancient times, a relationship between sleep and epilepsy was recognized by the Greeks. Aristotle believed that altered states of consciousness, such as sleep or seizures, involved disassociation of the soul from the body, allowing prophecy of the future.[1] It was not until the late 1800s though that Gowers recognized that approximately 20% of those patients with epilepsy experience seizure solely in sleep. With the dawn of EEG, Gibbs recognized that epileptiform activity increased during sleep. It was recognized that close to half of patients with generalized tonic-clonic seizures had a nocturnal predominance. In this review, we seek to explore some of these relationships between epilepsy and sleep. Sometimes there can be problems differentiating between nocturnal seizures from sleep disorders. It is often important to recognize sleep's effects on epilepsy, along with comorbid sleep disorders affecting the treatment of epilepsy.

Sleep's effects on Epilepsy

There are two main sleep states, nonrapid eye movement (NREM) sleep, and rapid eye movement (REM) sleep. Depending on the stage of sleep, epileptiform discharges can either be activated or inhibited. Typically epileptiform discharges are likely to propagate during NREM sleep along with traditional drowsy EEG arousal periods, as this is a more synchronized state, when we see such synchronized sleep architecture as sleep spindles and high amplitude delta waves. In contrast, during REM sleep, there are asynchronous cellular discharge patterns which make epileptic EEG potentials less likely to propagate. It has been seen that during NREM sleep, generalized epileptiform discharges are more frequent.[2] Generalized epileptiform discharges increase with deepening of non-REM sleep. These discharges can look irregular and focal at times in NREM sleep.[3] The differing stages of sleep also have an effect on focal epilepsy. NREM sleep has been shown to activate focal epileptiform abnormalities in patients with focal epilepsy, with more spikes seen during deeper stages of slow wave sleep compared to later stages of sleep.[4] Non-REM sleep is also associated with increased propagation of spikes with REM sleep more associated with a restriction of those abnormalities.[5] As a result, REM sleep can have helpful localizing

value for primary epileptogenic focus in temporal lobe epilepsy.[6] Interestingly enough, while interictal abnormalities are more prevalent in slow wave sleep, seizures tend to occur out of earlier stages of sleep more commonly.

Epilepsies Associated with Sleep

With epileptiform abnormalities being activated by certain stages of sleep, it is not unusual that there are certain types of epilepsies that occur more frequently out of sleep. There are multiple theories proposed to explain nocturnal seizures. As noted earlier, in NREM sleep seizures and interictal epileptiform abnormalities are activated, as this is a state of relative hypersynchronization, possibly leading to seizures. It has also been noted that arousals tend to activate certain types of epilepsies, such as juvenile myoclonic epilepsy, possibly pointing to the hyper synchronization during arousal was a cause for seizures. A third possibility points to circadian mechanisms playing a part in activating interictal epileptiform abnormalities. Several studies, including animal studies, have shown an afternoon or bimodal morning and afternoon peak for temporal lobe seizures, and evening peak for frontal lobe seizures.[7] Needless to say all these mechanisms might play a part in some of the sleep-related epilepsies. Many of the sleep-related epilepsies tend to start in childhood. In the pediatric population, one of the more common epilepsies is benign epilepsy of childhood with central temporal spikes, which has a characteristic EEG pattern and presents with focal motor seizures occurring during sleep.[8] About 70-80% of the seizures occur exclusively during sleep. Another common sleep related epilepsy seen in adolescence is Juvenile Myoclonic Epilepsy. Classically it presents with seizures upon awakening, and is associated with myoclonic jerks or generalized tonic-clonic seizures within 1-2 hours of awakening. A third type of sleep related epilepsy of childhood is Landau Kleffner syndrome. This epilepsy presents in childhood with language regression. On EEG there a continuous spike wave pattern during sleep, which is associated with cognitive and psychological deficits. In adults, focal onset seizures are the most common types of epilepsies occurring out of sleep. Of those, frontal and temporal lobe seizures are the most common types, with frontal lobe classically being the most common epilepsy to occur out of sleep. Classically nocturnal frontal lobe seizures are characterized by paroxysmal arousals with hyper motor movements with complex motor movements, lasting a brief amount of time. About half of the time the EEG is normal interictally, and can even be normal during the seizures. Sleep-related temporal lobe seizures are also quite frequent, representing one third of overall temporal lobe seizures in epilepsy monitoring units.[9] Many of these patients awaken from sleep with an aura, and then progress to their typical complex partial seizure, and have amnesia of the event.

Comorbid Sleep Disorders in Epilepsy

Patients with epilepsy can have comorbid sleep disorders. Excessive daytime sleepiness is a common complaint amongst epilepsy patients. Interestingly one study found little effect of the number of antiepileptic medications, seizure frequency, epilepsy syndrome, or nocturnal seizures on the complaint of excessive daytime sleepiness.[10] Sleep disordered breathing, such as obstructive sleep apnea, is thought to contribute to the excessive daytime sleepiness in some epilepsy patients. Approximately one third of patients undergoing epilepsy presurgical evaluation has been found to have sleep disordered breathing, with the most common one being obstructive sleep apnea.[11] Predisposing factors for obstructive sleep apnea include older age, male gender, obesity, and oropharyngeal narrowing, with an independent predictor in epilepsy being thickened neck circumference. Several retrospective studies have shown improved seizure control in patients with refractory epilepsy with continuous positive airway pressure treatment, with one study showing a comparable effect in some patients of adjunctive antiepileptic drug treatment; with 50-60% of patients experience a 50% or greater seizure reduction.[12] Insomnia can also affect patients with epilepsy. Arousals can be from a multiple factors, including epilepsy itself, medication effects, or other substance

abuse. Patients can also have fears associated with sleep, such as having a seizure out of sleep. Frequent arousals have been shown to be a trigger and manifestation of seizures themselves.[8] Patients with epilepsy have higher incidences of anxiety depression compared to the general population, with these disorders frequently being associated with insomnia.

Sleep Deprivation

Sleep deprivation has been classically associated with epileptic seizures and epileptiform discharges in patients.[13] Janz originally reported sleep deprivation or excessive alcohol precipitating the first seizure and 28 of 47 patients with juvenile myoclonic epilepsy. Sleep deprivation has also been shown to facilitate epileptiform discharges in patients with generalized epilepsy. However the question remains whether sleep deprivation has a genuine activating effect on epileptiform discharges, or acts as a way for sleep induction.[14] When comparing drug-induced sleep versus sleep deprivation-induced sleep, there is more epileptic discharges in activated patients with sleep deprivation versus drug-induced sleep. Awakening EEGs after sleep deprivation show more epileptiform discharges than sleep EEGs after sleep deprivation, suggesting that sleep deprivation as an independent activator of epileptiform discharges.

Effect of Epilepsy on Sleep

The effect of epilepsy on sleep can be related to the same pathophysiological mechanism causing epilepsy or to the effect of seizures or to the effect of antiepileptic therapy or a combination of these factors. Increase in sleep onset latency, increase in the wake time after sleep onset, increased instability of sleep stages, increased stage N1 and N2 NREM sleep (light sleep), decrease in sleep spindle density, and decrease in REM sleep have all been reported in patients with epilepsy. A seizure occurring out of sleep may be associated with decrease in REM sleep and sleep efficiency, and increase in light sleep. REM sleep and sleep efficiency may be further reduced if a seizure occurs before the first REM cycle.[15]

Many patients note postictal hypersomnolence following seizure which may last for more than a day at times.[16] Seizures can cause sleep disruption by decreasing sleep efficiency, increasing sleep stage shifts, and increasing periods of wakefulness in patients with primary generalized seizures or complex partial seizures compared with normal controls.[15] Increased sleep fragmentation and instability can happen on seizure-free nights as well.

Effect of Antiepileptic Drugs (AEDs) on Sleep

Antiepileptic drug, (AEDs) can cause sedation or may promote alertness and may have direct effect on sleep architecture. However, it is important to remember that it may be difficult to tease out the effect of AEDs on sleep from the effect of epilepsy itself. A review of studies describing the effects of AEDs on sleep reveals many aspects of effect of AEDs on sleep.[17] Phenytoin caused a decrease in sleep-onset latency. Phenobarbital and gabapentin reduced both sleep-onset latency and arousals from sleep. Increase in slow-wave sleep (SWS, N3 NREM sleep) was observed with pregabalin, carbamazepine and gabapentin whereas levetiracetam and ethosuximide caused a decrease. While ethosuximide and gabapentin potentiated REM sleep by increasing its duration, phenobarbital and phenytoin reduced REM sleep. Daytime sleepiness was not found to occur on topiramate, lamotrigine, zonisamide, and vigabatrin when tested by objective sleep measures like multiple sleep latency test (MSLT). Sleepiness may be associated with higher doses of phenobarbital, and possibly valproic acid and levetiracetam. Benzodiazepines increase NREM sleep but decrease SWS and sleep latency.[18] Increase in arousals has been reported with valproate.[19] Topiramate and zonisamide do not have significant effect on sleep architecture.[20,21] Lacosamide did not have any subjective or objective effect on sleep in healthy individuals.[22]

The effect of AEDs on sleep may vary from patient to patient. Therefore, patients should be closely monitored and questioned about changes in sleep patterns upon initiation or change in AED therapy. Knowledge of the effects of AEDs on sleep can help in medication selection based on the patient's sleep history. Patients with insomnia may benefit from being on an AED with higher sedating potential or a

higher dose of it in the evening. On the other hand, patients with hypersomnia or day-time sleepiness may benefit from being on an AED with less potential to cause sedation or one that promotes alertness in the morning.

Effect of Vagus Nerve Stimulation on Sleep

Studies looking at the effect of vagus nerve stimulation (VNS), a treatment modality in patients with medically refractory epilepsy, on sleep have shown variable results. Increased sleep latency on the MSLT indicating reduced day-time sleepiness was noted in patients on VNS therapy.[23] Patients with VNS therapy at relatively low stimulus intensities (output current of less than 1.5 mA) was found to have a significant improvement in sleep latency as observed on MSLT in another study.[24] Increased slow-wave sleep and stage NREM sleep in patients on VNS therapy have also been reported.[25] VNS has been associated with worsening of sleep-related breathing disorder in some cases, lowering the frequency and increasing the cycle time may be helpful to prevent worsening of sleep apnea during VNS therapy.[26]

Effect of Epilepsy Surgery on Sleep

Surgical treatment of epilepsy improves sleep in patients with epilepsy. A questionnaire based study to look at excessive daytime sleepiness and subjective sleep quality in patients who underwent epilepsy surgery for treatment of temporal lobe epilepsy (TLE) reported significant improvement in subjective sleep quality after epilepsy surgery.[27] Total sleep time and REM sleep significantly increased one year after TLE surgery associated with reduction in the frequency of seizures and interictal epileptiform discharges.[28]

Seizures and Parasomnias

Seizures occurring out of sleep can be difficult to distinguish from NREM- and REM-sleep related parasomnias. A clear description of the events is very important for differentiation between seizure and parasomnia but it may not always be available. Polysomnography with extended EEG montage may be necessary for a definitive diagnosis. NREM sleep parasomnias consisting of the disorders of arousal, which include sleep-walking, sleep terrors, and confusional arousals occur in the first-half or first-third of the night; they are typically associated with minimal or partial memory of the event. REM sleep behavior disorder is a REM sleep parasomnia characterized by patient's acting out their dreams due to absence of atonia during REM sleep; it is more common during the latter half of the night. Psychogenic nonepileptic spells (PNES) may occur during what appears to be behavioral sleep (pseudosleep) while EEG is consistent with wakefulness; eyes are typically closed during PNES whereas eyes are open during epileptic seizures. Epileptic seizures are characterized by their stereotypy, brief duration, amnesia for the event, and postical state with the caveat that consciousness may be intact and posticta state may be very brief with some frontal lobe onset seizures.

Sudden Unexpected Death in Epilepsy and Sleep

Sudden Unexpected Death in Epilepsy, (SUDEP), is defined as a "sudden, unexpected, witnessed or unwitnessed, non-traumatic and non-drowning death in patients with epilepsy with or without evidence for a seizure and excluding documented status epilepticus in which postmortem examination does not reveal a toxicologic or anatomic cause for death." The incidence may be as high as 6.0-9.3 per 1000 patient-years among patients evaluated for or treated with epilepsy surgery or those who continue to have seizures after epilepsy surgery.[29] The mechanism responsible for SUDEP remains unclear but the role of sleep has been suspected. In a Norwegian study 25 out of 42 patients were found dead in bed and 14 were thought to have died in sleep.[30] Several different mechanisms probably exist, and most research has focused on seizure related respiratory depression, cardiac arrhythmia, cerebral depression, and autonomic dysfunction.[29] Changes in autonomic function during sleep increasing vulnerability to cardiorespiratory decompensation during seizure may be a possible reason for increased occurrence of SUDEP during sleep.

Summary

In summary sleep and epilepsy are closely related, with certain stages of sleep providing a

hypersynchronous state, allowing more frequent epileptiform abnormalities, along with more frequent seizures. Certain epilepsies are associated with sleep, especially in childhood, with epilepsies in adults activated by both sleep and sleep deprivation. Comorbid sleep disorders are common in patients with epilepsy, and can affect epilepsy management. Sleep disorders are common and treatment of them especially sleep-disordered breathing may improve seizure control. Some parasomnias may mimic seizures – polysomnography with extended EEG montage may be necessary for characterization. Seizures can adversely affect quality and quantity of sleep whereas antiepileptic therapy (AEDs, VNS or surgery) can have negative or positive effect on sleep. Therefore, inquiring about sleep quality as well as screening, evaluation, and treatment for sleep disorders should be a part of care in patients with epilepsy.

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Disclosure

None reported. **MM**

Acute Aortic Syndromes: Diagnosis and Treatment

by Michael C. Murphy, MD, Catherine F. Castner, RN & Nicholas T. Kouchoukos, MD

Rapid diagnosis and institution of appropriate medical and surgical therapy can result in satisfactory outcomes for the majority of patients.



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Abstract

Acute aortic syndromes are disorders of the thoracic and abdominal aorta that are usually symptomatic and require urgent evaluation and treatment. They include acute aortic dissection, intramural hematoma, and penetrating atherosclerotic ulcer. Knowledge of the natural history of these conditions, prompt diagnosis, and surgical intervention, when indicated, are the keys to successful outcomes.

Background

Acute aortic syndromes are disorders of the thoracic and abdominal aorta that are usually symptomatic and require urgent evaluation and consideration for surgical intervention. They include acute aortic dissection and two variants: intramural hematoma, and penetrating atherosclerotic ulcer. Physicians will encounter patients with these conditions across a spectrum of specialties, including family and internal medicine, emergency medicine, critical care, radiology, cardiology and cardiac surgery.

Acute Aortic Dissection

Acute aortic dissection, (AAD), is the most common and most lethal of the acute syndromes, and requires urgent diagnosis and treatment. Untreated, it is associated with mortality rates of 1% to 2% per hour after the onset of symptoms, and 90% at three months. [1,2] Aortic dissection results from a tear in the aortic wall, and a column of blood enters the medial layer of the aorta creating a "hydraulic endarterectomy."[3] This divides the aorta into true and false lumens that are separated by a septum consisting of medial and intimal aortic tissue (See Figure 1). The medial tissue is often abnormal and weakened as the result of cystic medial degeneration. The separated outer layer, comprised of aortic medial tissue and adventitia, may be strong enough in some patients to prevent death from rupture of the aorta into the pericardial cavity and fatal cardiac tamponade, or rupture into the pleural cavities resulting in fatal exsanguination. The extent of the dissecting hematoma determines outcome.[3] This hematoma, which most commonly originates from a tear in the proximal ascending aorta, extends antegradely (or distally) for a variable distance, and may cause obstruction of critical aortic branches, including those to the brain, kidneys, abdominal viscera, and extremities. Occlusion of intercostal and lumbar arteries can result in paraplegia. If the dissecting hematoma extends proximally (retrogradely), it can occlude the ostia of the coronary arteries, resulting in myocardial infarction, and can disrupt the aortic valve, creating severe aortic regurgitation.

Risk Factors

Hypertension is the most common risk factor associated with AAD.[1] Cystic medial degeneration of severe degree is present in about 20% of patients. Other risk factors include the presence of genetically mediated syndromes (Marfan, Loeys-Dietz, Turner,Noonan, Ehlers-Danlos), a bicuspid aortic valve, dilatation of the ascending aorta and aortic root, and coarctation of the aorta (See Table 1). A genetic basis for nonsyndromic familial thoracic aortic aneurysm and dissection, another risk factor, has recently been identified.[4] Additional risk factors are aortic inflammatory disorders (aortitis), pregnancy, and extreme isometric exertion (such as weight lifting or other activity that results in marked and rapid elevation of systolic blood pressure). Extreme emotional upset associated with severe hypertension has resulted in AAD. We treated a patient who sustained an aortic dissection while berating the referees at his daughter's basketball game. Cocaine use is a risk factor. Catheter-based interventions on the aorta and the coronary arteries and manipulations during open cardiac surgical procedures can result in aortic dissection

Classification

Two classifications of aortic dissection are widely used (See Figure 2).[1,2] The Stanford classification is the most popular. Stanford type A includes any dissection that involves the ascending aorta, with or without involvement of the aortic arch or the distal aorta. Stanford type B includes any dissection that originates in the descending thoracic aorta, and the dissection can occasionally extend proximally into the aortic arch. In the DeBakey classification, type I is analogous to the Stanford type A, and type III is analogous to the Stanford type B. The DeBakey type II is a dissection that originates in the ascending aorta, is confined to it, and is the least common.

Symptoms and Signs

The most common symptom of AAD is sudden and severe chest pain.[1] However, other variants of chest pain and back pain have been described, and AAD can also occur in the absence of pain. In type A dissection, the pain is usually located in the anterior chest, and may

Figure 1



Figure 2

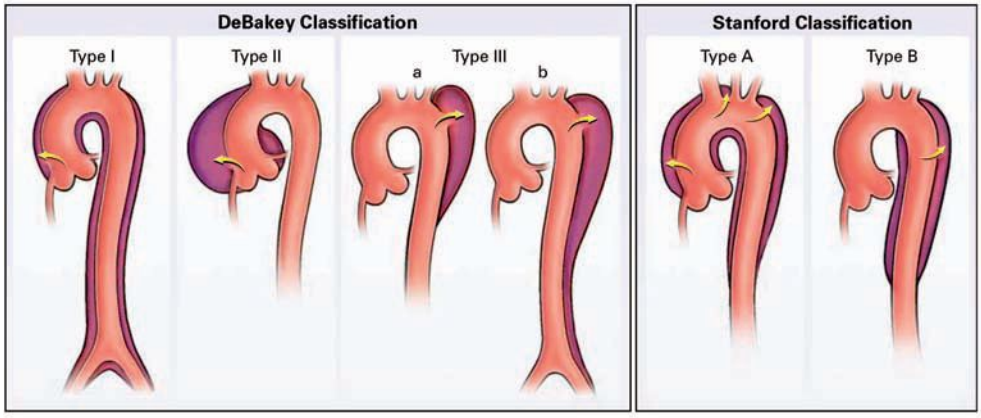


Table 1

Risk Factors for Acute Aortic Dissection

Hypertension	
Cystic medial degeneration	
Genetically mediated syndromes	Marfan Loeys-Dietz Turner Noonan Ehlers-Danlos
Bicuspid aortic valve	
Dilatation of ascending aorta and aortic root	
Coarctation of the aorta	
Non-syndromic familial thoracic aneurysm	
Aortic Inflammatory disorders (Aortitis)	Takayasu Giant Cell Arteritis Behcet's
Pregnancy	
Extreme Isometric exertion	
Cocaine use	
Aortic Intervention	Cardiac Catheterization Cardiac Surgery

Figure 3

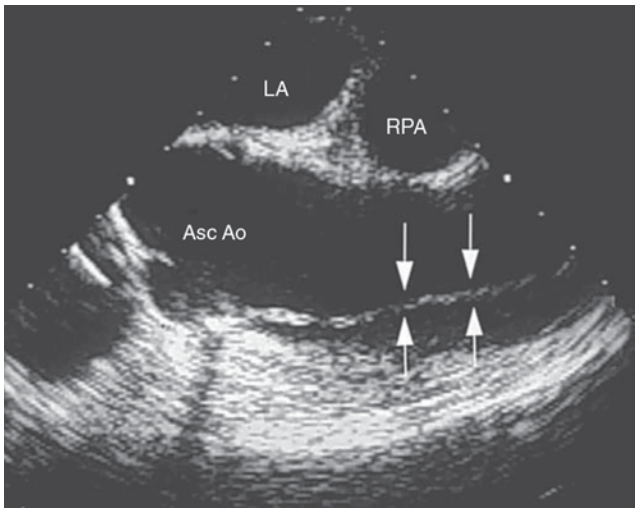
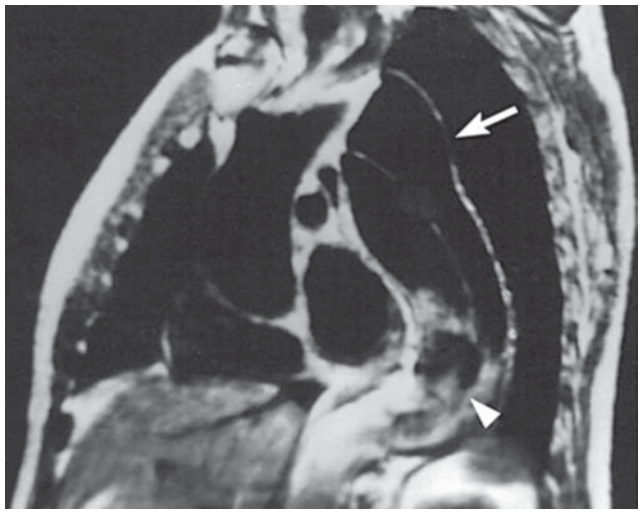


Figure 4



radiate into the neck, back or abdomen. In type B dissection, the pain usually occurs posteriorly in the chest and also in the abdomen. Other symptoms include syncope, caused by hypotension associated with cardiac tamponade or rupture of the aorta, and coma, due to occlusion or severe obstruction of the brachiocephalic arteries. Abdominal pain is caused by mesenteric and renal artery hypoperfusion. Renal failure in the setting of AAD is associated with a mortality rate of 50 – 70%, and mesenteric ischemia with a rate as high as 87%.[1] Absence of pulses in the lower extremities results from occlusion of the aorta and iliofemoral arteries.

Diagnosis

Patients presenting to the emergency department with significant chest pain will have an electrocardiogram and a serum troponin determination to rule out myocardial infarction. It is important to note however, that the electrocardiogram can be abnormal in up to 70% of patients with an ascending aortic dissection. If the diagnosis of myocardial infarction is in question, other diagnostic studies should be performed promptly to rule out aortic dissection, so that agents that affect coagulation are not administered. A chest radiograph may show widening up the upper mediastinal shadow, but is often unremarkable. Computed tomographic scanning with contrast (CT) is currently the most widely used diagnostic study to detect AAD, and should be obtained in any patient with chest pain and an uncertain diagnosis (See Figure 1). It is highly sensitive and specific for dissection. Not infrequently, an aortic dissection is demonstrated on a CT study that is performed to rule out a pulmonary embolus, although enhancement of the thoracic aorta may be suboptimal using the pulmonary embolus protocol. Unfortunately, failure to diagnose AAD by not performing a CT study in patients presenting with chest pain of uncertain etiology is a not infrequent cause of law suits when these patients are discharged from the emergency department and subsequently die of their dissection.

Transesophageal echocardiography (TEE) is a highly sensitive and specific study to detect AAD involving the ascending aorta, and is distinctly superior to transthoracic echocardiography. It can be performed rapidly but requires sedation and a cardiologist to perform the study. In addition to identifying the dissecting membrane, TEE can identify pericardial tamponade, aortic regurgitation, and involvement of the coronary arteries in the dissection. It may also identify the site of the intimal tear, which is helpful to the surgeon (See Figure 3). Transthoracic echocardiography (TTE) is limited to examination of only the proximal ascending aorta, the aortic valve and the contents of the pericardial cavity. Magnetic resonance imaging (MRI) is also a highly sensitive and specific study to detect AAD (See Figure 4). It does not require use of contrast medium and thus can be useful in patients with impaired renal function. In some situations it can provide information similar to that which can be obtained from echocardiography, CT and aortography. Disadvantages of MRI compared with CT and TEE include higher cost, a longer time to complete the study, inaccessibility to patients who are

connected to ventilators and monitoring devices, and limited availability.

Despite advances in noninvasive and minimally invasive techniques for diagnosis of AAD, aortography remains an important and highly accurate method for establishing the diagnosis, and remains the benchmark against which all other diagnostic studies are measured. However, it is used far less frequently, and most often in conjunction with coronary angiography in stable patients with AAD who are suspected of having significant coronary artery disease. Although some patients with AAD may have important coronary artery disease, the risk of rupture in hemodynamically unstable patients greatly exceeds the risk of a possible intraoperative myocardial infarction and consequently, the majority of patients with AAD do not undergo preoperative coronary angiography.

Treatment

The initial treatment of Type A AAD involves rapid control of blood pressure and heart rate thus reducing the velocity of contraction of the left ventricle (dP/dt), in an effort to prevent extension of the dissecting hematoma. Intravenous beta blocking agents are administered to reduce dP/dt and to induce bradycardia.[3] Afterload reduction is achieved with administration of intravenous sodium nitroprusside, clevidipine, or nicardipine. In our institution, all patients with AAD involving the ascending aorta who are considered suitable candidates for operative treatment are taken directly to the operating room from the emergency department or when they are transferred from other hospitals. Patients with type B (DeBakey type III) dissection are initially managed similarly with beta blockade, followed by afterload reduction, and are transferred from the emergency department to an intensive care unit for invasive monitoring and control of blood pressure and pain.

Type A Dissection

The goal of surgery for AAD involving the ascending aorta is to prevent death from pericardial tamponade or exsanguination. The surgical objective is to eliminate the site of the intimal tear by excision of the segment of aorta containing the tear and replacement with a synthetic graft, redirecting blood flow into the true lumen. The most common site of the intimal tear is in the ascending aorta just above the commissures of the aortic valve, and it is present in this location in approximately 70% of patients with Stanford type A and DeBakey types I and II dissections. The tear is present in the aortic arch in 10% of patients, and in the descending thoracic aorta in 20%.[5] If the tear is present in the aortic arch, the aortic arch is replaced as well. If significant aortic regurgitation is present, the aortic valve is repaired or replaced. Operative treatment is associated with significant risk, and is adversely affected by the presence of severe hemodynamic instability, malperfusion of important organ systems as a result of the dissection, and severe central nervous system dysfunction. However, given the natural history of the condition without surgical intervention, few patients are refused operation. Early mortality in experienced centers has ranged from 15% to 35%.[1]

Type B Dissection

The majority of patients who sustain a type B (DeBakey III) dissection can be managed with non-operative therapy, which involves aggressive management of hypertension. For patients who do not require surgical intervention, one-year survival is approximately 90%.[4] The indications for immediate surgical intervention include evidence for free or contained rupture, rapid expansion of the aortic diameter, organ or limb ischemia resulting from malperfusion, uncontrollable hypertension, and intractable pain. Presence of a genetically mediated syndrome such as Marfan or Loeys-Dietz may be an indication for intervention because of poorer results with medical therapy. Open surgical repair consists of resection of the segment of aorta containing the intimal tear and any aneurysmal aorta, and replacement with a synthetic graft, restoring flow to the true lumen Alternatively, and now more commonly, patients with acute type B dissection requiring intervention are treated with endovascular stent grafts which cover and exclude the intimal tear, and restore flow to the true lumen. These procedures have been associated with lower operative morbidity and mortality than open repair.

Intramural Hematoma

Intramural hematoma (IMH) results from rupture of vasa vasora (the blood vessels that supply the aorta),

Figure 5

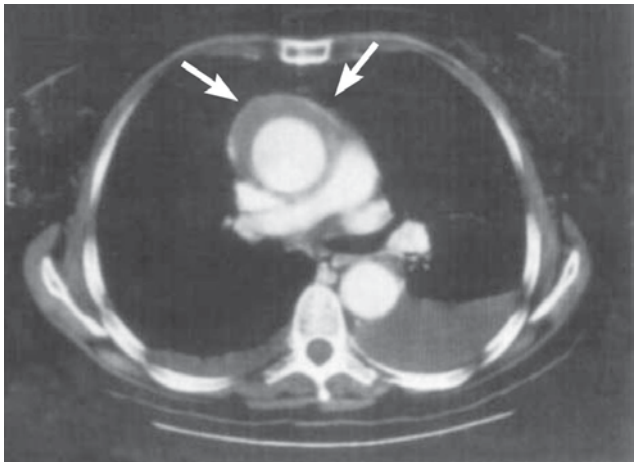


Figure 6A

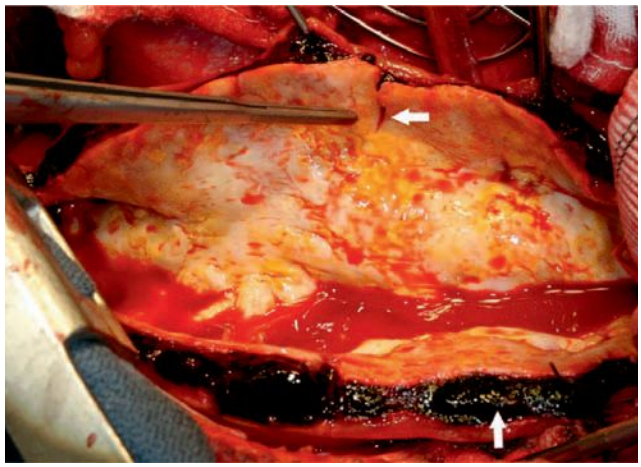
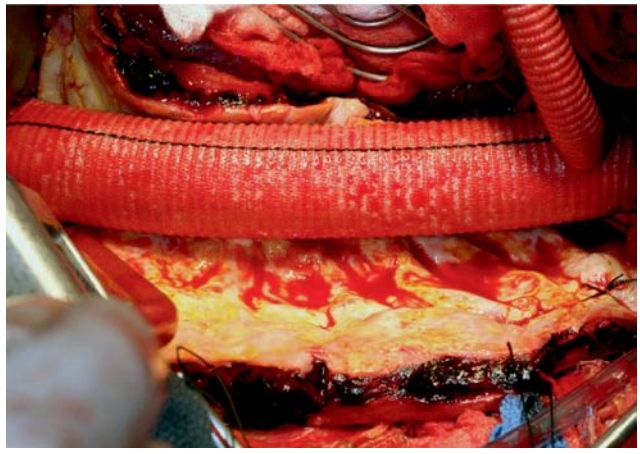


Figure 6B



and a hematoma develops within the aortic wall (See Figures 5 and 6A and 6B).[2] Less commonly it results from an intimal fracture of an atherosclerotic plaque. Patients can present with symptoms and signs identical to those seen in patients with AAD, and initial evaluation and management are similar to those for patients with AAD.

The natural history of IMH is variable. Progression to frank aortic dissection occurs in from 28% to 47% of patients in the largest reported series.[1] Larger aortic diameter (>5.5 cm) and hematoma thickness (>16mm) predict progression to AAD and a worse outcome.[6] Treatment of patients with these findings in the ascending aorta, and of patients who have severe chest pain or hemodynamic instability is identical to that for patients with type A AAD. In most patients with ascending aortic involvement, there is no intimal tear. The ascending aorta is resected and replaced with a synthetic graft. This will eliminate the risk of rupture and tamponade. In our practice, the majority of patients with IMH involving the ascending aorta undergo aortic replacement.

Patients who present with IMH in the descending thoracic and abdominal aorta are initially managed conservatively with beta blockade and control of hypertension. Serial imaging is necessary to monitor changes in aortic diameter and evidence for extention of the hematoma. Resolution of the hematoma occurs commonly. If there is evidence for enlargement of the aorta or extension of the hematoma, open or endovascular repair is indicated.

Penetrating Atherosclerotic Ulcer

Penetrating atherosclerotic ulcer (PAU) is generally a less lethal condition than AAD and IMH (Figure 7).[7] Patients can however, present with severe chest pain and require careful evaluation. More commonly however, PAUs are discovered incidentally on angiographic CT, or MRI imaging studies of the chest and abdomen that are performed for other indications (See Figure 8). They generally occur in densely calcified areas of atherosclerosis in the descending thoracic and abdominal aorta. A small percentage of the ulcers will progressively enlarge to form saccular aneurysms. They can also result in dissection and formation of an IMH. If surgical intervention is indicated for any of the above complications, endovascular repair is usually feasible if the ulcer is present in the ascending or abdominal aorta, and is preferred over open repair.

Follow-Up

Patients who survive acute aortic syndromes especially AAD, require close follow-up after initial therapy to detect aortic aneurysm formation in the remaining aorta, extension of the dissection or intramural hematoma, and enlargement of a penetrating ulcer. CT

Figure 7

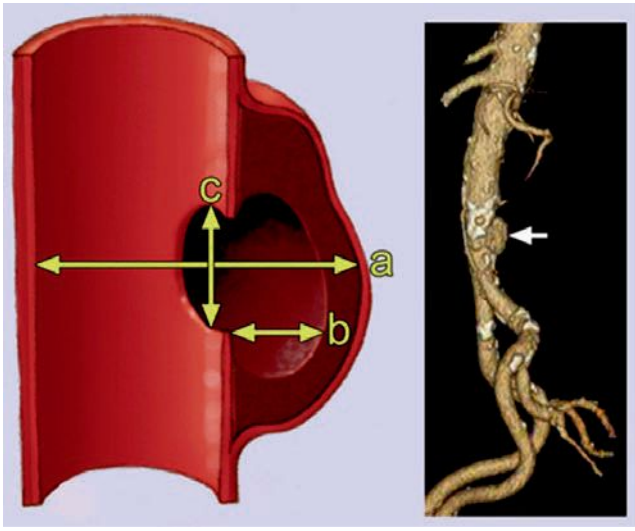
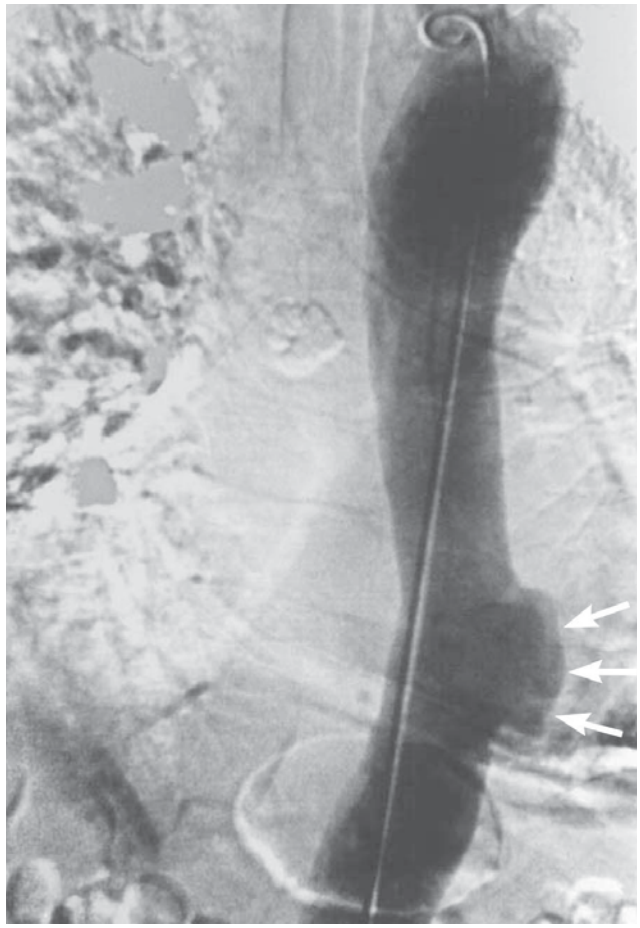


Figure 8



or MR imaging and meticulous control of blood pressure with beta blocking agents or other antihypertensive medications are the mainstays of management. Follow-up at a dedicated aortic surgical center is advisable.

Any patient who is found to have an enlarged thoracic aorta with a diameter of 4 cm or greater should receive appropriate medical therapy, and be followed at regular intervals to determine the need for surgical intervention.[8,9] Untreated hypertension is a risk factor for aortic enlargement, aneurysm formation and aortic rupture. Other risk factors, such as smoking and dyslipidemia should be addressed as well.

Currently, according to the American College of Cardiology/American Heart Association Guidelines, an asymptomatic patient with an ascending aorta measuring 5.5 cm or more in diameter, or who has evidence for aortic enlargement of more than 0.5 cm in a year should be considered for surgical intervention.[10] The size threshold is somewhat greater for aneurysms involving the aortic arch and descending thoracic aorta. For patients with genetically mediated conditions, the threshold may be lower.

Aortic dissections, intramural hematomas, and penetrating atherosclerotic ulcers are all treatable conditions and rapid diagnosis and institution of appropriate medical and surgical therapy will result in satisfactory outcomes for the majority of patients.

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Disclosure

None reported.

MM

The Microvascular and Macrovascular Benefits of Fibrates in Diabetes and the Metabolic Syndrome: A Review

by Pavan Malur, MD, Arthur Menezes, MD, James J. DiNicolantonio, PharmD, James H. O'Keefe, MD & Carl J. Lavie, MD

In pharmacology, the fibrates are a class of amphipathic carboxylic acids. They are used for a range of metabolic disorders, mainly hypercholesterolemia, and are therefore hypolipidemic agents.





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Abstract

Background

The purpose of this article is to discuss the evidence regarding potential macrovascular and microvascular benefits of fibrate therapy in general and fenofibrate specifically.

Methods

We performed a literature review summarizing the results of studies testing fibrates on relevant.

Results

Although statins are the first line therapy with an unparalleled amount of evidence for reducing the risk of cardiovascular disease (CVD) in patients with dyslipidemia and the metabolic syndrome (MetS), there are several landmark studies that have focused on the potential benefits of fibrate therapy for reducing CVD risk. Fibrates confer benefits mostly for patients with diabetes mellitus (DM), MetS, and atherogenic dyslipidemia. Recently, many studies have shown that fibrates confer benefits on the vascular system as well as the liver and kidneys. Fibrates also have demonstrable benefits in cohorts of patients with DM and renal disease.

Conclusions

Fibrates appear to provide significant microvascular and macrovascular benefits particularly in patients with DM, MetS, or renal disease.

Introduction

Early fibrate trials used clofibrate as monotherapy, which found that it improved lipid levels in hypercholesterolemic patients. Clofibrate was approved by the Food and Drug Administration (FDA) for hyperlipidemia treatment in the United States (US) in 1967.[1] Since then, additional fibrates were introduced in the late 1970s and early 1980s. During the 1990s and early 2000s, there have been several landmark clinical trials focused on potential clinical benefits of this class of medications.

Metabolic Syndrome and Cardiovascular Disease

Metabolic syndrome (MetS) is characterized by insulin resistance, abdominal or central obesity, hypertension (HTN), impaired glucose tolerance and atherogenic dyslipidemia, is a precursor of type 2 diabetes mellitus (T2DM), and is strongly associated with a high risk of major Cardiovascular Disease (CVD) events, particularly, coronary heart disease (CHD) adverse events.[2]

The Armed Forces Regressive Study (AFREGS) addressed the issue of dyslipidemia in MetS. By definition, two of the components comprising the ATP III definition of MetS are abnormal triglycerides (TGs) and low levels of high-density lipoprotein cholesterol (HDL-C).[3] Although there is an inverse relationship between TGs and HDL-C, elevated TGs are also associated with many other CHD risk factors, such as unhealthy diet, characterized by excess calories and high glycemic load, obesity, diabetes mellitus (DM), HTN, sedentary lifestyle, inflammation and a prothrombotic state.[4, 5]

A study based on the Third National Health and Nutrition Examination Survey data demonstrated that among the components of MetS, elevated serum TGs were strongly related to myocardial infarction (MI) and stroke.[6] Another study showed that among the components of MetS, elevated serum TG levels conferred the highest hazard ratios (HR) to independently predict coronary atheroma progression.[7] The Pravastatin or Atorvastatin Evaluation and Infection Therapy–Thrombolysis in MI 22 (PROVE IT-TIMI 22) trial demonstrated that patients with TGs levels less than 150 mg/dL had a lower risk of recurrent CHD events independent of the level of low-density lipoprotein cholesterol (LDL-C).[8] This finding may be secondary to the atherogenicity of TG-rich remnant particles and effects on the relative functionality of circulating LDL-C and HDL-C particles. [7, 9]

Pierre and colleagues published results of their study on the relationship of hypertriglyceridemia (HTG) waist phenotype (waist circumference >35.4 inches in men or >33.5 inches in women) and a plasma TG level >177 mg/dL) and CHD among patients with T2DM or glucose intolerance.[10] Patients who had the hypertriglyceridemic waist phenotype had a significant two-fold increase in risk of CHD (P=0.02) and on average experienced the first symptoms of CHD five years earlier than patients without the phenotype.

Furthermore, the Metabolic, Lifestyle, and Nutrition Assessment in Young Adults (MELANY) study evaluated the effect of variations in TG levels over time on CHD risk. In this trial, men aged between 26 to 45 years (N = 13,953) with baseline fasting TG levels <300 mg/dL had TG measurements taken at two time points over the span of five years; CHD was diagnosed by angiography-proven stenosis > 50% in at least one coronary artery or fatal or nonfatal MI. Men with TG levels (≤ 93 mg/dL) at the first time point experienced a 3.8-fold greater CHD risk if their TG levels increased to intermediate (94-147 mg/dL) or 6.8-fold increased risk if their TG levels increased to high levels (≥ 148 mg/dL) at the second time point, compared with men who maintained low TG levels over the five years. Additionally, men with low TG levels at the second time point had a 3.9-fold and 4.9-fold increased CHD risk if their TG levels were intermediate or high at the first time point compared with men who maintained low TG levels for the duration of the study. Men with high TG levels at both time points had a 8.2-fold greater CHD risk compared to men who maintained low TG levels, whereas men with high TG levels initially, but intermediate or low levels at the second time point, experienced a 6.8-fold or 4.9-fold increased risk as compared to men who continually had low TGs levels.[11] Thus, changes in TG seem to predict CHD risk and thus introducing fibrates to lower elevated TGs may lead to CV risk reduction. This data demonstrated that in addition to being an independent CHD risk factor, TG levels may have a cumulative effect on CHD risk.[11]

The National Cholesterol Education Program Adult Treatment Panel III (NCEP/ATP III) guidelines recommend focusing on LDL-C as the primary target for lipid therapy to prevent development and progression of atherosclerotic vascular disease.[12] However, many CHD events still occur in patients whose LDL-C levels (and other major risk factors) appear to be adequately controlled (suggesting that other factors play an important role in this complex disease).[13,14] This is perhaps why many guidelines have started to shift focus away from LDL-C and towards non-HDL to capture "all atherogenic lipoproteins."

In major trials of patients treated with statins, around 70% of major CHD events and 80% of all-cause mortality events were not prevented.[15] Some of these studies have also shown that low HDL-C may predict CHD events more so than high LDL-C: i.e. for every increase in HDL-C of 1 mg/dL, the risk of major CHD events decreases by 2% to 3% and the risk of CHD mortality decreases by 4% to 5%.[16, 17] The highest risk of CHD occurs when low HDL-C coexists with high LDL-C.[17,18] Thus, in patients with this phenotype, treatment with statins may not provide adequate CV protection and additional therapies might be needed.

The Role of Fibrates on Lipids

Fibric acid compounds are first line therapy in patients who require pharmacologic treatment for low HDL-C associated with HTG, and they are an alternative to niacin in patients with isolated low HDL-C. However, two recently completed large randomized controlled trials (AIM High, HPS-2/THRIVE) found that niacin is a) ineffective at improving CV outcomes and b) poorly tolerated with frequent adverse effects; which has stimulated increased

interest in the fibrate class of medication for individuals with HTG and/or low HDL-C.[19] Fibrates belong to a class of synthetic peroxisome proliferator activated receptor (PPAR) agonists,which are direct or indirect ligand-activated nuclear transcription factors that regulate a wide range of genes, some of which induce synthesis of apo A-I and apo A-II.

Fibrates can provide a greater than 50% reduction in TGs in some patients with very high TG levels and reductions of 25% to 30% are often noted in patients with moderately elevated baseline levels of TGs. Additionally, fibrates can produce an approximate 25% increase in HDL-C in patients with HTG, but increases in HDL-C of 10% are generally obtained in patients without HTG.[20] Although these drugs are very effective in reducing TG levels by up to 60%, they may also raise LDL-C.[21] However, this effect on LDL-C is minimal in those without significant HTG.

Slow-release fibrates, such as fenofibrate, have been found to be more effective than gemfibrozil in raising HDL-C and are effective even among patients who do not respond to gemfibrozil. The main advantage of fenofibrate is the lower risk of drug interactions and myopathy when it is used in combination with statins[5] ,although recently the FDA has removed the official indication for combining fibrates, particularly fenofibric acid, and nicotinic acid with statins.

In 2005, the Effectiveness and Tolerability of Simvastatin Plus Fenofibrate for Combined Hyperlipidemia (the SAFARI trial) demonstrated that combination therapy with simvastatin and fenofibrate among patients with combined hyperlipidemia resulted in additional improvement in all lipoprotein parameters measured compared with simvastatin monotherapy and was well tolerated. Patients (aged 21 to 68 years) with a diagnosis of combined dyslipidemia (fasting TG levels >150 and <500 mg/dL, and LDL-C >130 mg/dL) received simvastatin monotherapy (20 mg/day, n = 207) or simvastatin 20 mg plus fenofibrate (160 mg/day) combination therapy (n = 411) for 12 weeks following a six-week diet and placebo run-in period. From baseline to week 12, median TG levels decreased 43% (combination therapy) and 20% (simvastatin monotherapy treatment difference -24%, p <0.001]). Mean LDL-C levels decreased 31% and 26% (treatment difference -5%, P <0.001), and HDL-C levels increased 19% and 10% (treatment difference 8.8%, P <0.001) in the combination therapy versus monotherapy groups, respectively. No drug-related serious adverse experiences were observed. No patient experienced clinical myopathy or severe abnormalities in liver function.[22]

In late 1980s, Austin and colleagues published their findings on the association of LDL subclass patterns with elevated levels of TGs and low levels of HDL-C, showing that the enhanced CV risk associated with LDL subclass pattern B, characterized by a preponderance of small, dense LDL particles, is associated with a greater risk of MI and is highly influenced by the levels of HDL-C.[23] Given the efficacy of fenofibrate therapy on reducing levels of TG-rich lipoproteins (very low density lipoprotein and intermediate- density lipoprotein) and raising levels of HDL-C, it is not surprising that combination therapy with simvastatin 20 mg/day plus fenofibrate 160 mg/day also improved the LDL subclass pattern compared with statin monotherapy.

Macrovascular Benefits

Diabetic dyslipidemia (generally characterized as small and dense LDL-C, low HDL-C, and high TGs) can be substantially improved with fibrates. The Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study was designed to evaluate this hypothesis. This study included 9,795 patients with T2DM, aged 50–75 years, with a total cholesterol concentration between 3.0–6.5 mmol/L and a total cholesterol/HDL-C ratio of 4.0 or greater or a plasma TG concentration between 1.0–5.0 mmol/L. The population was composed of 2,131 patients with previous CVD and 7,664 without. Patients were not taking statin therapy at baseline and were randomly assigned to either micronized fenofibrate 200 mg/day or placebo.[24] Fenofibrate therapy was associated with a non-significant 11% reduction in the primary endpoint (CHD death, nonfatal MI) (P=0.16), corresponding to a significant 24% reduction in nonfatal MI (P=0.010) and a non-significant 19% increase in all-cause mortality (P=0.22). Furthermore, there was a significant 11% reduction in total CVD events (P=0.035) among patients allocated to fenofibrate. Finally, subgroup analysis demonstrated that reduction in total CVD events was significant only among patients in primary prevention and in those aged less than 65 years.[25]

Before the FIELD study, several important clinical outcome trials with fibrates were performed: the primary prevention Helsinki Heart Study[26] and the secondary prevention study Veterans Affairs HDL Intervention Trial (VAHIT)[27] with gemfibrozil and the secondary prevention study Bezafibrate Infarction Prevention (BIP) with bezafibrate.[28] Among the 4,081 males included in

the Helsinki Heart study, 135 had type T2DM; among these patients, gemfibrozil reduced CVD risk by 68%, but the difference was not statistically significant due to the small number of T2DM patients included in the study. VAHIT demonstrated that gemfibrozil provided a significant 24% reduction in the incidence of acute CVD events (P <0.001). And in the subgroup of 769 patients with T2DM, gemfibrozil induced a 32% reduction in the incidence of acute CVD events (P=0.004) and a 41% reduction in CVD mortality risk (P=0.02).[29]

In the BIP Study, bezafibrate treatment was associated with a non-significant 10% reduction in the incidence of CVD events in the entire population.[28] Among patients treated with bezafibrate, a significant reduction in fatal and nonfatal MI was noted in the subgroup of patients with MetS,[30] but not in the subgroup of patients with T2DM.[31]

Lee and colleagues conducted a systematic review and meta-analysis to investigate the influence of fibrates on vascular risk reduction among individuals with atherogenic dyslipidemia – HDL-C <40 mg/dL or TG >200 mg/dL. Their analysis of six trials that met selection criteria demonstrated that compared to placebo, the greatest benefit with fibrate treatment was seen among subjects with high TG, as well as high TG and low HDL-C (RR 0.75, 95% CI 0.65 to 0.86, and RR 0.71, 95% CI 0.62 to 0.82, respectively, P <0.001 for both). Less benefit (though still significant) was noted among the 15,303 subjects selected for low HDL-C (RR 0.84, 95% CI 0.77 to 0.91, P <0.001). Among 9,872 subjects with neither high TG nor low HDL-C, fibrate therapy did not reduce subsequent vascular events (P=0.53).[32] The authors concluded, "Fibrate treatment directed at markers of atherogenic dyslipidemia substantially reduced subsequent vascular event risk."[32]

Microvascular Benefits

In the FIELD study, fenofibrate therapy was associated with a significant improvement in DM microvascular disease with a 2.6% reduction in the grade of albuminuria (P=0.002) and a 1.6% reduction in laser treatment for retinopathy (P=0.0003).[25] These results demonstrate the beneficial effect of fenofibrate on the progression of albuminuria as reported in Diabetes Atherosclerosis Intervention Study (DAIS).[33] Additionally, there was a 38% reduction in the number of non-traumatic amputations among individuals on fenofibrate therapy (P=0.011), indicative of the microvascular benefits of fenofibrate.[24]

The mechanism behind an improvement on microvascular endpoints are unknown and cannot be explained by changes in A1C or by the minor reduction in blood pressure (BP) noted in the fenofibrate group according to Verges and colleagues.[25] Furthermore, this microvascular benefit of fenofibrate appeared to be at least partially due to its effect on the lipid profile. Statins have been shown to slow the progression of both nephropathy and retinopathy.[25] The vascular and/or anti-inflammatory effects of fenofibrate, mediated through the activation of PPAR receptors, could contribute to the microvascular benefits.[34]

Effect of Fenofibrates on the Liver

As mentioned previously, fibrates are potent PPARα agonists. Liver fat metabolism depends on PPARα activity and there has been interest in its role in non-alcoholic fatty liver disease (NAFLD) development, which is a spectrum of liver disease ranging from steatosis to non-alcoholic steatohepatitis (NASH). This spectrum of disease is associated with an increased risk of CV disease, DM and liver-related complications.[35]

An experimental study in laboratory animals suggested that fenofibrate might have a beneficial effect on apoptosis induced by bile duct obstruction as well as on hepatocellular damage. Fenofibrate improved cholestasis-induced histopathologic parameters, such as portal inflammation, hepatic necrosis and apoptosis while lowering the concentrations of total bilirubin, total bile acid, alanine aminotransferase (ALT), alkaline phosphatase, gamma-glutamyltranspeptidase (GGT), tumor necrosis factor-alpha and interleukin-1 beta in rats with experimental cholestasis.[36] To further test this in humans, a pilot trial was conducted with 16 patients with biopsy-confirmed NAFLD. They were treated with fenofibrate 200 mg/day for 48 weeks and a liver biopsy was performed at the end of the therapy. This study showed that there was significant decrease in TG, glucose, ALT, and GGT along with a decrease in insulin levels and an improvement in insulin resistance. Furthermore, the proportion of patients with abnormal aspartate transaminase and ALT decreased significantly, from 50% to 19% (P=0.02) and from 94% to 63% (P=0.02, respectively). Biopsy at the end of treatment revealed a decrease in the grade of hepatocellular ballooning degeneration (P=0.03), but the grade of steatosis, lobular inflammation, fibrosis or NAFLD activity score did not change significantly.[37]

Effect of Fibrates on the Kidney

There is additional literature that supports the use of fibrates for renovascular protection apart from the FIELD

study. It has been suggested that dyslipidemia can damage the kidney in a manner similar to atherosclerosis.[38] Lipid deposition in the kidney may trigger glomerular mesangial cell activation and proliferation, which ultimately causes diffuse inflammation resulted in renal fibrosis.[38, 39] Furthermore, these activated mesangial cells, foam cells and macrophages produce reactive oxygen species , which in turn produce oxidized LDL (oLDL), which advances monocyte recruitment, mesangial cell proliferation and cytotoxicity as well as endothelial dysfunction.[38-40]

Diabetic nephropathy or nodular diabetic glomerulosclerosis and intercapillary glomerulonephritis, is a progressive kidney disease caused by angiopathy of capillaries in the kidney glomeruli.[41] Metabolic abnormalities play a key role in the development of DM nephropathy. Hyperglycemia triggers mesangial expansion through increased matrix production and/or glycosylation of matrix proteins.[42] Diabetic dyslipidemia also adversely affects renal function through lipotoxicity. PPARα is implicated in metabolic pathways in T2DM.[43] Reduced or dysfunctional PPAR-α can impair glycemic control and raise free fatty acids and TG levels in DM.[43]

Bishnoi and colleagues explained that PPARα agonism by fenofibrate can prevent early pathological and clinical changes of diabetic nephropathy.[44] A recent experimental study by Kadian and colleagues suggested a protective effect of low-dose fenofibrate pre-treatment against biochemical (raised serum creatinine [SCr] levels, blood urea nitrogen and microalbuminuria) and histological changes (glomerular-capsular wall distortion, mesangial expansion and tubular damage) of diabetic nephropathy in streptozocin-induced DM rats.[45]

Fenofibrate may also protect against diabetic nephropathy abnormalities via vasoactive pathways. It is known that cyclooxygenase-2 and prostaglandins are overproduced by mesangial cells and glomeruli of diabetic kidneys in vivo. These are associated with hyperfiltration in the early stages of DM nephropathy. Hyperglycemia-related enhanced oxidative stress may be the stimulus for this abnormality in DM kidneys.[46]

An ACCORD substudy included 5,518 simvastatin-treated patients. These patients were randomized to fenofibrate or placebo. Mean SCr levels were increased (from 82 μmol/L [0.93 mg/dL] to 97 μmol /L [1.10 mg/dL]) in the first year in the fenofibrate group and remained stable throughout the study (mean 4.7 years). However, no difference between groups was noted in the incidence of end stage renal disease or hemodialysis. Despite adverse effects on estimate glomerular filtration rate a lower incidence of both micro- and macro-albuminuria was noted in the fenofibrate group compared with the placebo group (38.2 vs. 41.6% [P =0.01] and 10.5 vs. 12.3% [P=0.04], respectively).[47]

The anti-inflammatory and antioxidant effects of fenofibrate may also be relevant in hypertensive nephrosclerosis. An experimental study conducted in salt-loaded spontaneously hypertensive stroke-prone rats (this animal model develops systemic inflammation, HTN and proteinuria leading to renal and cerebral injury) indicated that fenofibrate significantly increased survival by delaying both the occurrence of brain lesions (monitored by magnetic resonance imaging) and proteinuria.[48] Moreover, fenofibrate significantly reduced proteinuria, inflammatory cell recruitment and extracellular matrix protein deposition in the kidney of spontaneously hypertensive rats without affecting BP.[49]

Kostapanos and colleagues emphasize that beyond theories on pathophysiology 1] increases in SCr levels are transient and reversible even without treatment discontinuation, 2] fenofibrate can limit proteinuria, which is an independent risk factor for both CVD events and chronic kidney disease, and, 3] fenofibrate was associated with long-term benefits on renal function. However, a close monitoring of SCr levels is relevant especially in high-risk patients. Increases in SCr levels greater than 30% can impose treatment discontinuation.[41]

Pleiotropic Effect of Fibrates

There have been numerous studies published on fibrates that elicit the pleiotropic effects of these medications. In addition to its pivotal role in treating dyslipidemia, many authors suggest that fibrates should also be evaluated in patients with cancer, heart failure, diabetic retinopathy, and nephropathy.[50]

Data from recent studies show that fenofibrate improves vascular endothelial function in healthy normolipidemic middle-aged and older adults by reducing oxidative stress and inducing an increase endothelial nitric oxide synthase.[51] Plasma oLDL, a systemic marker of oxidative stress, also decreased with fenofibrate treatment.[51]

Another study observed a significant improvement in endothelium-dependent vascular reactivity with fenofibrate compared to atorvastatin. This was trial was performed over 10 weeks and compared fenofibrate 200 mg/day to atorvastatin 10 mg/day. There was a significant decrease in indirect markers of chronic vessel wall inflammation such as c-reactive peptide and insulin, as well as in peak blood

flow, an index that measures endothelial-dependent post-ischemic change.[52]

PPARα may mediate fibrinogen gene expression, which if activated reduces plasma viscosity and red blood cell aggregation.[53, 54] There have been many studies that resulted in significant reduction of plasma fibrinogen levels in patients with primary dyslipidemia and impaired glucose tolerance when treated with fenofibrate.[55, 56] Additionally, studies show that fenofibrate reduced activity of factor VII, concentration of thrombin activatable fibrinolysis inhibitor, and the total amount of thrombin generated at the site of microvascular injury.[57-60] Fenofibrate also decreases tissue factor (TF) expression in human monocytes and macrophage. TF, a protein present in subendothelial tissue and leukocytes, is necessary for the initiation of thrombin formation in the clotting cascade.[61, 62] Fenofibrate also upregulates the expression of thrombomodulin (an anticoagulant protein) as shown from studies using carotid atheroma biopsies.[63] High levels of plasminogen activator inhibitor-1 (PAI-1), an inhibitor of plasma fibrinolytic activity, is another important risk factor for thrombotic disease and atherosclerosis.[64] And in patients with T2DM who have increased levels of PAI-1 and fibrinogen, fenofibrate significantly decreased levels of fibrinogen and PAI-1 after just 1-month of therapy compared to the controls.[65]

Studies have shown that serum uric acid is directly associated with CVD, independent of classic CVD risk factors. In their recent publication based on data from the Established Populations for Epidemiologic Studies of the Elderly, Iowa (Iowa-EPESE) and the Third National Health and Nutritional Examination Survey (NHANES III), Dutta and colleagues concluded that individuals age 70 and older without overt CVD, renal dysfunction, or diuretic use, serum uric acid greater than 7.0 mg/dL was associated with greater CVD mortality.[66] Hyperuricemia is also frequently present in patients with the MetS, so this is another measure which clinicians should pay attention in order to reduce risk for CVD.[67]

Li and colleagues studied 116 patients with HTG and hyperuricemia and treated them with 200 mg micronized fenofibrate for four weeks to investigate any changes in lipid profiles, serum uric acid and 24-hour uric acid levels. Not surprisingly, serum TG decreased 51%, HDL-C increased by 24%, total cholesterol and LDL-C decreased by 10% and 12%, respectively. Serum uric acid levels were significantly reduced by 28% and urine uric acid levels were increased by 36%. Fenofibrate was thought to exert its anti-hyperuricemic effect by increasing the urinary excertion of uric acid.[68] This increased urinary excretion of uric acid seems most likely through the inhibition of urate transporter 1 by fenofibric acid, a fenofibrate metabolite.[69]

Researchers have investigated fenofibrate in certain patients with gout. One study evaluated the relationship between urine pH and MetS. Their results suggested that insulin resistance plays an important role in the development of low urinary pH in patients with gout and that PPARα agonists are preferable for raising urinary pH of gout patients with HTG.[70] Another study in patients with gout compared fenofibrate plus anti-hyperuricemic agents, benzbromarone (50 mg once daily) or allopurinol (200 mg twice a day), vs. losartan plus benzbromarone. Additionally, both fenofibrate and losartan combined with benzbromarone was studied to measure the combined hypouricemic effect. The study revealed that a combination of fenofibrate or losartan combined with benzbromarone is a good option for the treatment of gout in patients with HTG and/or HTN, but the additional hypouricemic effect may be modest.[71]

Adverse Effects

A slight, but significant, increase in pancreatitis (0.5 with placebo compared with 0.8% with fenofibrate, P=0.031) was observed in FIELD. This excess in pancreatitis has been noted in many fibrate trials. Another important side effect is an increase in homocysteine plasma levels and venous thrombotic events. In FIELD, a 39% increase in homocysteine was observed in the fenofibrate-treated patients. As increased plasma homocysteine level is a risk factor for thrombosis, and Verges pointed out that the significant increase in plasma homocysteine induced by fenofibrate could account for the augmented number of venous thrombotic events.[25] The risk of myopathy is increased with statin-fibrate combinations.

Conclusion

There are many aspects of fibrates that make them an appealing adjunctive therapy to reduce the risk of CVD. As the PROVE IT-TIMI 22 trial highlighted, the role of TGs and risk of CVD events, independent of LDL-C, highlights the potential role of fibrates in the face of recurrent cardiac events in patients on statins. Several additional trials, such as SAFARI, FIELD, VAHIT, and BIP showed the beneficial effects of fibrates, especially in patients with certain conditions (most notably DM, MetS and atherogenic dyslipidemia). Fibrates function as PPARa agonists, which may be at the center of their pleiotropic effects. There have been many studies indicating benefits

of fibrates on the liver, kidney, and the vascular system. There are also potential benefits of using fibrates in patients with gout and further studies should be conducted in other patient populations. Larger randomized trials are required to ascertain these possible benefits, however, fibrates seem to have a plethora of evidence for providing both microvascular, especially in DM, and macrovascular benefits, especially in those with both HTG and low HDL-C.

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