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Missouri Medicine

The Journal of the Missouri State Medical Association - Since 1904

Volume 112 | Number 6 | November/December 2015 www.msma.org/MissouriMedicine



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Missouri State Medical Association

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In publication since 1904, Missouri Medicine, a peer-reviewed, award-winning medical journal printed on acid-free paper, is indexed by MEDLINE, the National Library of Medicine, and is linked to PubMed Central, which is the U.S. National Institutes of Health digital archive of biomedical and life sciences journal literature. Missouri Medicine can be found on EBSCOhost databases, which provides researchers with the ability to search full-text articles, and are the most-used, premium online information resources for tens of thousands of institutions worldwide, representing millions of end-users. Missouri Medicine also provides featured content for www.medhelp.org,world's largest online health community that reaches more than 140 million users worldwide each year.

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Missouri Medicine publishes Perspectives on a variety of medical trends, topics and policy matters including legal, legislation, advocacy, insurance, practice management, and public health issues. As I See It is a forum for opinion pieces, whimsy, humor, irony, and reflection on the practice of medicine. All pieces should be referenced and not exceed 1,500 words.

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Owned and published since 1904 by the Missouri State Medical Association. Missouri Medicine, the Journal of the Missouri State Medical Association [ISSN 0026-6620], is published bi-monthly at 113 Madison Street, Jefferson City, Missouri 65102. Periodicals postage paid at Jefferson City, Missouri and at additional mailing offices. Postmaster: Send address changes to Missouri State Medical Association, c/o Membership Dept., P.O. Box 1028, Jefferson City, MO 65102. Copyright 2015 by the Missouri State Medical Association. Printed by the Ovid Bell Press, Inc., Fulton, Missouri. The subscription price per year for non-members is $75.00. Annual subscription for members is included in the annual membership dues. Single copies are $12.00, if available.

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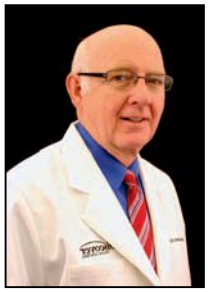
Passage of 2015 Tort Reform Law Demonstrates the Effectiveness of Physician Advocacy! *So What's Next in 2016?*

by John C. Hagan, III, MD

In 2005, MSMA passed tort reform. In 2012, after spending millions of dollars and seven years of all-out effort, the trial lawyers overturned reasonable caps on malpractice awards. In 2015, the Missouri State Medical Association led a coalition of health care and business interests that re-enacted permanent, meaningful tort reform into law.

Don't you just love stories with happy endings? Isn't it great to prevent the junk lawsuit industry from driving doctors into penury paying outlandish premiums for malpractice insurance? To stop the exodus of physicians into Kansas, Texas, and other states with working tort reform laws? To be able to offer new associates better salary and benefits because funds have been freed up from insurance premiums? To reduce the number of junk lawsuits and protect physicians from run-away juries and outlandish multi-million dollar awards? High fives all around!

Nothing so illustrates the power of physicians working together for the mutual benefit of their patients and their practices as does passing tort reform into law twice. And no organization did more on tort reform than the MSMA.



John C. Hagan, III, MD, FACS, is a Kansas City ophthalmologist and *Missouri Medicine* Editor since 2000. He is a multi-year Super Diamond Contributor to MMPAC.
Contact: jhagan@bizkc.rr.com

But every legislative year brings with it familiar challenges and unique threats: Insurance companies want to lower already parsimonious reimbursement, hospitals have become the largest employer of physicians and increasingly restrict physician prerogatives and mandate how they practice medicine, and everyone wants to practice medicine without going to medical school, and a particular concern of mine the coalition of pot users and entrepreneurial producers ("Big Weed") who want to make cannabis products legal for recreational and nebulous 'medical' uses.

Each year in November and December we need to recommit ourselves to engaging in the Missouri legislative process that begins in January and runs through mid-May. We need to remind ourselves that we are basically fair individuals, and it is not fair to fob the advocacy of our profession off on others. If you are involved now, recommit yourself; if you are not involved now, make this the year that you "get it" about the importance of legislative advocacy and participation in organized Medicine. This is a state and national election year, and as the ACA demonstrates it has never been more important to elect competent individuals to direct the state and nation's health care policy.

MSMA Members: Be sure your 2016 dues are paid. Be sure all physicians in your group are MSMA members. Set a goal to recruit one additional physician to membership. Make a generous donation to the Missouri Medical Political Action Committee (MMPAC). It is a



fantastic bi-partisan organization. Plan a trip to Jefferson City during the session; contact MSMA's Kenny Jackson about being Doctor of the Day at the Capitol. It's a fun day. Get to know your state senator and representative and keep in touch with them during the session. Read the weekly MSMA *Legislative Report* and follow their action items requests.

MSMA Leadership: Get out your checkbook and write a $1,000 check to MMPAC. If you are a physician leader then lead by example. It's really inexcusable that every member of the MMPAC Board and MSMA Council does not have a Super Diamond Membership. Contact MSMA's Linda Bremer on how to join.

Medical Students, Residents, Fellows: Join MSMA. The dues are extremely low ($8/year for Medical Students and $25/year Resident/Fellow), and you are enthusiastically welcome in MSMA. Students are invited to submit articles to *Missouri Medicine*. Come to Jefferson City to advocate, and join us at the MSMA Annual Convention. Many department chairs are willing to excuse you for these important functions.

Physicians Not MSMA Members: Especially if you are hospital-employed, you need an advocate. MSMA is that advocate and can work to be sure you are treated fairly and that decisions and choices that are the legitimate right of the physician on behalf of her/his patient are not usurped by your hospital employers. Physicians who are self-employed or work for physician-owned groups: You need to keep your practice competitive and need help with its administration and various compliance mandates. MSMA can be that help. Contact MSMA's Haley Wansing or Sarah Luebbert to become a member.

Renew your membership for 2016! You may ignore politics but politics will not ignore you.

'Special interest" groups work and dominate the Missouri and U.S. political systems because they take special interest in working the system for their benefit. They are there in Jefferson City. They are there with donations and assistance during election season. They know personally senators and representatives. Take your own special interest in the 2016 Missouri legislative session by joining MSMA and being an active member. You may ignore politics but politics will not ignore you.

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✶✶✶ Happy Birthday MSMA ✶✶✶

One hundred and sixty-five years ago on November 4, a large delegation of physicians met at 12:00 o'clock noon in the First Presbyterian Church in St. Louis to "devise a plan by which the entire medical profession of the State can be brought together."

The year was 1850, and the inhabitants of Missouri were fighting scourges of typhoid, malaria, smallpox, and diphtheria. Physicians composed what was entitled MSMA Resolution #1:

> *WHEREAS, In the opinion of the society, the time has arrived when it is both expedient and desirable to unite the medical profession of the State of Missouri for the purpose of mutual improvement and protection; be it therefore,*
> *RESOLVED, That a committee be appointed to address the regular members of the medical profession for the purpose of forming a State Medical Association with auxiliary societies in each town or county in the State.*

The Missouri State Medical Association then elected its first president, Dr. F. W. G. Thomas of Boonville. Matters of importance were the passage of a good medical practice act; the establishment of a uniform system of registering births, marriages, and deaths; the control of dispensing impure drugs, and competent inspections of medicines; and a liberal preliminary education for those entering the study of medicine. Annual dues were fixed at $2.00, and a Constitution and Bylaws were adopted.

One hundred and sixty-five years later, MSMA represents more than 90 medical specialties and is the voice of Medicine in Missouri. Happy Birthday MSMA.

On the cover: Physicians attend the Joplin Annual Meeting, May 12-14, 1914, at the New Joplin Theatre where the General Sessions were held that year.



Fearless Forecast

by Kenny Jackson

Just like years past, MSMA has had a busy interim preparing for that inevitable day that comes every first week of January. While the odds say it's unlikely all of the issues listed below will come up this session, our legislative intellect suggests they are much more likely to happen than not.

It being an election year sometimes complicates our outlook. How much attention these and other issues garner throughout the course of session is anyone's guess. Following, in no particular order, is a brief preview of some of the legislation we expect to see in 2016.

Statewide Medicaid Managed Care

Last year, the legislature along with the help of managed care companies found a way to move funds from fee-for-service to managed care in the state budget. So, beginning June 2016, pregnant women and children who receive Medicaid will do so under statewide managed care. We will be attempting to persuade the legislature, via its Task Force Examining Statewide Delivery Models, and the MO HealthNet division that shared-value delivery systems are a better option than old-fashioned capitation. Because this was a budgetary item, the money must be re-appropriated each year.

Real Time Determination of Benefits

We will introduce legislation in 2016 that will require insurers to use a realtime explanation of benefits. This would allow patients to make better-informed healthcare decisions by increasing price transparency and doing so prior to receiving the service. Realtime exchanges would be done via established HIPAA transaction sets.



Kenny Jackson is MSMA's Director of Legislative Affairs.
Contact: kjackson@msma.org

Visiting Team Physician Licensure

We will also likely introduce legislation to exempt sports team physicians from state licensure when treating athletes and team employees. This exemption would be time limited and only apply while the team is traveling or participating in a game in Missouri. This legislation would close this potential gap in the care of their athletes as well as protect team physicians from possible liability issues, while not hindering the state's Medical Board's authority to ensure patient safety.

Maintenance of Licensure

Last year, an unexpected shutdown of the Senate occurred with one week left in session. The shutdown put the final kibosh on any hopes of passage for this issue. We will again support legislation that would prohibit the Board of Healing Arts from using any type of maintenance of certification or any specialty board certification when making licensure decisions, including whether to approve or renew a license. In addition, this would prohibit the government from discriminating against non-specialty certified physicians.

Medicaid Expansion

During prior legislative sessions, Republican leaders had expressly stated that the issue of Medicaid expansion would not be an agenda item during session. There hasn't been any talk to change this course over the interim and we believe this issue will gather little steam, if any, this year.



Prescription Drug Monitoring Program

Missouri remains as the only state in the nation without a prescription drug monitoring program. This issue has been fairly contentious within the Missouri legislature over the years. However, there seemed to be a glimmer of hope last year with compromise language up for debate. Only time will tell, but we'll continue to advocate for a prescription drug monitoring program in the state.

Telemedicine

This issue will be a full head of steam this year, and a lot of things need to be worked out concerning telemedicine delivery. Past legislation sought to define what constituted an originating telehealth site and who could be reimbursed for telehealth services under Medicaid. In addition, it developed a framework for store-and-forward telehealth, in which health information is sent, but a diagnosis is made at some point in the future. We will provide our input and keep a close eye on these issues this year.

Punitive Damages

During the summer of 2014, the state Supreme Court, using the same reasoning from the noneconomic damages caps case in 2012, overturned the legislature's ability to cap punitive damages. This action spurred the legislature into action. A Senate resolution would have put the question of whether the legislature can cap punitive damages to the people in the form of a constitutional amendment. A House bill would have required the punitive damages phase of any trial to be prosecuted only by the Attorney General, with 50% of the amount awarded to the plaintiff going directly to the Tort Victim's Compensation Fund. Although the language may change, we expect this issue to appear again this year.

Expert Witness Reform

Legislation was introduced last year that would have directed who the courts could accept as an expert witness, how they are qualified as such, and under what circumstances they could provide testimony. In addition, the legislation would have taken the court's ability to determine when opinion testimony is objectionable. Generally speaking, it would have tightened up the state's expert witness rules, and included Missouri in the ever-increasing number of states that use the same expert testimony standards as the federal courts. We expect similar legislation to be introduced this year and we will provide our support.

Texting While Driving

It is no secret anymore that using a cell phone while driving is one of the leading causes of distracted driving accidents. Currently, Missouri law prohibits drivers under 21 years of age from texting while driving. Unfortunately, everyone else can still do it. This year, we anticipate legislation that would extend the law to adults. We will continue to support these and other texting while driving bans.

Spinal Procedures

A couple of years ago, we were able to reserve a few procedures to the purview of anesthesiologists only. Despite the fact their training doesn't allow certified registered nurse anesthetists (CRNAs) to do these procedures, a statute prohibiting them from performing fluoroscopically-guided injections into the spinal column, the ablation of targeted nerves, and laser discectomy, drove them bonkers. They were able to attach a sunset clause to the bill, which means if it is not removed by the end of the 2016 session, the CRNAs will be able to start performing these procedures again. We will argue to remove the sunset this year.

On The Defensive

It wouldn't be a true legislative session without the added gray hairs, heartburn and headaches associated with playing defense. Many special interest groups will continue to push the boundaries and infringe on the practice of medicine. Here are just a few of the no doubt laundry list of issues that will keep us on our already sore toes.

APRN Independent Practice

For the part three years, the APRNs have sought to eliminate the collaborative practice framework in which they practice nursing. Last session, a loosening of the collaborative practice statutes was requested, and the request was made by the chain retail pharmacies instead of the nurses themselves. This year we expect to see language that would allow for off-site review of charts and a change to the familiarity rule to benefit rural patients.

Motorcycle Helmet Repeal

As they do every single year, we expect the anti-helmet lobby to push to repeal the state's mandatory motorcycle helmet law. They are a very persistent and vocal group who garner a lot of support from the pro-liberty crowd in the legislature. We will continue to oppose any legislation that will virtually guarantee an increase in fatalities in the state.

Midwifery Licensure Board

We believe the midwives will again push for the creation of a midwifery licensure board. In the past, they have simply asked for the Certified Professional Midwives (CPMs) to be licensed, but last session they further muddied the waters by adding a new category, "licensed midwives." They also want to be reimbursed by Medicaid and private insurance. They don't want to carry malpractice insurance. It generally allows them to police their own and we expect to see very similar efforts again this year.

Summary

In just a few weeks we'll begin our turbulent climb to May 13, the last day of the 2016 legislative session. We'll revisit the issue that didn't pass last year all while wrapping our minds around a multitude of new ones. We can't do this alone. Don't be hesitant to get to know your local representative and senator. They hold your opinion on legislation that affects medicine in high regard. Read the weekly *Legislative Report*, and let them know how you feel about the issues. Hearing from their "docs back home" carries a lot more persuasion than anything we can say on your behalf. A phone call, text, letter, email, or a personal visit in the Capitol, can give us the momentum needed to better help you and your patients. **MM**



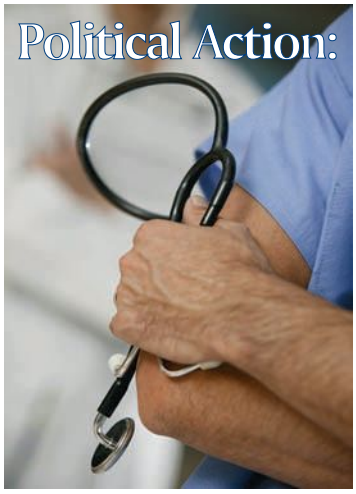
Volunteer to spend a day in the Capitol as MSMA's Physician of the Day in 2016!

Between January 6 and May 13, 2016, MSMA is lining up volunteers to spend a day in the Capitol as "Physician of the Day."

This excellent program is warmly received by the General Assembly and participating physicians.

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

If you are interested in serving in this worthwhile project, please contact MSMA's Kenny Jackson at 800-869-6762 or by e-mail at kjackson@msma.org. He will coordinate with you to outline the responsibilities and offer dates available.



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Get to Know Your Physician Legislators

Bob Onder, MD, Elected as Assistant Senate Majority Floor Leader

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



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

Dr. Onder founded his private medical practice in 1992, specializing in allergy and asthma. You can reach him at 573-751-1282 or email Bob.Onder@senate.mo.gov.

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

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



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

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

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

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



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

Contact: keithjfrederick@gmail.com or 573-751-3834.

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

Jim Neely, DO, a Republican, represents Clinton and Caldwell counties and parts of Clay and Ray (District 8) in the Missouri House of Representatives. He was elected to his first two-year term in November 2012. Rep. Neely is a graduate of the University of Missouri School of Medicine and received his DO from the Kansas City University of Medicine and Biosciences. In addition to his legislative duties, Rep. Neely is a physician at Cameron Regional Medical Center and a veteran of the US Army.



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

MM

Your Missouri Delegation Continues In Leadership Roles at the AMA Meeting

by the Missouri Delegation to the AMA and compiled by Ted Groshong, MD

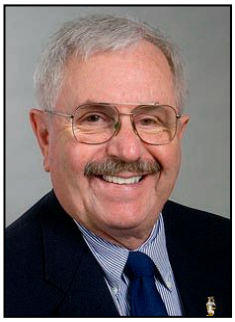
Your Missouri Delegation provided outstanding leadership to the American Medical Association House of Delegates at its 2015 Interim Meeting in Atlanta in November. David Barbe, MD, (Mountain Grove continued as a member of the influential Board of Trustees. Edmond Cabbabe, MD, (St. Louis) continued as the Chair of our Heart of America Caucus, and of our Delegation, as well as serving on the AMA Foundation Board. Two served on Reference Committees: William Huffaker, MD, (St. Louis), Legislation, and TedGroshong, MD, (Columbia), Education and Science and Public Health.

Among concerns which are increasingly important to us and our colleagues are the rapidly rising demands for Maintenance of Certification (MOC). The AMA has long supported the principle that physicians demonstrate continued competence. Certainly there is strong public, as well as government support for recertification. However, the currently designed periodic requirements have become progressively more onerous.

The House of Delegates approved a statement of principles and policies which will have to be met by certifying organizations. These include, among other things, that changes in MOC requirements not result in increased costs or burdens to participants, be evidence-based, directed at improving patient care, not be cost prohibitive, be transparent regarding the rational for their expectations, and include practicing physicians on the committees developing these requirements. There are a large number of additional principles and policies (more than 51 in all) which will have to be met to achieve support from the AMA. These will be available by the AMA for our membership to review.

It should be noted that there have been increasing demands from many doctors for creation of competing accrediting organizations, and some, like the National Board of Physicians and Surgeons, are already in existence. It is unclear whether certification by these organizations will be accepted by hospitals, health care insurers, or federal agencies. One result, however, is that the American Board of Medical Specialties is clearly being influenced by constant pressure from the AMA. A representative from ABMS was very direct in saying that there are going to be changes in some, hopefully many, of their current requirements for MOC.

During the last two years the AMA has been taking strong leadership role in medical education. In addition to our interest in reforming undergraduate education, there has been increasing demand from members to take leadership to expand graduate medical education positions. Most physicians know that there has been a major increase in class sizes of both allopathic and osteopathic medical schools However, there has been little increase in GME positions. As a result, we have seen graduates of US medical schools being unable to obtain residency positions. Last year more than a thousand of them were unsuccessful in entering post-graduate training. Our MSMA has made an effort to provide an innovative way to help those students



Ted Groshong, MD, Columbia, MSMA member since 1976, is a pediatrician and a Missouri Delegate to the AMA.
Contact: GroshongT@health.missouri.edu

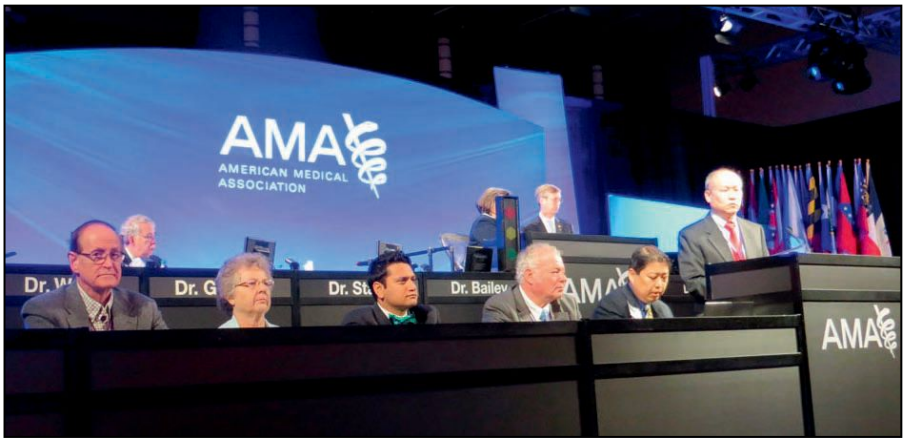
by establishing a program for Assistant Physicians. However that is not going to be enough. The Council on Medical Education has developed proposals for the financing of increased GME positions. Some in the House have recommended that we take on this challenge with the same vigor that we used to get rid of the hated SGR. The latter was critical for us as practicing physicians, the former is equally critical for our student members, as well as for the people of our state who are experiencing increased need for physicians to provide health care in their communities.

At long last, the House overwhelmingly voted to take on Big Pharma by voting to oppose direct-to-consumer advertising. There is little doubt that patient demand for vigorously advertised products are not only a major headache for physicians, but lead to enormously increased costs, and often increased risks for our patients. In some cases the advertised products are appropriate, but often, while being heavily advertised, are only appropriate for patients with very severe disease. In some cases, they are minimally effective if at all. The US and New Zealand are the only countries that allow direct to consumer advertising.

Top: Missouri Delegates to the AMA at the House of Delegates in Atlanta. From left: Drs. David Barbe, Edmond Cabbabe, Bill Huffaker, Jim Conant, Lent Johnson and Ted Groshong.

Bottom: Missouri Delegate Bill Huffaker, MD, St. Louis, (far left) hears testimony on Reference Committee B regarding EHR Interoperability at the AMA Interim Meeting in Atlanta.





For many of our patients, the lack of availability of organs for transplantation is an issue, literally, of life and death. For those of us who care for them, it has been disheartening, that while there has been no increase in the availability of organs, there has been a huge increase in patients awaiting them. Tens of thousands of Americans are awaiting organs. On average 18 people die each day as a result of the lack of organ availability. As is so often the case, it is the medical students who take leadership in proposing strategies to address what seems to be an insoluble problem. They proposed, and the House strongly supported, a proposal for the AMA to work with other appropriate organizations to explore ways to remove disincentives from organ donation, and study ways we can ethically provide incentives for organ donation, both from deceased and live donors. In short, the students have challenged us to "think outside the box."

The increased use of technology has included potential problems in health care, which the AMA membership feels should be addressed. For example, HealthCare.gov, the portal for people to use to access insurance under the ACA, collects a huge amount of personal data. There have been reports that the government has been sharing some of that information with third parties. The House of Delegates asked that the AMA work aggressively to obtain legislative support for protection of personal privacy.

Doctors have been particularly frustrated with the lack of interoperability of EHR. With the expenditure of large amounts of federal funds for promotion of electronic records, and increasing demands on our colleagues due to Meaningful Use (MU), there has been a noticeable lack of effort to pressure for interconnection between proprietary products. Indeed, it appears that the costs of obtaining commercial interfaces are currently prohibitive and not supported by any incentives from MU. This interoperability should be the responsibility of vendors of EHRs, not physicians. Furthermore, there is a real risk that we will be held accountable if we do not have access to intraoperative connections.

Standing with Dr. Barbe, is Larry Rues, MD, (left), a Missouri Delegate representing the American Academy of Family Physicians at the AMA Interim Meeting in Atlanta.



Additionally, there has been pressure on doctors in independent practice to purchase specific EMR systems as a condition for hospital privileges. The House felt strongly that any decisions for selecting or migrating to EMR systems should be independent from any hospital or health care system. Furthermore, if decisions are made to decertify certain products due to the lack of interoperability, physicians should not be accountable for costs

AMA advocates that hospital-sponsored EHRs must also provide physicians with unfettered data access and portability should the physician separate from the institution. Under those circumstances, even if the EHR sponsorship is withdrawn, access must continue in order to allow for continuity of patient care.

Health benefit plans must be held accountable for insuring adequate network access for all medically necessary and emergency care at an in-network benefit level with a timely and geographically accessible basis. In the event that physicians are considered out of network, then fair payment for their services is required.

The rising costs of prescription drugs are a leading issue profoundly affecting patients and doctors. AMA was directed to ensure fair and appropriate pricing for generic medications. The AMA should work with the FTC to prevent the ongoing mergers of pharmaceutical companies, which has resulted in reduced competition in the marketplace. We should also work to enhance transparency of drug pricing among pharmaceutical companies, benefit managers and health insurance companies. It is also essential that CMMS be allowed to negotiate pricing for medications covered under Part D Medicare plans. Currently it is illegal for them to do so. This has resulted in unnecessarily high costs.

Among the most challenging and rapidly changing technological advances in health care is telemedicine. The Council on Ethical and Judicial Affairs (CEJA) attempted to develop a definitive statement on this rapidly growing technique. The issue is extremely complex. Among the challenges is the reality that the practice of medicine is primarily regulated by the states, generally through state medical boards. Issues such as conducting telemedicine across state lines are currently unclear. Does one need a license in both states, and perhaps multiple states? If there is a physician/patient relationship, must it be established first by an initial physical visit? Is it possible, following a telemedicine visit across state lines, for a physician to prescribe in that state? Certainly, physicians who offer health care services across state lines must be held to the same standards of care as in traditional health care practice. When diagnostic studies are performed across state lines by telemedicine (radiology), are the requirements lower than that required for direct patient care?

These issues for physicians are difficult enough. However, when we toss in the possibility of telemedicine services being provided by advanced practice nurses, or other health professionals employed by proprietary corporations, there presents an even more concerning scenario. It is fairly clear that addressing this is complex and challenging. While CEJA presented an excellent report, it is clear more is needed. It is intended that a revision will return to the House in 2016.

An additional report of CEJA was directed at the controversial subject of sample medications. Perhaps it is not controversial for most physicians. As stated in the report: "Physicians' rationale for dispensing sample medications has not been extensively studied, but available data suggest that samples are used to enable therapy to begin immediately, to try out one or more medications for the individual patient, and to help overcome cost-related obstacles to care for the individual patient." Nevertheless, there are potential legal and practical issues which have arisen, including requirements fordocumenting the receipt and dispensing of each agent, assuring that the agents are not expired, and that, should there be an adverse reaction, the agent can be quickly identified. Pharmacies have strict guidelines. However, when translated into individual medical practices, particularly small ones, some are simply too onerous. Again, CEJA did an excellent job, but they obviously need to do more. This issue has been returned for more work.

We would encourage you to see a more comprehensive review of our AMA House of Delegates meeting at www.ama-assn.org or contact **Edmond Cabbabe, MD**, Chair of the Delegation at ebcsl@aol.com. **MM**

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Advocacy Has Many Forms

by John O. Stanley, MD

I have benefitted from the advocacy efforts of organized medicine groups such as MSMA and AMA in many ways throughout my career. There is no way that an individual physician like me can afford to spend the time and money that would be required to make a meaningful difference in my professional life, but your MSMA has lobbyists who are dedicated to helping me and YOU to achieve a multitude of professional goals. I assist these groups in their efforts by being a dues-paying member, and also by accepting leadership roles. I continually encourage my colleagues to lend their support as well.

As members of MSMA, or even as non-members, Missouri physicians are mostly on the receiving end of the advocacy efforts of MSMA's fine staff. But, as physicians, we often need to be advocates ourselves. Many of us find ourselves advocating for the health care needs of low-income patients who are underinsured or uninsured, and we go about this advocacy in a variety of ways.

I grew up the son of an "old-school" general practitioner who dealt with the economic realities of his patients on a case-by-case basis. Most of his patients were well known to him, and he generally knew if they were between jobs, or had a family matter which was financially draining at the time. He would reduce or even eliminate his charges to these patients, knowing that when their situations improved, he would be able to collect more on a future visit. Most patients felt obligated to pay something, and, if you'll pardon the pun, these contributions seemed to contribute to their recovery. Others paid by bartering — they would provide plumbing or carpentry services, for example, in exchange for care. I fondly remember the delicious homemade tamales we would frequently receive from one large family.

As a solo practitioner in the 1980s and 90s, I was able to extend credit to many of my patients, and help them "wait out" some difficult financial times, and many patients brought gifts of food to thank me for lowering their fees. Like father, like son, I guess. But I totally understand that in this day and age, we have to find other ways to help our impoverished patients. The costs of running an office, paying staff and paying providers in a group practice mount up, and physicians must also be in compliance with a variety of contracts, many of which prohibit reducing fees or giving away services. From a business perspective, this makes sense. Even doctors with private independent practices face restrictions. They can reduce or "no charge" a patient, but only if the patient is not a Medicare or Medicaid recipient — the law requires that all visits with those patients be coded and charged appropriately. Some insurance companies may also restrict these private practices from giving away care. So the "old-school" approach is becoming much more difficult.

However, though I can no longer care for my uninsured and underinsured patients the way my dad did, by reducing or eliminating charges, I can still find ways to advocate for them. Simply by being a member of MSMA, I am helping our lobbyists work with



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There is no way that an individual physician like me can afford to spend the time and money that would be required to make a meaningful difference in my professional life, but your MSMA has lobbyists who are dedicated to helping me and YOU to achieve a multitude of professional goals.

legislators to reduce health care costs and help low-income patients become eligible for assistance. This is what I think of as a "hands-off" approach. But there are a couple of "hands-on" avenues as well. Physicians can support local free health clinics by volunteering to work an evening or two every month. I especially encourage young physicians to try to find time to do this. A relatively small donation of time can benefit many patients, and can bring the physician closer to understanding the needs of this particular patient group. In addition, it can be a wonderful way to learn, or relearn, how to examine and treat a patient without the luxury of expensive CT or MRI scans, or costly lab tests. I've never left a shift at a free health clinic without having a warm, satisfied feeling, even though I've been dealing with patients who are struggling with seemingly insurmountable obstacles.

There are also programs that allow physicians to see select patients in their offices without having to charge them. In Kansas City, physicians are able to volunteer with an organization called MetroCare that is set up in such a way. Under MetroCare, a primary care physician can volunteer to manage a set number of patients in her or her office. Several labs, radiology centers, and hospitals offer their services, and specialty physicians are available if referrals are indicated. Patients remain in their primary care physician's MetroCare panel until they are able to obtain insurance through an employer or A.C.A. If they skip appointments, they are removed from the plan. These patients are truly thankful for the care they receive, and several have become regular paying patients of mine when they become financially stable. This hands-on program is a great way for many KC area physicians to advocate for less fortunate patients without having to leave their offices.

Though there is a lot of controversy surrounding the use of pharmaceutical samples by physicians; I'm certain that many of us rely on drug samples to help our needy patients. Samples can be a great way to try out a class of medication on a patient at no cost, knowing that if the medicine is well-tolerated and efficacious, a generic or formulary medicine within that class could then be prescribed. In some cases, the name-brand medication might be the best choice for the patient, but many times, that will not be the case.

Whether the hands-on or hands-off approach is preferred, I think every physician should make patient advocacy part of his or her life as a physician. The rewards include gaining a better understanding of the current state of medicine as well as an appreciation for the struggles many people encounter in their lives. But the heartfelt appreciation we receive from the patients we serve is the best reward of all. **MM**

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The SGR Fix: Was It?

by David W. Parke II, MD

Initially implemented as a part of the Balanced Budget Act of 1997, the sustainable growth rate (SGR) system was designed to control rising Medicare payments to physicians by indexing aggregate physician costs to target expenditures and the gross domestic product. Since 2003, Congress has had to step in 17 times with a temporary "patch" to avoid a drastic decrease in payments that would otherwise have occurred under the SGR system.

Over the years, the SGR achieved legendary status by being opposed by nearly everyone—physicians, Congress, CMS, health care economists, policymakers, and patient groups. However, the funding needed to permanently fix the SGR rapidly rose into the hundreds of billions of dollars and became a political football in a partisan Congress.

For ophthalmology, which has one of the highest percentages of Medicare patients of any specialty, the temporary "patches" applied since 2003 have resulted in average inflation-adjusted Medicare payment rates tumbling by about 17 percent.

Strong Bipartisan Support

The recently passed fix, H.R. 2 ("Medicare Access and CHIP Reauthorization Act of 2015") was a true bipartisan anomaly. House Republicans and Democrats came together by a vote of 392-37 and passed a permanent $200 billion fix to the SGR—only a portion of which was partially offset by new revenue sources or "pay fors." Some of that money came from hospitals, some from post-acute care facilities, and some from means testing of more affluent Medicare beneficiaries.

Some constituencies in Washington complained that "the doctors themselves aren't providing any of the funding for the fix." Wrong. The physician community has paid, and is paying hundreds of billions of dollars. Had they received (as hospitals have) a positive annual update approaching medical inflation, the fix would have been unnecessary. Physicians have paid for it over a 12-year period, during which annual payment increases averaged about 0.3 percent, while the cost of running a medical practice increased about 3 percent a year. And they are still paying for it: Annual increases will be only 0.5 percent for the next five years—regardless of medical inflation.

A Mixed Reaction

The SGR fix is not universally popular. The Republican right wing isn't happy that it adds to the deficit. The Democratic left wing is unhappy that the Children's Health Insurance Program is funded for only two years instead of four. The AARP complained that the legislation places "unfair burdens on beneficiaries … through greater out-of-pocket expenses." Hospitals wish they weren't shouldering part of the cost, and physicians were hoping for more robust annual updates. But everyone is happy to finally—after 12 years—see that the nation's physicians are no longer being held hostage to an annual threat of draconian payment reductions, and that the nation's Medicare beneficiaries are no longer threatened with a mass exodus of physicians from Medicare.

A few physicians even said, "Don't support the fix. Let physician payments drop 21 percent, and then the whole system will unravel and physicians' economic value will be restored." While not disagreeing at all that the SGR fix is difficult to embrace enthusiastically, the fact remains that if such an unraveling were to occur, the biggest losers would be patients, who would face at least transient market disarray, loss of long-standing physician relationships, and even pockets of extreme difficulty with access to care. Finally, the disruption to physicians' lives would be impossible to predict, as some practices would see immediate drops in payments, while others would be inundated with new patients from those physicians exiting the Medicare system.

Key Provisions of the Bill

What was really in the SGR fix bill? First of all, the bill is over 38,000 words long (well over 100 pages). It touches a number of specific physician payment issues. Special issues to note include:



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- First and foremost, the SGR system is permanently repealed.
- Fee-for-service Medicare is set with a 0.5 percent positive annual update to payments for each of the next five years. It is then 0 percent for 2020 through 2025. For 2026 and beyond, it is 0.75 percent for eligible alternative payment model (APM) participants and 0.25 percent for all others.
- The scheduled unbundling of postoperative visits from 10- and 90-day global surgery fees (as per the 2015 Final Rule) is gone.
- Many of the features of the Physician Quality Reporting System (PQRS), meaningful use (MU), and Value-Based Payment Modifier (VBM) are incorporated into a single "Merit-Based Incentive Payment System" (MIPS). The last PQRS, MU, and VBM reporting period would be for 2018.
- Physicians enrolled in qualifying APMs would receive annual bonuses of 5 percent for services in 2019-2024 and would not be subject to MIPS requirements. Examples of APMs include accountable care organizations (ACOs), bundled pricing, and shared savings systems.

Impact on Ophthalmology

Several provisions of the bill warrant additional commentary.

Unbundling of postoperative visits. It is impossible to overstate the impact of the reversal of the 2015 Final Rule as it pertains to unbundling of postoperative visits. Of all specialties in medicine, this change would have hit ophthalmology and cardiothoracic surgery the hardest—60 percent of ophthalmology payments would have been affected. For some major procedures, the drop in total reimbursement was anticipated to be between 10 and 15 percent! Think of it as half of an SGR payment cliff. As you can imagine, many of the nonprocedural specialties supported this unbundling—their underlying assumption being that dollars not spent would be redirected to primary care initiatives. In the end, the Academy played a major role in the coalition to get language into H.R. 2 that reversed this CMS-planned unbundling. A huge win!

MIPS. As it is currently drafted, MIPS lumps all the penalties of PQRS, MU, and VBM together in a single entity after 2018. While touted as being more flexible (with the opportunity for substantive bonuses as well as penalties) and more clinically relevant, MIPS is highly problematic for specialists who are not a part of large multispecialty integrated practices.

MIPS bonuses and penalties begin at 4 percent in 2019 and rise to 9 percent in 2022. Remember that, in general, the cost of bonuses must be offset by penalties. Moreover, unless this system is subsequently amended, it will be very difficult for ophthalmologists in private practice to avoid MIPS penalties (let alone qualify for bonuses).

One aspect of H.R. 2 that provides some potential relief for ophthalmologists, however, is the legislated opportunity to use approved clinical registries (like IRIS) as an alternative to enrollment in APMs. Therefore, IRIS may provide members with a vehicle to save up to 9 percent per year.

Updates. While 0.5 percent annually is not much of an update in an environment of more rapidly rising practice costs, it beats the 0 percent physicians have been used to receiving. But it is still inadequate—unless there is a genuine substantive opportunity to qualify for quality bonuses. This needs to be fixed.

Putting It in Perspective

In summary, H.R. 2 is far from a perfect bill. I believe that it must be viewed in perspective. The perennial risk and threat of a massive 20 percent or more cut in payments was far worse, even if it never came to pass. It was worse because it created uncertainty, disruption in payments, wasted time and effort—and it sucked all the air out of the room for serious discussion about other important health care issues. Every year, Congress and the physician community were both placed in the position of negotiating, advocating, and threatening to get to a short patch and a 0 percent update. And if you think MIPS is bad, the status quo was even worse, with PQRS, MU, and VBM poised to combine for an even larger potential penalty scenario (would have been 11 percent in 2018) and more complex regulations and reporting.

And for those few ophthalmologists who dislike where Medicare is going so much that they will choose to opt out of the Medicare program, H.R. 2 actually makes that a little easier as well.

Looking Forward

Now we can shift the debate to those elements of H.R. 2 that need clarification and fixing: updates and MIPs/APMs. And we can also turn our attention to other elements of medical practice, including electronic health records and MU, research funding, narrow networks—and the many, many other hot issues that were shunted aside by the SGR discussions.

All of you who communicated with your members of Congress, who contributed to the political process, or who engaged your family, friends, or patients in the SGR fix process deserve the sincere congratulations of your peers—and your patients. It took over a decade, but you won. Congratulate yourselves - but much work remains. **MM**



A New Book by Steven Brill

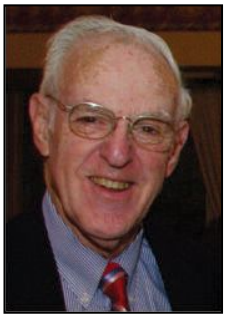
Who Won? Who Lost?

The Money, Politics and Back Room Deals That Resulted in Obama Care: America's Bitter Pill

by Arthur Gale, MD

A recent book titled *America's Bitter Pill* by Steven Brill (Random House, December 2014) describes the money, politics and backroom deals leading up to The Patient Protection and Affordable Care Act otherwise universally known as Obama Care.[1] Brill, a journalist is most famous as the author of the landmark 2013 Time magazine article "Bitter Pill: Why Medical Bills are Killing Us." This article, which was reviewed in the May/June 2013 issue of *Missouri Medicine*, blamed much of the high costs of health care on hospitals and their outrageous bills and arbitrary billing method known as the 'chargemaster'.[2]

In this new book Brill addresses Obama Care. He names and describes the secretive, un-elected "experts" who crafted the law. They were mainly economists, lawyers, Ivy League academics, Wall Street consultants and an array of Washington insiders. There were no representatives of practicing physicians or organized medicine. There were no representatives of Congress or the American public. It was strictly a top down fiat decision by these semi-secret panelists whose main task was to figure out what was politically acceptable to powerful special interests. It may also have been crafted as an important issue to aid in the 2008 election of Barack Obama.



Arthur H. Gale, MD, MSMA member since 1976, is a *Missouri Medicine* Contributing Editor. He practices Internal Medicine in St. Louis.
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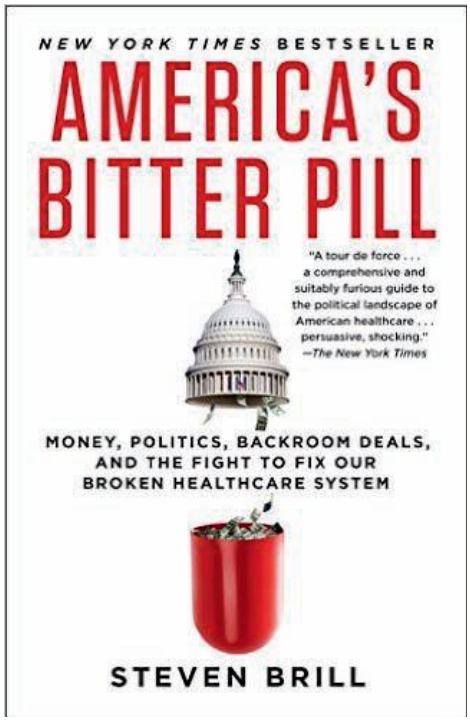
The final Obama Care bill became law despite not receiving any Republican votes in the House or Senate. Each of three major interest groups: insurance companies, drug companies, and hospitals got what they wanted, making only minor concessions here and there. Some uninsured Americans got some insurance. In spite of Obama's assurances it would not happen, many insured Americans lost insurance plans they were pleased with and were forced into less satisfactory Obama Care. Many had to change doctors. The program is financially unsustainable. Doctors are made into scapegoats. They are blamed for the high cost of health care and are subjected to oppressive cumbersome regulations.

Brill asks rhetorically: *"Should we be embarrassed and maybe even enraged that the only way our country's leaders in Washington could reform health care was by making backroom deals with all the interests who wanted to make sure that reform didn't interfere with their profiteering?"*

Brill answers his own question: "*Of course. We'll be paying the bill forever."* Brill concludes that although millions of Americans obtained insurance coverage under Obama Care the costs of the program were not addressed.

One of the most influential panelists was Peter Orszag who was then head of the non-partisan Congressional Budget Office or CBO. Orszag, considered a wunderkind economist trained at Princeton and the London School of Economics, is described by Brill as being obsessed with Fee-For-Service. He believed that Fee-For-Service had to be eliminated. Doctors and hospitals had to be paid through "bundeled payments," and all aspects of care had to be consolidated under Accountable Care Organizations (ACOs). Orszag also maintained that the best way to reduce costs was "to use information technology to judge and act on the comparative effectiveness of drugs, medical devices, and other treatments. "

Most of Orszag's recommendations have been enacted. They are responsible for much of the malaise and frustration that physicians experience in practicing medicine today. Orszag and the other authors of Obama Care never considered that their mandated radical changes in medical practice and their effects on the functioning of our health care system should be conducted on a trial basis or that their effects on costs and quality should be carefully studied through pilot projects before they were inflicted on physicians and patients. After serving on the Obama health care panel Orszag went to work for the Wall Street firm Citigroup where his salary was $3.1 million per year in 2013; it was to be increased by 25% to $3.9 million in 2014 (presumably paid on a Fee-For-Service basis).[3]



So there you have it. Basically an elitist unelected influential economist, with the acquiescence of a tiny group of other unelected putative "wise men" are responsible for the revolutionary changes in the practice of medicine that affect America's 800,000 physicians. The real drivers of high health care costs-hospitals, insurance companies and drug companies are essentially left untouched. So much for the "wise men" appellation.

This is too much for Brill:

"In other words doctors-whose incomes had never increased during the recent decades boom the way earnings for hospital administrators, drug executives, or CT scan equipment salesmen had-were assumed to be the prime drivers of costs, and they would, therefore, have to pay for driving them too high." Brill further adds, "We should recognize that the quality of medical care is going to continue to be jeopardized by the broken economics of the marketplace, which provides rich incentives to everyone except those actually treating all of those newly covered patients. As doctors remain bogged down in paperwork and face mounting business pressures, the portion of our best and brightest who want to care for the sick instead of cashing in on the business of health care is likely to drop."

Obama Care, Medicare Advantage, and Medicaid Managed Care are all cut from the same flawed cloth. They all incorrectly focus on the physician as the primary source of high health care costs rather than the obscene charges and profits of hospitals, insurance companies, and drug companies.

At the conclusion of his book Brill asks: *"Is Obama Care affordable for the country? Can we continue to let the health care industrial complex that negotiated those deals prosper at our expense when we have now given them so many millions of new customers whose bills taxpayers are paying through Medicaid or those exchange subsidy premiums?"*

Brill answers his own question: *"...Like its Romney Care predecessor, Obama Care was the product of a choice - most would say forced by political reality - to increase coverage and deal with costs later, if ever."*

Romney Care, developed for the state of Massachusetts, under its then governor, was the template for Obama Care. Not only did it not lower costs, it is nearly bankrupting the state. As one eminent critic of Obama Care wrote:

"Almost all Massachusetts residents now have health insurance, but premiums, deductibles, and copayments have increased, and some people have found they cannot afford to use their insurance. Massachusetts now spends more per capita on health care than any other state, and health spending consumes over half the current state budget, at the expense of nearly every other state function-including education, public safety, human services, and infrastructure."[4]

The Medical Industrial Complex has taken over Obama Care, Medicare and Medicaid with remarkable brazenness. An example occurred recently when Marilyn Tavener, the Director of CMS, the agency that runs and is supposed to regulate Medicare, Medicaid, and the Obama Care exchanges was hired by America's Health Insurance Plans (AHIP) to be their chief lobbyist.[5] Her replacement, if confirmed by the Senate is to be Andy Slavitt, a former United Health Care executive.[6]

The Wall Street Journal, the most influential and widely circulated conservative newspaper in the nation, was outraged at this power grab. In an editorial titled "The Government Insurance Complex" called Obama Care:

"A vast transfer of wealth and power to the political class from markets, and the big insurance conglomerates were the brokers of this bargain in return for more subsidized customers."..."The



next time some politician burbles about public service remember that a tour in government is often a form of deferred compensation with no accountability for results or competence"…"Whether Ms. Tavener is a lobbyist or the head of CMS her job description is the same."[7]

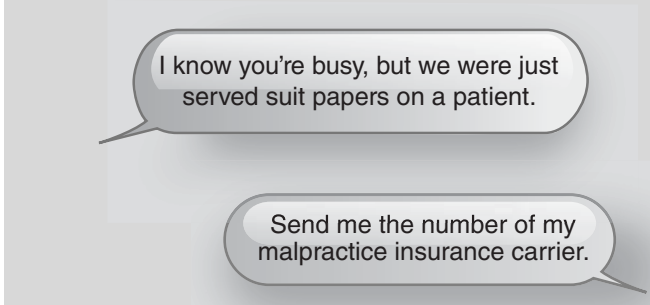
Whew! That just about says it all. All the radical changes that have occurred in medicine over the past forty years including Obama Care were theoretically based on how free market competition was supposed to lower health care costs. There are no free markets in Obama Care, Medicare HMOs like Medicare Advantage, or Medicaid Managed Care. These entities are big profitable corporate conglomerates that thrive on big government subsidies. The phony free market competition that we have in health care today has increased costs to the point that the United States has by far the most expensive health care system among Western industrialized democracies without any measureable improvement in quality.[8] Health care costs will continue to rise until the bubble finally bursts. No doubt that failure will be blamed on physicians by the Medical Industrial Complex and government elites.

As the election season heats up is it any wonder why the public is so disgusted with our political leaders that they turn to outsiders. It's time for the American people to take back their government from elitist fallible economic experts and corporate lobbyists representing insurance companies, drug companies, and hospitals. The American people must demand accountability and responsibility from their government and its agencies. Whether anything can be done about the current health care mess is questionable but to do nothing is to accept eventual economic and health care disaster.

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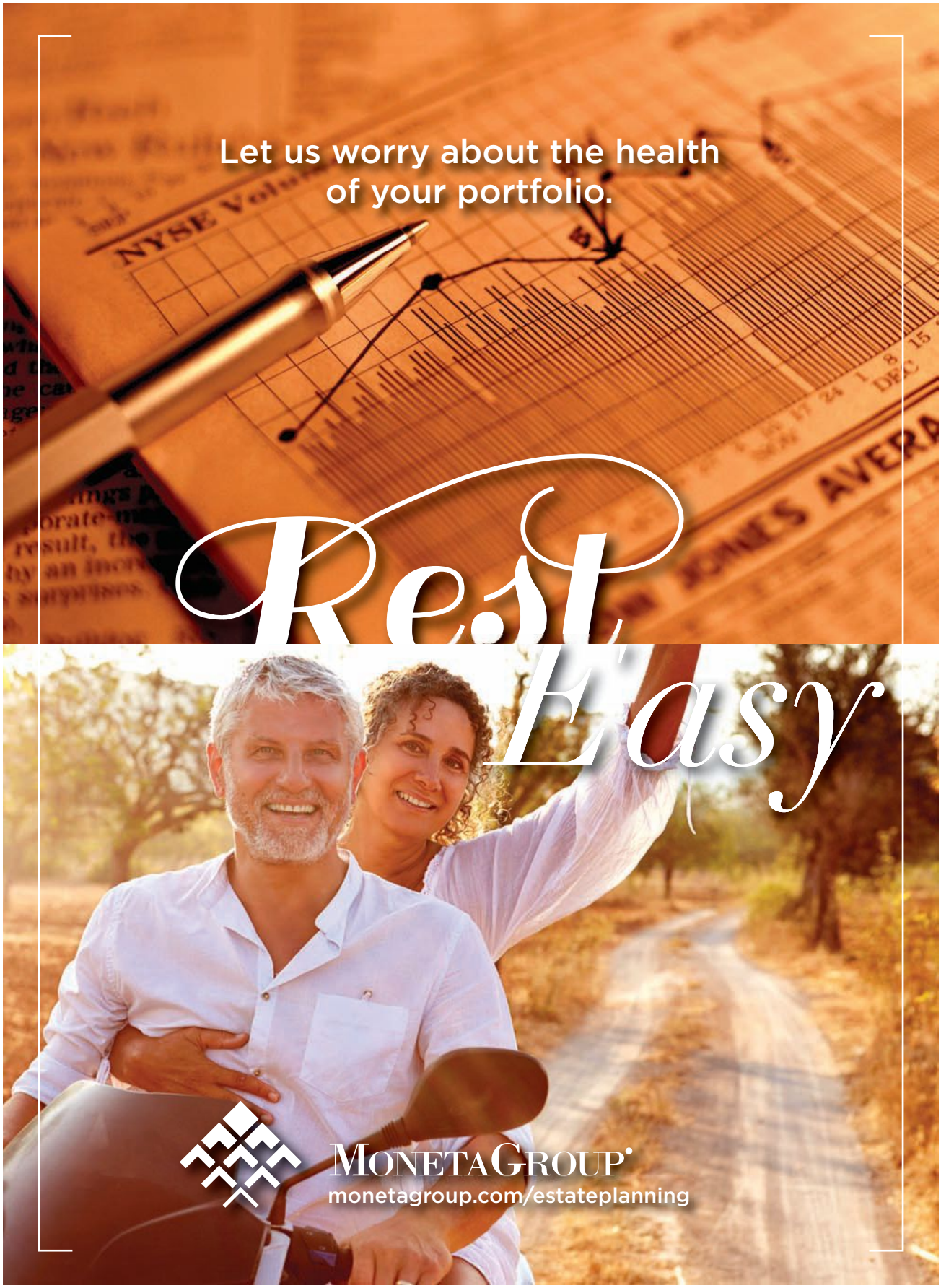
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Manage False Claims Risk Before It's Too Late!

by Matthew Schelp & Lorinda Holloway

Introduction

The onslaught of FCA litigation in the health care industry is unrelenting and most attorneys agree things will only get worse. In 2014 the U.S. Department of Justice (DOJ) recovered a record breaking amount of nearly $6 billion from False Claims Act matters.[1] More than $2.3 billion of this stemmed from health care fraud recoveries and the Obama administration intends to continue FCA enforcement as a top priority for the DOJ.[2]

In 2014 more than 700 false claims actions were filed, with most actions being filed under the Act's whistleblower, or qui tam, provisions that allow whistleblowers to file lawsuits alleging FCA violations on the Government's behalf.[3] The landscape surrounding the qui tam arena has never been more favorable to relators because of a series of record-setting settlements[4] and changes to the FCA that are favorable to whistleblowers.[5]

FCA liability has clearly become a major business threat to health care entities and mitigation of these risks will be a key component of any successful strategy. Implementing a robust health care compliance program sets the foundation, and help in that regard abounds with knowledgeable counsel and consultants and even the Government itself providing useful information.[6] But as discussed in this article, there are several additional risk management steps that can further mitigate FCA risk.



Risks of a FCA Suit and the Procedural Background

First, providers must accept the fact that the risk of becoming an FCA claim target is real. The risk is real in part because the bar for proving an FCA case is relatively low. The FCA imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses or caused to be made or used, a false record or statement material to a false or fraudulent claim."[7] But "knowingly" does not necessarily mean that the provider knew the claim was a lie or that the provider intended to improperly bill or defraud the Government (billing for services not provided, upcoding, illegal kickbacks, and the like).[8] Less obvious conduct can also support an FCA claim. For instance, billing for a product or service that is not supported by documentation as being medically necessary (even if it was in fact medically necessary) can support an FCA claim.

The risk is also real because those with knowledge of your practice are incentivized to attack it. The statute allows a private citizen or "relator" to bring, on behalf of the Government, a lawsuit for a violation of the FCA.[9] A successful relator can garner up to 30% of the proceeds of a case and even potentially recover attorney's fees, costs and expenses.[10]

The financial risk presented by an FCA claim is exceedingly high. Not only will a provider likely incur its own fees and costs associated with responding to the matter, but the FCA allows for recovery of triple the actual damages, civil penalties of $5,500 to $11,000 per claim, potential recovery of attorney's fees and costs for a relator, exclusion or debarment from the applicable Government program, and criminal liability. Even when the Government settles an FCA matter, it tends to demand double damages, and if a relator is in the wings, relator's counsel will no doubt be looking to recover fees and costs incurred in researching and filing the qui tam and aiding the Government's investigation.

As a practical matter, a provider's practice may be a target and the provider may not even know it. Qui tam FCA lawsuits are filed under seal for a period of 60 days and shall not be served on a defendant until ordered by the Court.[11] The purpose of the seal period is to allow the Government time to consider whether it wants to intervene and proceed itself with the action.[12] In most cases, the

In 2014, more than 700 false claims actions were filed, with most actions being filed under the Act's whistleblower, or qui tam, provisions.



Government cannot make its intervention decision within 60 days and can, "with good cause shown," move the Court for extensions of time "during which the complaint remains under seal."[13] In reality, a lawsuit's seal period can last for months or years while the Government investigates the relator's claims. During the seal period a defendant will not be privy to the actual case filing, but could be subject to Government inquiries related to its investigation of the allegations made in the relator's lawsuit. These Government inquiries are often the only signs available to a defendant that a qui tam threat looms.

Treat Government Inquiries Like A Lawsuit

Government inquiries driven by a qui tam action may take a variety of forms: a search warrant, a subpoena, a Civil Investigative Demand, service of an actual FCA lawsuit or simply contact from the Government lawyer. Regardless of the form it takes, providers are wise to recognize that they are being invited to a party they would rather not attend. But rather than trying to figure out how to get out of it or why the Government is wrong to even consider extending such an invitation, providers should first focus on getting the matter into the process designed to protect them. Contact the practice's carrier (see coverage discussion below) and find a qualified health care lawyer familiar with the particular form that the FCA risk has taken. In other words, providers should treat Government inquiries like a potential or filed malpractice claim. The advocate will want and need your insight and expertise, but the very first step is to get the matter into the right hands for evaluation.

Take Stock of Your Insurance Coverage

Insurance is a traditional risk management tool that should not be overlooked in the FCA context. Insurance does not typically cover fraud or crimes, but neither intent to defraud nor a crime is required to prove an FCA case. Providers should also not assume there is no coverage merely because there may be a fraud aspect to an FCA claim. Some policies such as Errors and Omissions (for professional negligence), Directors and Officers (for "wrongful acts"), and Employment Practices Liability (for employment related issues) can cover FCA investigations and exposure depending on their terms. There are also newer specialty policies sometimes called Specialty Errors and Omissions, Healthcare Regulatory Liability, and Billing Errors and Omissions (which is typically not just for billing errors) that are intended to cover loss from Government investigations, FCA claims, and more. These nontraditional forms of coverage are worth exploring particularly because they may pick up prior acts going back as much as six years.

As with any insurance policy, the details matter. Key definitions in the FCA context include "claim," "loss," "covered defense expenses," and "insured." Fraud exclusions are common but can often be negotiated to apply only in the event of a final, non-appealable adjudication. Other exclusions such as for intentional acts, gross negligence, illegal profit, billing errors, and contractual liability must also be evaluated. Depending on your state's insurance laws, the goal is often to find just one covered claim because that can trigger a duty to pay for the defense of all claims.

Providers are wise to consult both an insurance broker who specializes in health care and a lawyer familiar with FCA issues, and to inventory policies annually to look for coverage gaps as the practice or related business grows or changes. Also, be aware of how all of the policies work in relation to one another because some policies are not triggered if other insurance is available.

Use the Right Kind of Indemnity Provisions in Contracts

Another tool for managing FCA risk is having the right kind of indemnity provisions in contracts with vendors, consultants, and business partners who create or expand FCA exposure. Indemnity simply shifts loss from one party to another. Generally speaking, the right to indemnity must come from a statute, common law, or a contract. The FCA itself does not provide indemnity rights because public policy is against allowing an FCA-liable person to shift responsibility to another, which is why courts tend not to recognize common law claims for FCA indemnity either.[14] This policy makes sense, especially in terms of possible counterclaims against a whistleblower. After all, the Government wants to encourage not discourage whistleblowers.[15]

This leaves contractual indemnity. To date, no court has held that the FCA bars a party from trying to enforce a contractual indemnity claim. Case law provides guidance on how to improve the chances of an indemnity claim in the FCA context, such as:[16]

- *do* hinge indemnity on incurring loss, costs, and fees incurred as a result of the business partner's breach of:
  - warranty that it will comply with all applicable regulatory requirements;
  - representation that it will advise of regulatory non-compliance; and
  - the duty of reasonable care in the course of its business (negligence); and[17]
- do *not* hinge indemnity on FCA liability (even though this seems counterintuitive[18]).

When seeking indemnity, highlight factual allegations that are not raised in the FCA case. It is also critical to ensure there is no finding or admission of FCA liability in the FCA case. Additionally, any FCA settlement agreement should state that it is:

- only for the settling parties' benefit;
- not admissible to show fault or facts; and
- not a release of claims against others.

Seeking indemnity from others that created or enhanced your FCA exposure may not make you whole, but it can potentially help backfill the financial hole that FCA matters tend to create.

Keep up With Changes to the FCA, Including the 60-Day Rule

Another risk management step to take is to keep up generally with changes to the FCA and the decisions interpreting it, whether through journals or continuing education. For instance, many providers are aware that the Affordable Care Act created FCA liability for individuals who retain overpayment for longer than 60 days after it is identified.[19] Overpayments retained after the 60-day window closes are then considered "obligations" under the FCA, entitling the Government or qui tam relators to pursue civil penalties.[20] As with any FCA liability, penalties can include $11,000 per false claim submitted and three times the amount of damages the Government sustains because of the act.[21]

This important change to the FCA presented a natural and critical question—when is an overpayment considered to be "identified" and therefore when does the 60 days begin to run? These ACA-imposed provisions are just now being tested for the first time in a qui tam case filed against New York City's Mount Sinai Health System. A United States District Court in New York rejected Mount Sinai's request to dismiss the Government's case against it for violating the 60-day rule.[22] Many speculated that the Court would accept the defendant's argument that "identified" means "classified with certainty," but the Court sided with the Government and concluded that "identification" of any overpayment occurs when "a person is put on notice that a certain claim may have been overpaid."[23]

This decision begins to bring daunting clarity to the 60-day rule and demonstrates that strict standards are being used to interpret this potential area of FCA liability. To properly mitigate FCA liability, healthcare providers must carefully deal with allegations of overpayment of certain claims and must be on high alert for the timely return of overpayments. The broader risk management point is that providers are wise to generally keep up with changes to the FCA and the decisions interpreting it.

Conclusion

FCA liability has become a major business threat to healthcare providers and mitigation of these risks is key to any successful strategy. Applying a few risk management techniques to FCA risks can help: treat all Government inquiries like lawsuits, meaning get them into the hands of counsel and carrier; revisit insurance coverage; use the right kind of indemnity provisions in contracts with those that present or increase FCA risk; be mindful of the 60-day clock that may be ticking with regard to alleged overpayments; and pay attention through journals and continuing education to changes to the FCA and the decisions interpreting it.

Finally, remember the basics of FCA risk management—work with knowledgeable and experienced attorneys and consultants to create a compliance and ethics program. In other words, develop policies and procedures within your practice to foster a compliance culture. This can be a helpful barrier to a successful false claims case and discourage the Government from intervening in a whistle blower action.

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14. See, e.g., Mortgages, Inc. v. US Dist. Ct., 934 F.2d 209 (9th Cir. 1991) (per

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15. To those who argue that whistleblowers with unclean hands should not be protected from claims for indemnity when he/she participated in the conduct at issue, courts explain that the FCA addresses this scenario by reducing whistleblower awards when they were a part of the problematic conduct. See Mortgages, 934 F.2d at 213.

16. See, e.g., Cell Therapeutics, Inc. v. Lash Group, Inc., 586 F.3d 1204 (9th Cir. 2009); U.S. ex rel. Wildhirt v. AARS Forever, Inc., No. 09 C 1215, 2013 WL 5304092 (N.D. Ill. Sept. 19, 2013).

17. For good measure, include indemnity for fees, costs, and expenses incurred in seeking to enforce the indemnity should that become necessary. The noted warranty and representation should be included in the terms of the agreement.

18. Remember, the Government wants to encourage not discourage whistleblowers so allowing an FCA defendant to blatantly shift blame to another goes against public policy and is not something courts will enforce. The reality is that a properly worded indemnity provision can potentially help defray costs incurred in defending an FCA matter without on its face looking like that is what it is accomplishing.

19. 42 U.S.C. §1320a-7k (d)(2).

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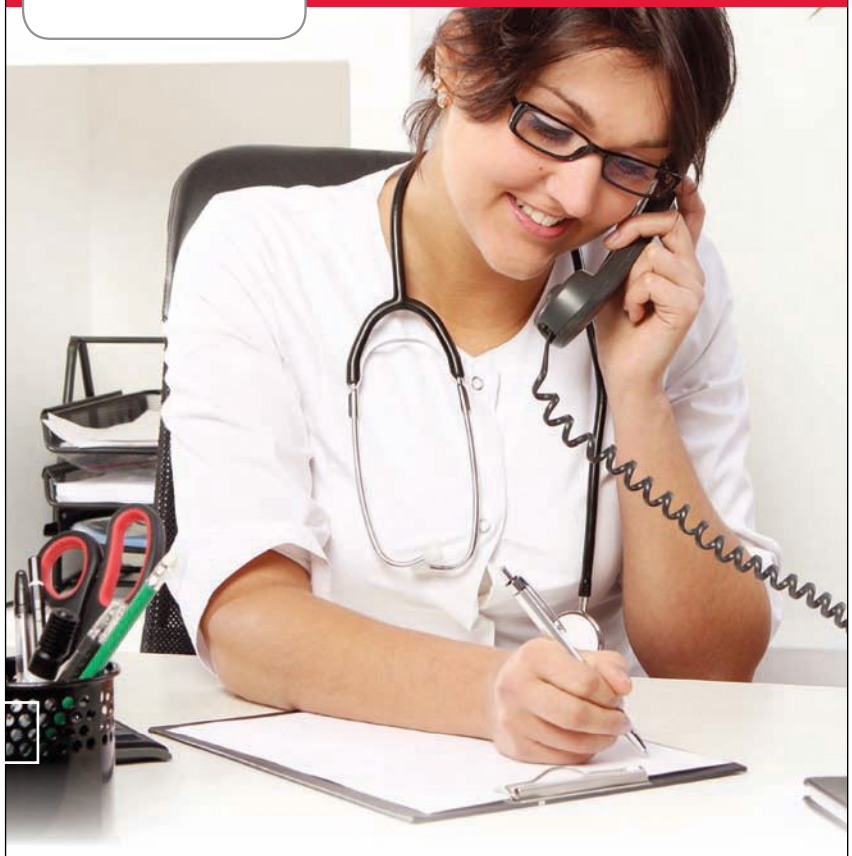


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BEWARE

Tax Identity Theft Scam Targets Physicians Again

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

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

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



Take these steps as soon as possible:

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

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

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

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

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

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Defining Wellness as a Balance

by Margaret Wilson, DO

ATSU defines wellness as a balance of intellectual, physical, spiritual, emotional, social, environmental, and professional development. This has become increasingly important as demands on aspiring health care providers are at an all-time high.

For nearly 125 years, A.T. Still University's Kirksville College of Osteopathic Medicine (ATSU-KCOM) has educated students to become highly competent osteopathic physicians and health care leaders. The College has successfully blended time-tested knowledge and methods with cutting-edge technology and modern practices. Today, ATSU-KCOM's outstanding curricula ensure students receive the best learning experiences possible.

Last year, ATSU-KCOM's Doctor of Osteopathic Medicine (DO) program fully transitioned to a systems-based curriculum using a patient-case presentation model. In this model, all student learning is clinically contextualized. For instance, the physiology of the gastrointestinal system is taught alongside the principles of medicine and the exam and diagnosis of gastrointestinal issues. This model has proven effective as ATSU-KCOM students' board scores are above the national average.



Margaret Wilson, DO, '82, MSMA member since 2012, is the dean and a professor at ATSU-KCOM.
Contact: mwilson@atsu.edu

ATSU-KCOM has created a phenomenal human patient simulation (HPS) lab that serves as a training site for medical and dental students, residents, and community members. The lab grew significantly within the past year and now includes 12 Laerdal third generation, high fidelity simulators; one Gaumard birthing simulator; and two colonoscopy trainers. The simulators are programmed to parallel the curriculum, and students and residents put their knowledge into practice as they improve their assessment, communication, and interprofessional skills to diagnose and treat patients.

First- and second-year DO students and dental students from ATSU's Missouri School of Dentistry & Oral Health attend mandatory HPS sessions throughout the year, and DO students have the option of additional training sessions. The HPS lab is unique because it is the first to offer dental students the opportunity to practice emergency medical scenarios that are not typically taught in a dental curriculum.

Taking HPS to an even higher level, the College recently introduced hybrid simulations to students using a combination of simulated patients and standardized patients. In these situations, a student must glean a simulated patient's health information from a real person acting as a family member or friend – increasing the realism by adding an interpersonal aspect to the situation.

Additionally, the HPS lab serves as an American Heart Association Training Center. Basic Life Support, Advanced Cardiac Life Support, and Heartsaver courses

for providers and instructors are offered to individuals on campus and throughout the community. Within the last year, 437 individuals from ATSU's Missouri campus and more than 2,800 community members received certifications.

The ultrasound portion of the ATSU-KCOM curriculum has also grown significantly within the last few years. Ultrasound education, which is completely integrated into the first two years of the DO program, helps students bridge the gap between form and function, didactics and clinical practice. The College began with 10 ultrasound machines, and based on student feedback and interest, the number grew to 25 machines. Now students have ample time for hands-on training with three to four students per machine.



ATSU-KCOM students work in teams in the HPS lab.

Ultrasound labs for first-year DO students are aligned with the gross anatomy labs and allow students to visualize living anatomy through the correlation with cadaveric dissection. Beginning with the second semester, labs are correlated with the system blocks. Recently a new workshop combining electrocardiography and echocardiography was integrated into the cardiology block of the second semester.

During the second year, students are exposed to clinical applications of ultrasound and its use to diagnose pathological conditions, such as pneumothorax and the presence of pathological fluids in the lung, heart, and abdomen as part of the focused assessment with sonography for trauma (FAST) exam. Second-year students receive additional clinical training by using ultrasound training models, which simulate effusions with different amounts and locations of fluids. They learn to perform central line placement under ultrasound guidance using the central line training model and to safely perform lumbar/epidural injections using the lumbar training model. Simulation training phantoms are also used in conjunction with ultrasound. For example, breast ultrasound phantoms help students learn to perform ultrasound breast examinations and find pathological lesions in the breast in the office. With the curriculum's emphasis on rural and underserved areas, these training opportunities become even more essential to a student's future success in the field.

While ATSU-KCOM focuses primarily on education, the College's research mission is strong considering a small faculty. In 2010-14, clinical researchers published 37 papers, while basic science researchers published 97 papers. Overall, these biomedical research publications averaged 27 per year (2010-14) and primarily focused on bench, patient care, or medical education research. Some of these papers were published in prestigious journals such as Proceedings of the National Academy of Sciences (USA) and PLoS One. Research presentations at national conferences averaged 49 per year (2010-14), and the top six research topics included medical education, cancer biology, osteopathic manipulative medicine, cardiovascular disease, bone and joint disease, and muscle biology. Researchers have benefitted from the College and University's strong research support. Recent purchases of sophisticated research equipment included a confocal microscope, fluorescence-activated cell sorter, and DNA sequencer.

Coinciding with ATSU-KCOM's research projects is the College's ongoing grant activity. The Curriculum and Faculty Development in Evidence-based Medicine (R25) Project,* funded by the National Institutes of Health, National Center for Complementary and Alternative Medicine, focused on enhancing evidence-based medicine (EBM) coverage in clinical training and affiliated residency programs, while working to more deeply entrench preclinical, campus-based advancements in EBM into the curriculum. Specifically, the project aimed to strengthen faculty knowledge and skills in EBM by expanding training to complementary and alternative medicine (CAM) clinical

faculty; increase trainees' exposure to, understanding, and appreciation of EBM and scientific thinking, especially in clinical settings; and expand opportunities for CAM trainees to seek advanced, hands-on mentored training in applying EBM skills in the clinical environment.

In July, ATSU-KCOM was awarded a $1.2 million, five-year grant from the U.S. Department of Health and Human Services' Health Resources and Services Administration. Grant funding will enhance the College's primary care education and better prepare medical students to reduce health disparities and barriers to care for vulnerable populations, improve patient engagement, and become leaders in the Primary Care Workforce Competencies endorsed by the Patient-Centered Primary Care Collaborative. Developing leaders for communities to address issues such as chronic disease management, health disparities, and patient engagement will improve health for all.

ATSU-KCOM also received a $21,000 grant from the American Academy of Family Physicians Foundation to fund equipment and supplies for Still Caring Health Connection (SCHC), a free health and dental patient experience that provides high quality, patient-centered education for underserved populations in northeast Missouri. SCHC is affiliated with Volunteers in Medicine, an organization that promotes development of free healthcare services to improve access to care for underserved, especially uninsured, populations. Through grant funding, SCHC's student, resident, dental, and medical volunteers will be able to better promote health to patients.

The updates to ATSU-KCOM's curriculum mentioned within this report are just some the main highlights of the College's continual efforts to do what it does best – educate students. However, the College also focuses on students' wellbeing, inside and outside the classroom. Through the Still-Well Student Wellness Program, students learn the value of balancing rigorous academics with other parts of life. ATSU defines wellness as a balance of intellectual, physical, spiritual, emotional, social, environmental, and professional development. This has become increasingly important as demands on aspiring health care providers are at an all-time high.

Without resting on its laurels, ATSU-KCOM is doing everything possible to ensure its students are thriving professionally and personally. Going forward, the College will remain committed to providing a quality osteopathic medical education in a research environment that prepares students for graduate medical training and clinical service. Ultimately, by providing students with the resources and skills to succeed, the College continues to produce graduates who will improve the state of health care in communities locally and around the world.

Disclosure

*The project described was supported by Award Number R25AT003579 from the National Center For Complementary & Alternative Medicine. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Complementary and Alternative Medicine or the National Institutes of Health.

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MSMA Members in the News

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



Elizabeth A. Piontek, MD, MSMA member since 2013, is the new Urology Editorial Board member, replacing James Magera, MD, who served on the board since 2014. Dr. Piontek practices at Advanced Urologic Associates in Independence and Lee's Summit, Missouri, and is a staff physician at St. Luke's East Hospital, Lee's Summit Medical Center, and St. Mary's Medical Center in Blue Springs.

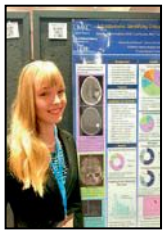
MSMA congratulates medical school Deans **Steven Kanter, MD**, University of Missouri - Kansas City, and **Bruce Dubin, DO**, Kansas City University, for joining the MSMA as they take the helm of each of their schools of medicine.



Mark Adams, MD, MSMA member since 2009, presented Missouri State Medical Foundation scholarships to four second-year medical students at UMC. The recipients, all student members of MSMA, are (from left to right) **Rebecca Ringling, James Hart, Julia Hagan** and **Kelly Lacey**.

A new MSMA member from West Plains, **Christopher Cochran, MD,** spoke at the Allscripts Client Experience conference in Boston, Mass.





Fourth-year medical student **Danielle Cunningham,** of UMKC, received a travel scholarship to attend the next Society of Interventional Radiology Annual Scientific Meeting.

MSMA wishes to congratulate these loyal members on the opening of their new primary care clinic in Cape Girardeau: **Brett M. Dickinson, MD,** member since 2007; **William D. Johnson, DO,** member since 2003; and **Rustico A. Ramos, MD,** member since 2001.









Humam Farah, MD, MSMA member since 2014 from Hannibal, is making headlines for his work in treating COPD in clinical trials.



Amira Ghazali, MD, MSMA member since 2011, recently began practice at Western Missouri Medical Center, helping meet the growing advanced surgical needs of the community.



Timothy R. Isakson, MD, joined MSMA last year and recently sponsored the 1st Annual Wallyball Tournament benefiting Relay for Life in Rolla.



MSMA member since 2010, **Jeffrey Jorgensen, MD,** earned his certificate by the MD Anderson Cancer Network for meeting the standards in cancer diagnosis and treatment.



MSMA member since 1987, **Douglas W. Kiburz, MD,** is now partnered with Bothwell Regional Health Center in Sedalia and Missouri Health in Columbia.



An MSMA member since 1985, **Benjamin Lampert, MD,** is shining brightly for being honored as Springfield Business Journal's Top Doctor of the year. As such, he is the recipient of the Health Care Champion Award.



An MSMA member since 2011, **Jeff Lehmen, MD,** of Jefferson City, achieved board certification by the American Board of Orthopaedic Surgery with special focus in spine surgery.



Congratulations to MSMA member physician and **Missouri Senator Bob Onder, MD,** of St. Louis, for his election as Assistant Majority Floor Leader. Dr. Onder has been an MSMA member since 1992 and we are fortunate to have him in the Senate.



Justin Puckett, DO, FAAFP has been recognized by the Obesity Action Coalition with the Bias Buster of the Year Award. He's from Kirksville and has been an MSMA member since 2008.



Congratulations to **Keith Ratcliff, MD,** on opening Renaissance Family Health Care, the first direct primary care practice in Washington. He has been an MSMA member since 1984 and serves as president of Tri-County Medical Society. Standing to his left is **Missouri Representative Physician Keith Frederick, DO,** of Rolla. Photo courtesy of *The Washington Missourian*.



Congratulations to **Assad Shaffiey, MD,** of Sedalia, who joined MSMA last year, and received the 2015 Physician Summit Award.



Jeffrey R. Tedrow, MD, MSMA member since 1983, is a recipient of the Donald J. Babb Award this year for his service to the Bolivar community.

Harold (Hal) Williamson, Jr., MD, MSPH, has been appointed the Executive Vice Chancellor of Health Affairs for the University of Missouri Schools of Health Professions, Medicine and Nursing, as well as the clinical operations of MU Health Care's five hospitals and more than 50 outpatient clinics throughout mid-Missouri. Dr. Williamson, family physician, has been a member of MSMA since 1996. **MM**



1 Picture = 1,000 Words

Medscape Best Places to Practice 2015: Missouri 14th Best State



Source: Medscape

Welcome New Members!

(Joined before December 8, 2015)

Ali, Syed, MD
Kansas City
Ansari, Noushin, MD
Kansas City
Asif, Muhammad, MD **PD**
Warrensburg
Boehr, Nathan, DO
Kansas City
Bray, William, MD **OPH**
Columbia
Byle, Chadwick, MD
Kansas City
Cabral, Jennifer, MD
Kansas City
Chappell, Christopher, DO
Kansas City
Christiansen, Edward, MD
Kansas City
Claxton, Cassondra, DO
Kansas City
Dubin, Bruce, MD **PUD**
Kansas City
Dunn, Charles, MD **GS**
Springfield
Elledge, Dianne, DO
Kansas City
Fleming, James, MD **P**
Lee's Summit
Fotopoulos, Christopher, DO
Kansas City
Green, Georgina, MD
Kansas City
Hall, Ashley, DO
Kansas City
Hanson, Anna, MD
Kansas City
Idicula, Joanita, MD
Kansas City
Jarstad, John, MD **OPH**
Columbia
Johnson, Kendall, DO
Kansas City
Johnson, Zachary, DO
Hannibal
Kanter, Steven, MD **NS**
Kansas City
Kosa, Steven, MD **N**
Kansas City
Martin, Caroline, DO
Kansas City
Munger, Kevin, DO
Kansas City
Neil, Jayson, MD **NS**
Kansas City
Nguyen, Huong, DO
Kansas City
Olive, G. Chapman, MD **GS**
Springfield
Person, Stephen, MD **US**
Kansas City
Ramaswamy, Raja, MD **DR**
St. Louis
Richter, Jessica, DO **CHP**
Kansas City
Rooney, Melissa, MD
Chesterfield
Samani, Tommel, MD
Kansas City
Shepherd, Jacob, MD
Kansas City
Stokes, Gretchen, DO
Kansas City
Stokes, Ryan, MD
Kansas City
Tonkin, David, MD **AN**
Springfield
Tovey, Jonathan, MD **OPH**
Kansas City
Turner, Amanda, MD **FP**
Nevada
Whitaker, Racheal, MD **OBG**
Farmington

In Memoriam



Jack L. Croughan, MD, the medical director of the Missouri Physicians Health Program for over 20 years, and MSMA member since 1982, died August 10, 2015, at the age of 72. Dr. Croughan was a board-certified psychiatrist with a subspecialty in alcoholism and chemical dependency.

Born in Santa Cruz, Calif., Dr. Croughan received both his undergraduate and medical degrees from the University of Kansas. He completed his internship at the University of Southern California Medical Center and his residency at Washington University.

In addition to his private practice and work with MPHP, he also served as medical director of Chestnut Health System and was a board member of the National Council on Alcoholism and Drug Abuse-St. Louis Area. He was on the faculty at Washington University, and on staff at Barnes-Jewish Hospital, St. Anthony's Medical Center and the former Incarnate Word Hospital.

If you would like to make a donation to the MPHP in honor of Jack Croughan, email Bob Bondurant at rbondurant@themphp.org. Source material: *St. Louis Metropolitan Medicine Magazine*.

Robert M. Hazen, MD, 93, Prairie Village, KS, Otolaryngology 6/7/2015
Joseph G. Ernst, MD, 88, St. Louis, MO, Internal Medicine 7/4/2015
C.E. Gene Ridenhour, MD, 84, Columbia, MO, General Surgery 9/1/2015
Bruce I. White, MD, 75, St. Louis, MO, Plastic Surgery 9/2/2015
H.H. Lurie, MD, 93, Springfield, MO, Internal Medicine 9/10/2015
Eugene T. Hansbrough, MD, 90, Poplar Bluff, MO, General Surgery 6/29/2015
Leroy J. Miller, MD, 92, Columbia, MO, Family Practice 12/3/2014
Frederick H. Hartwig, MD, 91, Roeland Park, KS, General Surgery 9/15/2015
Michael J. Curry, MD, 75, St. Charles, MO, Internal Medicine 5/18/2015
Bashir Ahmad, MD, 87, Ballwin, MO, Anesthesiology 10/15/2015
Vincent P. Perna, MD, 89, Chesterfield, MO, Pathology 10/28/2015

The United States vs. the World

I recently had my left knee replacement surgery. Making an appointment with my orthopedic surgeon, Dan Martin, MD, took less than a week. I could have scheduled surgery within two to three weeks; however, I requested the surgery be done at the end of August, and it was scheduled. I know all of you are wondering why I did not have the surgery in a country with socialized medicine. Well, I preferred to have the procedure done without delay, so I stayed in the United States; besides, my insurance would not cover the out-of-network procedure in another country.

Let's look at the facts:

The **AVERAGE TIME** from office visit to surgery is:

- 3 weeks in the U.S.
- 8 weeks in Canada
- 12.6 weeks in Great Britain

If we look at the percentage of patients **WAITING OVER 12 WEEKS** in several European countries:

Netherlands	15.2%	Norway	28.0%
Switzerland	16.1%	Italy	36.3%
Spain	18.5%	United Kingdom	41.7%
Germany	19.4%	Portugal	58.1%

If you want to go to an English-speaking country, the percentage of patients who **WAIT OVER FOUR MONTHS** include:

United Kingdom	38%
Canada	27%
New Zealand	26%
Australia	23%
United States	5%

Now all is not so swift in the U.S. when one looks at the Veterans Administration system. The Baltimore VA has an average wait for a knee replacement of four and one-half months. In fairness to the VA, I must report on the Michael DeBakey VA Medical Center in Houston. This medical center did a miraculous turnaround and reduced the waiting time from 18 months to four to six months. So, at the present time, you are best having your knee replacement in the U.S. If you are a veteran, you better move to Houston to get your care.

I am not sure what the future brings as the Affordable Care Act gets overwhelmed, over-utilized, and underfunded. So, go out and get that knee replaced now before our medical care system approaches that of Europe or the above-mentioned English-speaking countries.

Richard J. Gimpelson, MD
MSMA Member since 1983
St. Louis, Missouri, Obstetrics/Gynecology

This letter is based on an article appearing in St. Louis Metropolitan Medicine Magazine and the opinions are my own.

It's Important To Be 'Well-versed" About the Panniculus

What to avoid, an absolute *must*; a protruding bulging *panniculus*.
And more urgent one should *try* to avoid the hazards of *panniculi.*
The fascial planes are stretched and *strained*; the musculii abdominii severely *pained*.

The waist line gone—lost its *poise*, because of rampant *avoirdupois*!
A strain is put upon the *spine*. The knees are stressed—get out of *line*.
With upper legs and burdened *hips*, as body inevitably frontward *tips*.

And so, my friends, it's worth real *fuss*, to avoid the unsightly, unhealthy, *panniculus*!

Donald E. Kuenzi, MD
Kansas City, Missouri
MSMA Member since 1977



Missouri State Medical Association Alliance

Holiday Sharing Card

From the following who most generously gave to the Missouri State Medical Association Foundation & Alliance Scholarship Funds.

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

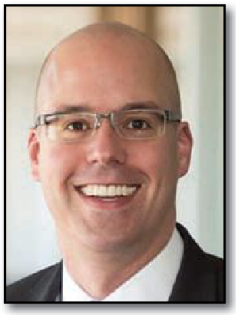
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Mrs. Angela Zylka

158th Missouri State Medical Association

March 18-20, 2016 ◆ St. Louis Renaissance Airport Hotel

Annual Convention

GENERAL SESSIONS & EVENTS



American Medical Association Presentation

Steven Stack, MD
AMA President
Friday, March 18 ◆ 8:00 am



What Physicians Need to Know about MACRA, MIPs & APMs

Richard Deem
Saturday, March 19 ◆ 8:00 am



Ethical Issues in Clinical Uses of Genomic Screening

John Lantos, MD
Friday, March 18 ◆ 1:30 pm



Update on Stroke Management

Vikas Gupta, MD
Saturday, March 19 ◆ 10:00 am



Drug Pricing: Can We Afford the Cure?

Steve Miller, MD
Friday, March 18 ◆ 3:30 pm



Burning Out in Medicine: Causes, Consequences & Strategies

Liselotte Dyrbye, MD
Saturday, March 19 ◆ 1:30 pm

PLUS

◆ Multiple Medical Specialties Programming ◆ Two-Day Exhibit Showcase
◆ House of Delegates ◆ Foundation Fundraiser/Dinner "Wild Wild West"
◆ Presidential Inauguration & Reception

MSMA's Annual Convention is EARLY this year! Make reservations now!

www.msma.org/annual-convention



www.msma.org/annual-convention

Pre-Convention Meetings

Thursday, March 17

2:15 pm	MSMA Insurance Agency Board Meeting
3:30 pm	MSMA Executive Committee
3:30-6:30 pm	Convention Registration
3:30-6:30 pm	Exhibitor Setup & Registration
5:00 pm	**MSMA Council Meeting**
6:30 pm	Alliance Dutch Treat Dinner [Offsite]
6:30 pm	University of Missouri Awards Reception & Dinner [Offsite]
7:00 pm	**MSMA Council Reception & Dinner**

Convention Meetings

Friday, March 18

6:30 am-4:00 pm	Convention Registration
6:30 am	University of Missouri Breakfast
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	Physicians Health Committee Meeting & Luncheon
Noon	SLMMS Caucus & Luncheon
Noon	KCMS Caucus & Luncheon
Noon	"Spirit of the Alliance" Awards Luncheon
1:30 pm	**MSMA General Session**
2:00 pm	Missouri Million Hearts Meeting
2:30 pm	Alliance Past President's Reception
3:30 pm	**MSMA General Session**
5:00 pm	OMSS Business Meeting
5:30 pm	Medical School Alumni Receptions
7:00 pm	Alliance Foundation Fundraiser/Dinner "Wild, Wild West"

Saturday, March 19

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

Sunday, March 20

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

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

Subject to Change. Refer to Convention Official Program for times and meeting locations. All meetings held at the St. Louis Renaissance 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.

Convention is EARLY!

Make Hotel Reservations Now

www.msma.org/convention-registration-lodging

Call St. Louis Renaissance 1-800-468-3571

Group rates available until February 24, 2016.

Double or King at $98 per night plus charges and taxes.

If calling, mention "MSMA Attendee."

Unique Aspects of Sleep in Women

by Navina Mehta, MD, Fariha Shafi, MD & Abid Bhat, MD

While many aspects of sleep are similar in men and women, there are a number of important differences that need to be identified and confirmed by the health care provider. This article reviews the unique aspects of sleep in women.



Navina Mehta, MD, is a Fellow, Sleep Medicine Fellowship Program; Fariha Shafi, MD, and Abid Bhat, MD, (above) are both Associate Professors; all are in the Department of Internal Medicine, University of Missouri - Kansas City School of Medicine, Kansas City, Missouri.
Contact: bhata@umkc.edu

Abstract

Sleep in women differs in many respects from that of men. In general, women appear to report a greater need for sleep and more subjective complaints of non-refreshing sleep than men. Sleep in women is affected at least partially by hormonal factors, with women typically suffering from sleep disturbance in connection with the menstrual cycle, pregnancy, and menopause. Menstrual cycles are associated with prominent changes in reproductive hormones that may influence sleep. Sleep apnea and restless legs syndrome may be aggravated by pregnancy. Women may also develop insomnia during pregnancy, childbirth and menopause.

Introduction

Different phases of the life cycle in female population are associated with unique features of sleep disruption. Changes in sleep patterns are often linked to hormonal factors leading to disturbed sleep in connection with the menstrual cycle, pregnancy and menopause (See Figure 1). It has also been shown there may be a long interval between the onset of symptoms and the correct diagnosis of some sleep disorders.[1, 2]

In general, women tend to have slightly more slow wave sleep than men (13% vs 9%) and less stage 1 sleep (8% vs 11%).[3] Women also report having a greater sleep need and report poor or insufficient sleep than men.[4] Since most studies on sleep and sleep loss have been conducted in males, it is still unclear what factors contribute most to the sleep disturbances in women. It is also clear more research is required to fully elucidate the impact of life cycle on sleep parameters in women. This article will summarize what is presently known about different aspects of sleep and sleep disorders in women in relation to various lifespan stages.

Sleep during Adolescence

The transition to puberty brings with it a myriad of changes both physical and mental. These changes are influenced by age, developmental status, as well as changes in sleep schedule. In studies using actigraphy, adolescent boys were noted to sleep less, have less sleep efficiency, and awaken earlier than girls in the same age group.[5] The onset of menses may also be linked to an increased risk of insomnia. This increased risk of insomnia corresponds with an increased risk of depression, which in turn is a risk factor for insomnia.[6]

In adolescence, a striking feature in the polysomnographic data is the steep decline in the slow wave (delta) activity of non-REM sleep, by almost 50% between the ages of 10 and 20 years.[7,8] This decline in delta activity may be a component of widespread brain reorganization, of which other manifestations include

reduction in brain metabolic rate, decreased plasticity, and the emergence of adult cognitive capacity.[9] Studies have also indicated that adolescent girls undergo the steep drop in the slow wave activity earlier than boys in the corresponding age.[10]

Sleep During the Menstrual Cycle

Female reproductive hormones, specifically estrogen and progesterone, not only regulate reproductive tissue function during menstrual cycle, but also influence other physiologic principles, including sleep and circadian rhythms. Conventionally, in a normal menstrual cycle of 28 days, day 1 is identified as the first day of bleeding (menses). Ovulation usually occurs during day 14, dividing the cycle into two phases: a preovulatory follicular phase and a postovulatory luteal phase. The follicular phase is when estrogen is the predominant hormone. After ovulation, the luteal phase lasts 14-16 days and is when concentrations of estrogen and progesterone are high, and body temperature is elevated by about 0.4 degree Celsius when compared to the follicular phase. This rise in temperature is attributed to the rise in progesterone levels. Many women of reproductive age have recurrent emotional and physical symptoms in association with the menstrual cycle, particularly during the late luteal (premenstrual) and menstrual phases. These symptoms may interfere with social and occupational functioning, as well as with sleep; women who have menstrual-related problems are between two and three times more likely than other women to report insomnia and excessive sleepiness.[11]

Approximately 60% of women experience mild symptoms of premenstrual syndrome (PMS), and an estimated 20% have moderate PMS that they feel requires treatment. For 3-8% of women, the cyclical pattern of symptoms is severe and labelled as premenstrual dysmorphic disorder (PMDD). [12] Most common complaints include irritability, mood swings, depression, fatigue, headaches, bloating and cramping. Sharkey and colleagues studied twenty-seven healthy women to determine the relationship between sleep fragmentation and different points in the menstrual cycle.[13] Hormone levels were measured at two time points during a single menstrual cycle: the follicular phase and the peri-ovulatory to mid-luteal phase. A single night of home polysomnography (PSG) was recorded on the day of the peri-ovulatory/mid-luteal-phase blood draw. The study determined that the rise in progesterone level in the peri-ovulatory through mid-luteal phase resulted in an increase in the wake after sleep onset resulting in an increase in sleep fragmentation.

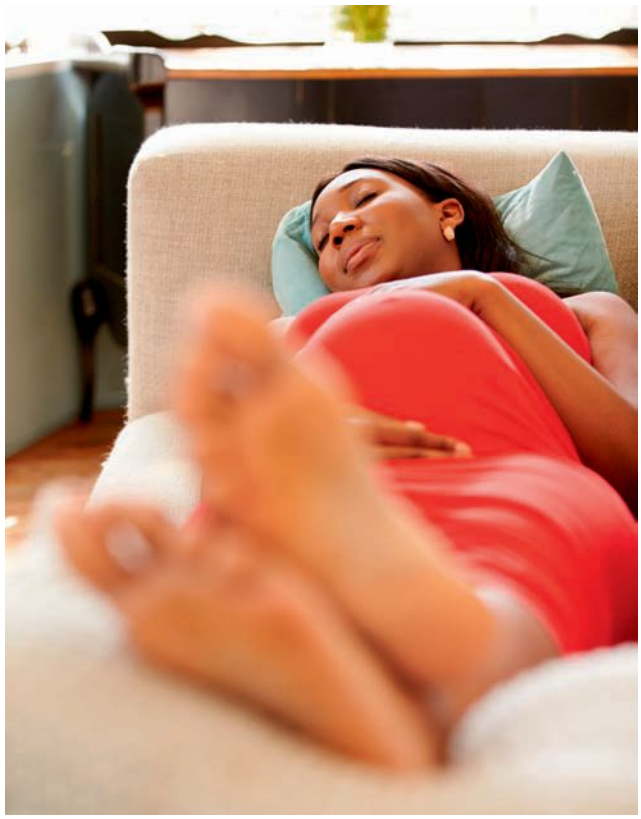


Figure 1
Changes in women's sleep patterns are often linked to hormonal factors leading to disturbed sleep in connection with the menstrual cycle, pregnancy and menopause.

It is surprising to note that limited research has been done on the effects of oral contraceptives (OCs) on sleep since OCs are so frequently used by women. Ho compared the sleep of three women (ages 24-34) with regular ovulatory menstrual cycles to three females taking fixed dose OCs. There was an increase in slow wave sleep (SWS) in the premenstrual phase in the cycling group, compared to the OC group in which SWS declined.[14] Another study described the sleep of three women at the follicular and luteal phases who were taking OCs. REM sleep latency was shorter in women taking OCs compared to 13 women with ovulatory cycles.[15] It is obvious that no clear link can be made about the effects of OCs on sleep, and additional research is therefore required.

Women also have more difficulty adapting to shift work than men.[16] Shift work, particularly at night, is problematic for the worker. It represents a serious risk factor for sleep disorders, such as insomnia and daytime sleepiness.[17] The frequency of sleep complaints in this population is twofold higher than in the general population. These problems are mainly due to a disruption of the normal sleep/wake pattern

but also involve other factors such as age, gender, stress at work, health problems and social and family factors.

The finding that neurons in the suprachiasmatic nucleus (the circadian clock) contain receptors for estrogen and progesterone indicates a functional interaction between the circadian system and the menstrual cycle.[18] Female shift workers experience several menstrual cycle irregularities.[19] Compared with all other fixed schedules (including nights only), rotating nurses reported lengthened menstrual cycles, visited the clinic more often with menstrual associated complaints, and experienced more "tension, nervousness, weakness, and sickness at menstruation." Shift work may also increase the risk of some forms of cancer in women. One proposed explanation is the exposure to light at night suppresses melatonin production which has potential oncostatic action. The risk of breast cancer is higher among women who frequently do not sleep at night, with an increased risk among subjects working in the bright places.[20] Another study indicated that working a rotating night shift at least three nights per month for 15 or more years increased the risk of colorectal cancer in women.[21]

Sleep During Pregnancy

Pregnancy is not free from its share of sleep-related issues. Many factors contribute to sleep disruption during pregnancy, including increased progesterone and prolactin levels, diaphragmatic elevation, fetal movement, bladder distension, temperature fluctuation and gastrointestinal discomfort. Anatomical changes during pregnancy, such as weight gain, decreased respiratory functional reserve capacity and nasopharyngeal edema (due to estrogen), and hyperventilation with increased sensitivity to carbon dioxide may predispose women to developing sleep disordered breathing (snoring, obstructive and central sleep apnea).[22,23,24,25] Despite the physiological changes conducive to the development of sleep apnea during pregnancy, a number of other physiologic adaptations may provide protection against sleep apnea. [26] For example, elevated progesterone levels during pregnancy increase the pharyngeal muscle tone. Reduction in REM sleep duration during pregnancy may also protect against sleep apnea. During late pregnancy, there is also a greater tendency for women to sleep on sides as opposed to laying supine, thereby reducing the tendency to manifest severe sleep apnea. Hedman and colleagues surveyed 325 pregnant women with a series of five questionnaires to assess the effects of pregnancy on sleep.[27] The questionnaires were asked before becoming pregnant, once during each trimester, and a final questionnaire three months post-partum. The total hours of sleep increased during the first trimester, lessened during the second trimester, and further decreased during the third trimester.

Emerging evidence suggests an increased incidence of sleep disordered breathing (SDB) during pregnancy and exacerbation of pre-existing SDB, particularly during the later stages of pregnancy. A longitudinal questionnaire study of symptoms of SDB found cumulative increase in apnea symptom scores from 14 weeks until delivery. Although 1.3% of participants in the study reported witnessed apneas on at least three nights per weeks at 14 weeks gestation, by 28 to 29 week's gestation, the figure had increased to 15% of the cohort.[28] The prevalence of obstructive sleep apnea (OSA) is approximately 5% in nonpregnant women of reproductive age.[29] The risk for OSA in women who are obese pre-pregnancy was shown to be significantly higher than in those who are non-obese. Maasilta and colleagues found that patients who were obese pre-pregnant had 1.7 events per hour versus 0.2 events per hour in the nonobese group ($P < 0.05$), and 5.3 events per hour of 4% oxygen desaturation versus 0.2 events per hour ($P < 0.005$). [30] The obese women snored 32% of the time, whereas the non-obese group snored only 1% of the time. OSA may also contribute to a higher risk of hypertension during pregnancy.[31] Women with pre-eclampsia have upper airway narrowing in both upright and supine postures.[32] These changes could contribute to the upper airway resistance episodes during sleep in patients with pre-eclampsia, which may further increase their blood pressure. Pregnant women with apnea symptoms have a higher likelihood of gestational hypertensive disorders, gestational diabetes, and unplanned Caesarian sections.[33] Treatment for OSA in pregnant patients remains to be continuous positive airway pressure (CPAP), which has been shown to be safe during pregnancy.[34] Mild OSA may respond to the use of an oral appliance or conservative measures such as sleeping on one's side.

Restless leg syndrome (Willis-Ekbom disease) is a common complaint among pregnant women. Restless leg syndrome (RLS) is defined as an irresistible desire to move the legs in response to uncomfortable sensations in the legs and is relieved by movement. RLS is two to three times more prevalent during pregnancy than in the general population, affecting 15 to 25% of pregnant women in western countries.[35,36,37] The previous three studies also noted a peak in the number of women affected by RLS in the third trimester and resolution of symptoms for many by one month after delivery. Preexisting RLS also predicts greater severity during pregnancy.[38] The exact pathophysiology is not completely understood. A study determining the relationship between estradiol and RLS



Figure 2
Women whose insomnia is apparently related to mood symptoms benefit from hormone therapy as do some women with insomnia but without vasomotor symptoms.

found that pregnant women who reported RLS had higher levels of this hormone.[39] Iron and folate deficiencies are well-recognized factors associated with RLS in pregnancy. Levels of hemoglobin, ferritin, and Vitamin B12 start to fall in the second half of pregnancy, regardless of taking iron and vitamin supplementation, due to fetal growth and hemodilution.[40,41]

The management of RLS includes behavior modification in addition to medical management. Any underlying condition should be excluded. Pregnant women suffer from leg cramps, particularly in the second part of the pregnancy. Sleep related leg cramps is reported as a primary reason for sleep disruption during pregnancy.[42] These symptoms should be carefully assessed and differentiated from RLS. Avoiding anything that can worsen RLS is beneficial. This includes smoking, certain antidepressants, and caffeine. If medication is needed for RLS, pharmacological treatment (Ropinirole, Pramipaxole, Carbidopa) should be used only during the third trimester and at the lowest effective dose owing to their possible teratogenic effects.[43] Iron supplementation is an option for pregnant women with iron deficiency. Additionally, Folate supplementation should be considered.

Postpartum blues, or baby blues, is a transient form of moodiness experienced by up to 85% of new mothers three to four days after delivery, which usually dissipates within a week.[44] A smaller but notable percentage of mothers experience a major perinatal depressive disorder during pregnancy (up to 20%) or the postpartum period (about 12%-16%).[45] Several psychosocial factors have been shown to increase the risk for perinatal mood disturbances, including antenatal anxiety and depressive symptoms, the presence of psychiatric history, stressful life events, marital conflict and lack of social support.[46] Although postpartum blues is generally considered a normal event that does not impair functioning, perinatal depression is a psychiatric condition that requires clinical attention. Breast feeding, compared with bottle feeding, has been found to influence sleep, with marked increase in slow wave sleep that may be attributed to increased levels of circulating prolactin levels.[47]

Sleep During Menopause and Post-Menopause

Menopause is defined as permanent amenorrhea for a period of twelve months. The age range for natural menopause is from 45 to 55 years with a mean age of 51 to 52 years.[48] During the climacterium, or menopausal transition, women are at increased susceptibility for several symptoms that significantly reduce their quality of life. The hallmark symptoms during the climacterium comprise hot flashes and sweating (Vasomotor symptoms).[49] Hot flashes are described as a sudden onset of redness and intense feeling of warmth or hot resulting in perspiration. Hot flashes may be the result of decrease in the levels of estrogen.

Approximately, 75% of postmenopausal women and 40% of perimenopausal women suffer from vasomotor symptoms.[50,51] The vasomotor symptoms usually last for 1 to 2 years, but about 25% of women report them for 5 years and 9% may have it all their lifetime after menopause.[52,53] When present during the night, these symptoms often disturb sleep and may result in somatic, mental, and cognitive problems.[54,55] Insomnia was reported by 25% of the women and severe insomnia by 15% of the women between 50 and 64 years of age.[56] The clinical picture of menopausal insomnia is no different from common insomnia, which manifests itself as difficulty in falling asleep, frequent awakenings or awakening too early in the morning.[57] Although vasomotor symptoms correlate strongly with sleep complaints, insomnia may occur in the absence of

vasomotor symptoms and can be the exclusive climacteric symptom.[58] During the climacterium, other symptoms including palpitations, headaches, dizziness, numbness, dry eyes and mouth, and reduced skin elasticity are commonly noted. Vaginal dryness, nocturia, and other urinary tract symptoms also get worse after menopause.[59] Mental symptoms, including anxiety, depression, a decline in libido, loss of concentration, and memory impairment commonly occur, and may in fact surpass the severity of vasomotor symptoms.

Sleep disruption associated with hot flashes can impact the quality of life and therefore may require treatment. Hormone replacement therapy (HRT) has historically been the standard treatment. Hormone therapy is as an effective therapy for reducing climacteric vasomotor symptoms and related secondary insomnia.[60,61] Women whose insomnia is apparently related to mood symptoms benefit from hormone therapy as do some women with insomnia but without vasomotor symptoms.[62] (See Figure 2.) The results of the Women's Health Initiative results showing increased risk of breast cancer, stroke, heart disease, and vascular dementia in individuals who were on HRT regimen for one to seven years suddenly changed this common practice.[63] Women are counseled to use HRT for only a short period of time to alleviate extreme form of hot flashes and other vasomotor symptoms. Those with history of breast cancer or stroke should be excluded. In women who seek treatment but prefer to avoid hormonal therapy, or for whom hormone therapy is contraindicated, other options exist. A large body of literature suggests that noradrenaline and serotonin have a central role in the pathophysiology of hot flashes.[64] Thus Clonidine (an α_2 adrenergic agonist) or serotonin-reuptake inhibitors have been found to alleviate climacterial symptoms, and accordingly, related sleep problems. Gabapentin has also shown to be beneficial although the adverse events such as dizziness, rash, or weight again, often result in discontinuation of the treatment. Good sleep hygiene can also be useful to promote good quality sleep. If a woman has vasomotor symptoms, low ambient temperature is often helpful; and lightweight bed clothes may be more comfortable. Caffeinated beverages, smoking and alcohol intake close to the bedtime can also cause sleep disruption.

Sleep disordered breathing may also contribute to sleep disturbance during menopause. The Wisconsin Sleep Cohort Data suggest that apnea hypopnea scores of 5 or higher were more prevalent among women who were 50 to 60 years old than among younger women.[65] Another study found that 3.9% of post-menopausal women had OSA defined as apnea-hypopnea index of at least 15 per hour of sleep.[66] This number was statistically greater than that found in pre-menopausal women (0.6%). However, in post-menopausal women taking hormonal replacement therapy, the prevalence of sleep apnea was not statistically different from the pre-menopausal group, although this group may have included some peri-menopausal subjects. Proposed mechanisms for this apparent rise in sleep breathing disorders have included a change in the distribution of body fat and a decrease in progesterone.[67,68] With menopause, body fat composition changes, leading in particular to increases in the waist-hip ratio and neck circumference. The decrease in female sex hormones, particularly progesterone, may partly be responsible for sleep breathing disorders. Progesterone has respiratory stimulant properties and affects genioglossus muscle tone.[69] The most effective therapy for obstructive sleep apnea is continuous positive airway pressure. Other options include positional therapy, surgery and oral appliances. The therapeutic role of hormonal therapy for sleep apnea in menopausal patients has been considered, with conflicting outcomes. Improvement of nocturnal breathing, especially reduced AHI, with hormone therapy has been found in some but not all studies.[70,71,72] Progestin has been shown to decrease the duration of apneas as well as improvement in ventilation.[73] However, because the data is limited and conflicting, no definite recommendation of hormone therapy as an option for sleep-disordered breathing can be made.

Conclusion

While many aspects of sleep are similar in men and women, there are a number of important differences that need to be identified and confirmed by the health care provider.

It is also important to recognize there are clinically unique differences in the sleep of women at different stages of life. The risk of developing sleep disruption and disorders, including insomnia, sleep disordered breathing and restless legs syndrome is also higher during key phases, including menstrual cycle, pregnancy, postpartum period and menopause. As most basic and clinical studies have been performed in male subjects, more research is needed to clarify the influence of the life cycle on sleep framework in women.

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References exceeded space. For listing, email bhata@umkc.edu.

Disclosure

None reported. **MM**

Missouri Medicine Series

PAIN MANAGEMENT

Opiate Analgesics and the Perioperative Management of Patients with Obstructive Sleep Apnea

by Quinn L. Johnson, MD & Anthony Netzer, MD

Narcotics are a leading cause of avoidable complications associated with obstructive sleep apnea and high risk patients, but are often needed to ensure pain control for patients.



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Abstract

As the rate of obesity and subsequently obstructive sleep apnea (OSA) continue to rise in North America and prescriptions for narcotic analgesics number in the tens of millions, it has become increasingly important to understand the interaction between OSA and opiate analgesics. Understanding the mechanism of action of opiate analgesics and the pathophysiology of OSA can help medical professionals understand the unique risks associated with pain management in this population of patients.

Introduction

The relationship between respiratory depression and the use of opiate medications is well understood and discussed in the medical literature. However, there is a certain subset of individuals who appear to have increased sensitivity to opiate induced respiratory depression; adults and children with obstructive sleep apnea (OSA). Every year there are multiple reports of morbidity and mortality associated with the use of opiates in patients with OSA. In recent years, this has prompted the Anesthesia Patient Safety Foundation to address many of these issues and even propose changes to guidelines regarding the monitoring of patients receiving postoperative opiates. While anesthesiologists may be administering the majority of opiates intraoperatively and facilitating the immediate postoperative monitoring of patients, there is a great deal of education and opportunity to educate surgeons and internists who may be writing postop analgesic prescriptions.[1] (See Figure 1).

Pathophysiology of OSA

OSA occurs when the airway becomes physically obstructed; however, the underlying cause of the obstruction is not always simple. OSA has been linked to anatomic, neuromuscular, or neuroventilatory disorders or a combination of these factors.[2] It is a chronic condition that classically develops and worsens over years resulting in frequent episodes of upper airway collapse during sleep.[3] The pharynx is susceptible to collapse because it is long, composed mainly of soft tissue, and is surrounded by additional layers of tissue in the neck. Collapse of the pharynx occurs when either the mechanical load placed on the pharynx exceeds or neuromuscular responses are insufficient to maintain patency of the airway.[2] Once the airway collapses it creates a physical



Figure 1
Careful monitoring of OSA patients is needed to optimize care and outcomes.

obstruction preventing the exchange of oxygen and carbon dioxide leading to oxyhemoglobin desaturations. The body's response to the deoxygenation is to decrease the depth of sleep, relieving the obstruction, but disrupting normal sleep patterns thus resulting in non-restorative sleep.

The most significant risk factors for OSA include obesity, age, male gender, post-menopausal female,[2] and smoking.[4] As the rate of obesity has risen in the western world so has the prevalence of OSA, which represents an increasing burden to the health care costs[2] both for treatment of OSA and associated comorbidities. Comorbidities associated with OSA include hypertension, cardiovascular disease, stroke, motor vehicle accidents,[5] or strokes.[4] Recognition and treatment of those patients who are at risk for OSA may help improve or prevent the development of these comorbid conditions. Equally important is understanding what treatments should be modified or avoided in patients diagnosed with or likely to have OSA.

Mechanism of Action of Opiate Analgesics

The mechanism of action of opioids is well understood, but the individual response to opioids is widely variant requiring titration of opioids to achieve clinical goals. Opioids act by binding presynaptic opioid receptors and prevent impulse propagation by preventing the release of the neurotransmitter substance P via membrane hyperpolarization. Opioid receptors responsible for mediating pain are sub classified based on the different effects they produce. Three of the subtypes that will be discussed are: μ, κ and δ.[6] Any opioid that stimulates the μ receptor can theoretically be used for pain control.[7] However, this same receptor can also produce unwanted side effects including miosis, bradycardia, hypothermia, and respiratory depression. Additional side effects that need to be considered include the possibility of physical dependence[8], urinary retention and constipation. The κ and δ opioid receptors also play a role in pain control, but have also been associated with dysphoria, sedation and diuresis. The prescriber of opioids needs to appreciate the probability that the unwanted side effects may precede the analgesic effects and alternative opioids or therapies may need to be considered. Twenty-one to thirty percent of patients treated with opioids will experience the most common negative side effects of nausea, constipation, and dizziness.[9] Tolerance to opioids may develop with prolonged administration of opioids resulting in receptor up-regulation. As a result of an increased number of receptors, higher doses of opioids will be needed in order to achieve the same clinical results. Patients can develop tolerance to the analgesic properties as well as some of the negative side effects. Interestingly, tolerance does not develop for either constipation or miosis, hence the frequent co-administration of stool softeners for patients on opioid therapy.

Perioperative Management of Patients with OSA

The recognition of a patient with OSA is the single most essential step in developing an appropriate treatment plan. Unfortunately, many patients that have OSA have neither been officially diagnosed nor prescribed the necessary interventions. If there is inadequate time for formal evaluation of the patient, those individuals who are suspected of having OSA should be assumed to have the condition and treatment plans modified to increase the margins of safety. A wide variety of screening tools have been developed to identify those patients who are at risk, but no single screening criteria can identify all patients with the condition.[10] Despite these limitations, one screening tool, the STOP-BANG model (SBM) has been shown to identify patients likely to have OSA, estimate the severity of the condition[11] and help formulate a care plan. The STOP acronym stands for four key symptoms of OSA.

The S is for snoring, T is for daytime tiredness, O is for obstructed breathing, and P is for high blood pressure.[12] "Yes/no" responses are provided by the patient for if any of these symptoms are present. The second part of the SBM, the BANG acronym, provides more objective measures. The B is for a BMI of greater than 35 kg/m,^{2} A is for age greater than 50, N is for neck circumference greater than 40 cm, and G is for male gender. Patients who answer "yes" to five or more of the eight questions listed above are considered to be high risk for OSA and should, if possible, have surgery delayed to allow for a more thorough evaluation and treatment.[12] Patients who have five or fewer "yes" responses can be considered to be low risk, but still require extra precautions to be taken.

For patients who have been diagnosed or are considered to be high risk for having OSA, careful consideration of the total dose of narcotics and the type of narcotics (i.e. long acting versus short acting narcotics) need to be taken under careful consideration. If possible, multi-modal pain control should be pursed for OSA/high risk patients. Non-steroidal anti-inflammatories, acetaminophen, the use of local anesthetics at the surgical/procedural site, and regional anesthesia should be strongly considered whenever possible in order to reduce or eliminate narcotics used for pain control. Patients that have or are likely to have OSA should receive lower initial doses of narcotics with an ability to titrate for pain control while assuring the patient's respiratory status is not compromised. Practitioners need to be extremely cautious in mixing long acting narcotics and shorter acting narcotics as the combined effects may create an excessively high peak concentration resulting in respiratory compromise. If IV narcotics are used they should be dosed to ensure that the expected peak concentration has passed prior to a repeat administration of the medication is possible.

Strong consideration should be made for observing patients in a higher acuity environment to ensure patient safety. If the patient was scheduled for outpatient surgery, a 23-hour observation should be considered, or use of a step-down/ICU setting instead of a regular hospital room. If the patient uses a CPAP machine, they should be encouraged to bring it for any procedure involving anesthesia or sedation, even if it is scheduled as an outpatient. The use of a pulse oximeter to help monitor for desaturations may provide some additional safety to recognize those patients that are experiencing obstruction and allow for appropriate intervention, but pulse oximetry is not considered to be a standard of care.[1] (See Figure 2.) The use of supplemental oxygen for OSA/high risk patients is controversial in part because apneic periods have been reported to increase in duration with oxygen use.[13] Finally, both the patient and their family members need to be educated regarding the risks of the medications and the need for CPAP or careful observation after these types of procedures.

Use of Opiates in Pediatric Patients with OSA

The pediatric population demands special attention when considering the use of opiates in patients with OSA. Due to the increase of childhood obesity, the incidence of OSA and sleep-disordered breathing has risen dramatically.[13] Because untreated OSA may lead to significant morbidity,[14] tonsillectomy is commonly performed to help reduce OSA symptoms. As the need to conserve medical resources and expenditures has pressured physicians to treat more patients in ambulatory surgery centers, the postoperative observation period for many procedures has dramatically decreased. Three decades ago, a patient undergoing tonsillectomy would have stayed in the hospital for up to three days postoperatively. Today, the average time from operation to discharge is often less than one hour.[15] This short time frame does not allow for complete recovery from anesthesia or from the medications that may have been administered intraoperatively. Reports of postoperative deaths after discharge in pediatric patients with OSA prompted further investigation and recommendations to observe this specific population for a period of 24 hours prior to discharge.



Figure 2
Pulse oximetry is a valuable tool for monitoring patients diagnosed with or suspected of having OSA that have received pain medications.

The increased risk to pediatric patients with OSA is multifactorial. In children with adenotonsillar hypertrophy there is a diminished response to elevated CO_2 levels[1] and an increased susceptibility to opioids in patients with nocturnal hypoxemia.[16] Opiate doses that would normally be considered appropriate for children may be relative overdoses in this population. Reductions of 50% or more may be necessary depending on the particular patient.[14] Chronic

intermittent hypoxia and OSA upregulate opioid receptors and give affected children an exaggerated analgesic response as well as increased respiratory depression[16]. This phenomenon is largely due to the disproportionate upregulation of the inhibitory μ receptor in favor of the excitatory neurokinin 1 receptors[16]. Autoresuscitation of respiratory drive is also impaired because OSA increases levels of inflammatory cytokines including interleukins and TNF – α that increase airway inflammation, narrow air passages and impair normal respiration.[14] Deaths following tonsillectomy appear to be the result of cyclical desaturation events. The cycle begins with a collapse of the upper airway resulting in hypoxemia and triggering of the brain to cause an arousal. As the patient awakens, they briefly hyperventilate causing hypocapnia. The hypocapnia that develops reduces airway tone and central respiratory drive.[16] Desaturations may happen particularly quickly in very small children because of their higher oxygen consumption relative to body weight and a reduced functional residual capacity. This cycle then repeats and may eventually result in death if the desaturation becomes severe enough that the brain is not capable of triggering arousal. Patients that have received opiates appear to have the highest risk and in particular those that have received codeine.

Codeine presents a special case because of its unique metabolism to morphine. Codeine undergoes demethylation by cytochrome P450 2D6 (CYP2D6) to become morphine.[16] However, wide variation in the function of CYP2D6 results in highly variable metabolism of codeine to morphine. Reports of the amount of codeine metabolized to morphine range from as low as 0% to as high as 75%.[19] Problems arise when patients fall into a group categorized as ultra-rapid codeine metabolizers. These are individuals that possess more than two copies of genes for CYP2D6.[17] Ultra-rapid metabolizers convert normal doses of codeine to toxic or lethal doses of morphine. As recently as 2012 the FDA was prompted to place a new "black box" warning, the FDA's strongest warning, in association with codeine use for post-operative pain control in children following tonsillectomy and/or adenoidectomy.[18] Simply stated, the FDA recommended that codeine should not be used for pain control in children having these procedures. Their recommendation followed several reports of deaths in children who had received codeine prescriptions for post-tonsillectomy pain control. In each case the children were rapid metabolizers of codeine.

Summary

OSA is a growing problem that faces all physicians regardless of their specialty. The condition itself is associated with significant comorbidies and can lead to premature death. Narcotics are a leading cause of avoidable complications associated with OSA/high risk patients, but are often needed to ensure pain control for patients. Identification of those patients at highest risk and careful planning of medications and monitoring are needed to ensure patient safety. Ensuring that the patient uses the prescribed equipment, consideration of increased levels of observation, and alternative methods of pain control are all key elements that should be explored when caring for this patient population. When narcotics are necessary, care should be used in determining the frequency, type and total dose that will be administered to the patient. With appropriate preparation, the OSA patient can be cared for effectively and with improved safety by all physician specialties.

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Disclosure

None reported.

MM

Vaginal Hysterectomy: The Present Past

by Dionysios K. Veronikis, MD

Our surgical community must maintain its focus on sound rigorous research studies and not on the voices of the technology sales personnel or marketing campaigns when making appropriate decisions about the best surgical approaches for our patients.



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Introduction

For over a century, trans-vaginal hysterectomy (TVH) was the original minimally invasive surgical procedure before these terms were conceived and popularized to both patients and physicians. Today, many identify "minimally invasive hysterectomy" as laparoscopic and robotic assisted approaches despite the fact that TVH is without any incisions on the anterior abdominal wall and its structures. Therefore, perhaps it should be referred to as the "non-invasive hysterectomy." The American College of Obstetricians and Gynecologists (ACOG), the American Association of Gynecologic Laparoscopists (AAGL), and committees on behalf of the Society of Gynecologic Surgeons (SGS) all vocalize their support of vaginal hysterectomy as the preferred approach for benign disease through position statements and other commentary reports.[1-3] Reflected in the literature is a plethora of data that firmly support these groups' assertions that vaginal hysterectomy offers the greatest benefit to patients with significantly lower rates of morbidity and mortality and to society with less cost.[4-5] This article will review the historical evolution of hysterectomy and the evidence supporting vaginal hysterectomy for benign disease while emphasizing the absolute need to continue to develop residency and post-graduate training in the techniques.

A Historical Perspective

For most of the 20th century, the two modalities used to perform surgical removal of the uterus included the trans-abdominal hysterectomy (TAH) and the TVH. The evidence detailing the differences in patient experience between these two approaches was notable. With significantly lower rates of morbidity and mortality, encompassing outcomes such as febrile episodes, surgical blood loss and length of hospital stay, TVH remained the preferred modality.[4] In 1984 the first laparoscopic-assisted vaginal hysterectomy (LAVH) was reported in Germany by Kurt Semm ushering in a new era in hysterectomy.[6] The further evolution toward total laparoscopic hysterectomy (TLH) was published by Harry Reich and unleashed a move toward increased utilization of minimally invasive approaches to complete hysterectomy[7] and for the next decade, laparoscopic approaches were added to the armamentarium of the gynecologist to remove uteri. However, during this time, the literature on costs, quality of life, and healthcare resource utilization remained in favor of the vaginal approach.[8] In 2002, a case series of eleven patients was reported using laparoscopic hysterectomy with robotic assistance, thus broadening the methods available to remove

uteri. Shortly thereafter, an intense marketing campaign was launched to persuade physicians to utilize technology in place of their vaginal and conventional laparoscopic skills without strong Level I evidence to support this change in surgical approaches.[9]

Defining "Technically Feasible"

In the ACOG Committee Opinion No. 444, the Committee on Gynecologic Practice concluded, "Vaginal hysterectomy is the approach of choice whenever feasible, based on its well-documented advantages and lower complication rates."[1] An important element to advancing the frequency of vaginal hysterectomy is a discussion of factors affecting the feasibility of the vaginal approach. Many physicians have incorrectly accepted certain patient characteristics as absolute contraindications in part due to the persuasive marketing campaigns that have been put forward to popularize other approaches, particularly robotic hysterectomy.

There are several common clinical conditions that physicians use to support a non-vaginal approach to hysterectomy, including large uteri, nulliparity or lack of previous vaginal delivery, and prior cesarean section or pelvic surgery. (See Figures 1-3.) The evidence in the literature, however, reports that these factors are not contraindications to vaginal hysterectomy.[10-14] Further studies have shown that dedicated efforts to increase the utilization of the vaginal approach for hysterectomy have been notably successful and also refute that there are clinical criteria that are contraindications.[15-16] Interestingly, the conclusion of Varma, et al, stated, "A major determinant of the route of hysterectomy is not the clinical situation but the attitude of the surgeon. There is no need for extra training and special skills or complicated equipment for vaginal hysterectomy."[16]

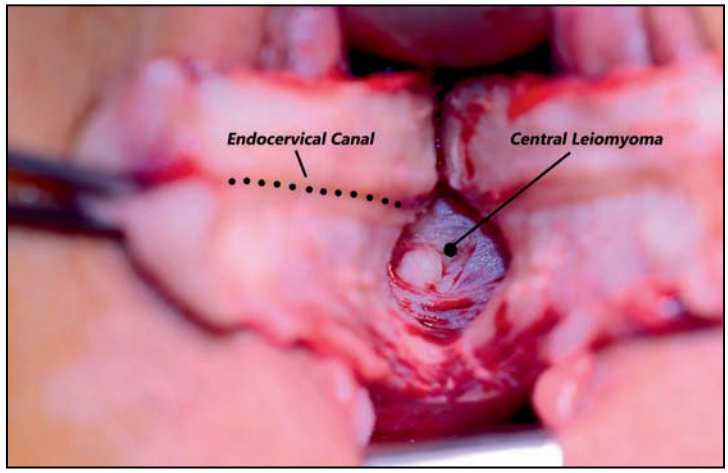


Figure 1 shows a large leiomyoma with a bivalve approach to extraction.

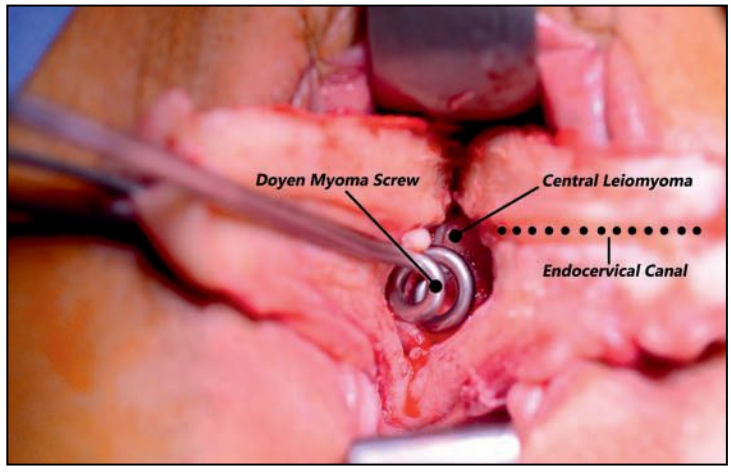


Figure 2 shows the Doyen myoma screw that is essential for extraction.

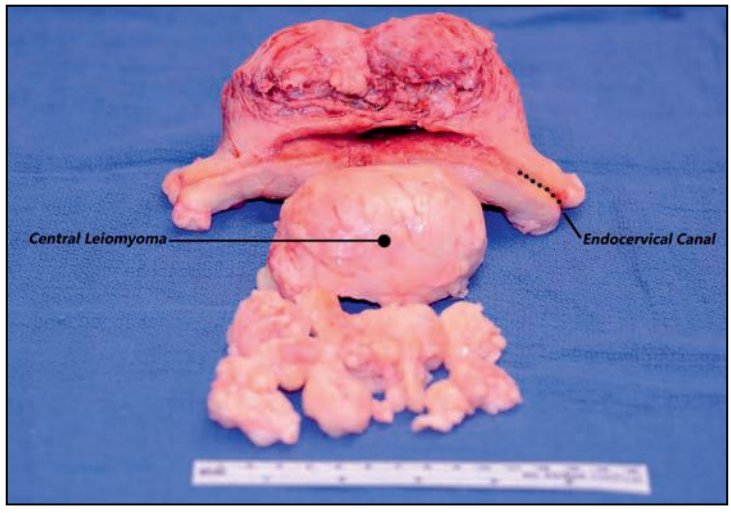


Figure 3 shows the removed uterus and leiomyoma.

Advocating for the Best Outcomes and Value

The literature supports both the feasibility of vaginal hysterectomy, but also reveals the improved outcomes of this non-invasive approach. The most recent Cochrane review on hysterectomy in benign disease reports several statistically significant advantages of TVH over other approaches.[4] Findings from the Cochrane review report improved outcomes with TVH including a quicker return to normal activities, shorter length of stay, and decreased reported pain ratings as opposed to TAH.[4] In addition, it revealed advantages of TVH over TLH such as shorter operative times, a decrease in significant bleeding, and decreases in urinary tract injuries.[4]

Other studies report a decrease in vaginal cuff dehiscence with vaginal approaches over laparoscopic or robotic modalities. Although this is a rare complication, it can have dramatic implications for the patient, both physically and emotionally.[17]

When considering the most common gynecologic procedure performed in the United States, quality of outcomes, as well as the cost associated to achieve the quality, become critical elements. The concept of "value" in health care is one that physicians, patients, hospitals, and payers should have a vested interest in understanding yet documenting the link between healthcare dollars spent and patient outcomes remains an elusive task across many areas of medicine. However, large cross-sectional queries of national databases reveals that vaginal hysterectomy has the lowest mean charge per case with laparoscopic and abdominal approaches costing an additional ~$5000 per case and robotic approaches an astonishingly higher $16,000 per case.[18] A large cohort study reported the average total cost of a robotic hysterectomy approached an additional $2200 per case over conventional laparoscopic methods without benefit of improved outcomes.[19]

Research on same-day vaginal hysterectomy has been performed revealing few perioperative complications and hospital readmissions, further establishing the financial benefit of vaginal hysterectomy in the setting of today's finite supply of health care dollars.[20] Indeed, payers have noted the relationship in this instance between outcomes and cost. United Healthcare recently took the initiative to cite the advantages for vaginal hysterectomy over laparoscopic or abdominal and announced their new policy effective April 2015 to require prior authorizations for all hysterectomies, except vaginal hysterectomy, performed on an outpatient basis.[21]

Residency and Post-Graduate Training in Vaginal Hysterectomy

In a society of medical professionals who rely heavily on the principles of evidence-based medicine, why must vaginal hysterectomy continue to be an "exception" to the decision-making algorithm?[22] Given the evidence, what would lead surgeons to conclude that the best modality for benign indications is something other than the vaginal approach? The Education Committee for the SGS postulated three factors leading to the decline in performance of TVH, including inadequate residency surgical training, low volumes to maintain vaginal hysterectomy skill sets, and the marketing campaign that exists to promote other alternatives, potentially creating the façade that vaginal hysterectomy is "less attractive as a surgical option."[3]

It is not surprising that Obstetrics and Gynecology (OBGYN) residents who report more training and performance of cases in residency indicate their training was adequate for future practice based on a recent survey of Chief residents in OBGYN US residency programs.[23] They appear to understand the evidence in their 76% response that vaginal hysterectomy is the least invasive route for hysterectomy yet only 41% plan to utilize TVH as their preferred route once in future practice.[23]

Unfortunately, despite the existence of the Accreditation Committee for Graduate Medical Education (ACGME) and the OBGYN Residency Review Committee (RRC) requirements for training in vaginal hysterectomy and the absence of any requirements for robotic hysterectomy training, the numbers of TVH procedures are declining.[24-25] A multicenter retrospective cohort study conducted by the SGS Fellows' Pelvic Research Network reported on the proportion of benign hysterectomies performed vaginally before and after introduction of robotic technology.[25] Despite the clearly defined purpose of robotic technology as a way to replace abdominal hysterectomy modalities only, the authors actually described a decline in the performance of TVH from 42% to 30% after initiation of robotic hysterectomy.[25] ACOG has recognized this educational crisis and need to devote a serious commitment to performance of TVH and developed a CME-accredited educational skills module and faculty development opportunities to guide teachers in training residents to perform TVH.[26]

Gynecologic patient volume for most physicians early in their practice is low, which further compounds the problem for the newly graduated resident to continue to refine and develop their vaginal hysterectomy skills.

When new graduates have a senior partner proficient in TVH, they have a benefit of continuing to develop their skills under the guidance of more experienced hands. Furthermore, studies examining surgical volume reveal that perioperative morbidity and surgical complications were significantly lower in patients who were treated by high-volume vaginal surgeons.[27] In addition, the cost and resources utilized by high volume surgeons are less compared to low volume surgeons.[27] An acceptable practice might be an expectation or standard where patients are referred within networks to surgeons who have better expertise and are established as high-volume surgeons. Other authors and groups have previously made this recommendation, yet it remains to be seen if this framework will be adopted by the larger population of practicing OBGYN physicians.[3, 28]

Conclusion

Our surgical community must maintain its focus on sound rigorous research studies and not on the voices of the technology sales personnel or marketing campaigns when making appropriate decisions about the best surgical approaches for our patients. While it may seem intuitive that the marriage of improved technology with excellent surgeon technical skills would drive innovative health care that benefits our patients, a review of the history uncovers the need for our vigilance to maintain our reliance on evidence-based medicine. As David Nichols stated in the preface to the first edition of Vaginal Surgery, "A heritage all too readily lost, the techniques of vaginal surgery must be sought for, recorded carefully, and practiced, if competence and skills are to be maintained."[29] The educating surgeons and those mentoring practitioners newly in practice must remain committed and steadfast in their resolve to advance the preservation of technical skills in our residency graduates and practicing surgeons.

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Disclosure

None reported.

MM

Health Management and Informatics

Secondary Use of Clinical Data to Enable Data-Driven Translational Science with Trustworthy Access Management

by Abu Saleh Mohammad Mosa, PhD, Illhoi Yoo, Nate C. Apathy, Kelly J. Ko & Jerry C. Parker

The system will facilitate the secondary use of EHR data in order to enable data-driven clinical and translational research at MU, while working toward the ultimate goal of providing better health care through research.



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Abstract

University of Missouri (MU) Health Care produces a large amount of digitized clinical data that can be used in clinical and translational research for cohort identification, retrospective data analysis, feasibility study, and hypothesis generation. In this article, the implementation of an integrated clinical research data repository is discussed. We developed a trustworthy access-management protocol for providing access to both clinically relevant data and protected health information. As of September 2014, the database contains approximately 400,000 patients and 82 million observations; and is growing daily. The system will facilitate the secondary use of electronic health record (EHR) data at MU to promote data-driven clinical and translational research, in turn enabling better healthcare through research.

Introduction

Over the past two decades, clinical data collection methods have been changed significantly with the introduction of electronic health record (EHR) systems. The transition from traditional paper-based medical records to electronic systems was accelerated by several national legislative initiatives including the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 and The Medicare and Medicaid Incentive Programs for "meaningful use" of certified EHR systems.[1] As a result, a significant amount of clinical data is now available in electronic systems, which creates the opportunity for secondary use of this clinical data in clinical and translational research (CTR).[2,3] The secondary use of such data in the CTR includes cohort identification, feasibility study, retrospective data analysis, and hypothesis generation. But work needs to be done before such data can be used in these ways. EHR systems were primarily designed for recording clinical encounters and billing purposes, not for research; data from those systems need to be cleaned, integrated, rendered queryable, and made exportable in order to facilitate secondary use. In addition, regulatory authorities governing human subject research, such as institutional review boards (IRB) and the U.S. Department of Health and Human Services (DHHS), require a trustworthy access

management plan for clinical data; access must be secure and HIPAA-compliant[4]. As a result, informatics frameworks and tools are needed to leverage secondary use of clinical data for CTR. The objective of this article is to describe the implementation of a clinical research data repository at the University of Missouri (MU).

The MU Institute for Clinical and Translational Science (MU-iCATS) leads development of the informatics framework for CTR at MU. MU Health Care is one of the largest and most comprehensive health networks in Missouri; it includes an extensive network of facilities, clinics, and specialized centers of excellence and has been recognized as one of the nation's "most wired" hospitals in the last three years (i.e., 2011, 2012 and 2013).[5] MU Health Care employs more than 5,000 clinicians, educators, researchers, and other health care providers and is adjacent to the main campus of the University of Missouri; this teaching and research hospital is the largest medical facility in the mid-Missouri region. Researchers in the School of Medicine have a proven track-record of successful research that includes conducting clinical trials, clinical outcome-based research, retrospective data analyses, and quality improvement projects. These research initiatives are funded through both external and internal sources.

All of the hospitals and clinics within the MU Health Care network produce a large amount of digitized clinical data on a daily basis. To assist in the development of a clinical research informatics framework, MU-iCATS partnered with an EHR vendor, Cerner Corporation, to implement a clinical research data repository. In order to query and extract EHR data, researchers needed an informatics platform that could be used by those who lack knowledge of programming languages. Data query tools such as Informatics for Integrating Biology and the Bedside (i2b2)[6] and Harvest,[7] were designed to support the data query needs of CTR researchers and do not require any knowledge of programming languages or tools for querying and data extraction. Therefore, the i2b2 system was implemented to meet the data query and retrieval needs of the CTR research community; i2b2 is an open-source system that was originally developed at Partners HealthCare System in Boston, Massachusetts through NIH funding and has already been implemented by most of the NIH Clinical and Translational Science Award institutions.[8]

Methods

Data Sources

The data in the MU i2b2 system are extracted from the EHR systems used at the MU Health Care. The Cerner Millennium EHR system and the IDX billing system provide coded diagnosis and procedure data. Lab and microbiology results and inpatient-administered medication data are extracted from the Cerner PathNet system and the Cerner PharmNet system, respectively. All MU Health Care patients seen after December 31, 2009, are included in the database.

Data Processing and Mapping

Figure 1 presents the entire extraction, transformation, and loading (ETL) process. The raw data are extracted nightly from the source systems (i.e., EHR, lab, and pharmacy) and securely transferred to the Cerner Data Center. Then, the data cleaning process is performed to remove redundant data, make the data complete, and conform to healthcare data standards. The healthcare data are encoded using "International Classification of Diseases, Ninth Revision" (ICD-9) codes for diagnosis and procedure codes, "National Drug Code" (NDC) for medication data, "Logical Observation Identifiers Names and Codes" (LOINC) for lab results, and "Systematized Nomenclature of Medicine – Clinical Terms" (SNOMED-CT) for microbiology results. Before loading the cleaned data into the i2b2 database, a quality assurance check is performed in order to ensure accuracy with respect to the source systems.

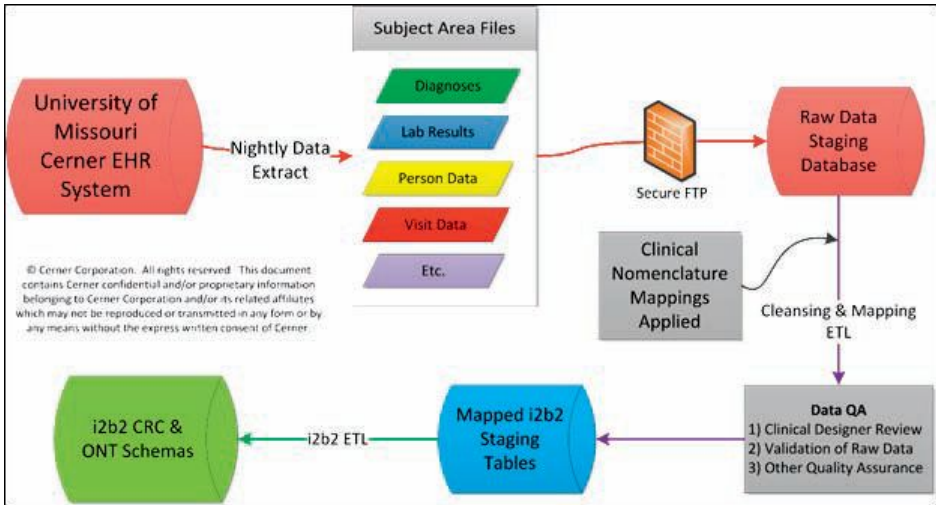
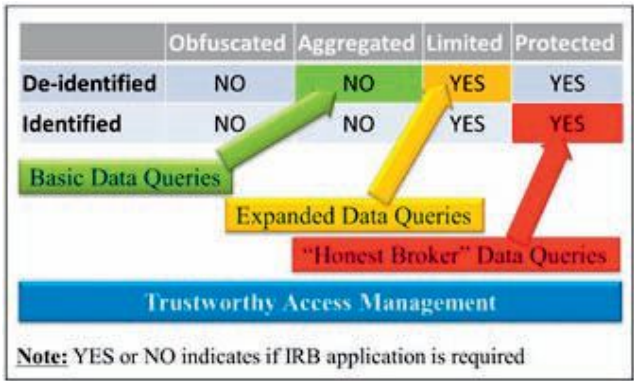


Figure 1
Data Cleaning, Pre-processing and Mapping

Databases

Following data processing and mapping to the i2b2, two versions of the EHR data are made available for research purposes: (a) de-identified, and (b) fully identified. The de-identified version is developed according to the HIPAA requirements.[4] Specifically, the requirements mandate that any identifiers such as name, birth date, medical record numbers (MRNs), and geographic indicators (e.g., zip code), will be removed to protect the privacy of protected health information (PHI).[9,10] The fully identified version includes protected health information such as name, birth date, and/or MRN.

Figure 2
Trustworthy Access Management



Trustworthy Access Management

A trustworthy access management process is required in order to protect patient privacy and to comply with the regulatory requirements of HIPAA and IRB. Access to each of the two versions of the EHR data is managed using four levels of data granularity available in the i2b2. These four levels are as follows: (a) obfuscated, (b) aggregated, (c) limited, and (d) protected. First, the obfuscated level generates approximate and aggregated patient counts and allows a maximum of three queries to run within a specified period. Second, the aggregated level generates aggregated patient counts, and there is no restriction on the number of queries a user can execute. Third, the limited data set level generates aggregated patient counts and allows the exporting of all fields except medical record numbers (MRN). Lastly, the protected level generates aggregated patient counts and allows the exporting of all fields including MRNs.

Prior to medical data access, such access may require IRB approval, depending on which of the four data levels is being used. Figure 2 (the 2 x 4 matrix) helps to determine whether IRB approval is required, based on the combination of database and access level.

In the MU i2b2 system, data queries are categorized into one of the three types: (a) basic data queries, (b) expanded data queries, and (c) "honest broker" data queries (see Figure 2). Basic data queries only generate aggregated patient counts from the de-identified database. Expanded data queries allow users to access to a de-identified limited dataset. In that case, an IRB application is required because these queries have the potential to yield clinically relevant information that meets the DHHS definition of human subject research. "Honest Broker" data queries allow full access to an identified database so that a user can export both clinically relevant data and protected health information; such a user is an "honest broker" or someone who extracts and delivers PHI to researchers in an IRB-approved manner[11]. The data exported from i2b2 are deposited in a secure research data repository as approved by the IRB (e.g., Research Electronic Data Capture [REDCap][12]) .

Results

Patient Population Overview

Overall, the MU i2b2 database includes about 82 million observations with an average of 197 observations per patient. The observations are discrete clinical observables that are recorded in the EHR (e.g., a single record of a lab result at a specific time or a single instance of a recording of a diagnosis). Among the 82 million observations, 415,074 unique patients are represented. The ratio of females to males is 1.19; 12.8% of patients' gender are unknown (see Table 1). Most patients indicated their marital status as single, and age data is shown to be evenly distributed, ranging from pediatrics to older adults (see Table 1).

Visit/Encounter Type Overview

Unique encounters are defined as the number of unique visits within the particular setting. Outpatient encounters make up the vast majority of unique encounters within the MU i2b2 database (80.98%); all other encounters make up $<$ 3% of the database, and of those, 10% are missing encounter data (see Table 2).

Clinical Data Overview

Clinical data in the i2b2 are encoded using standard medical terminologies including ICD-9 codes for diagnoses and procedures, LOINC codes for lab tests, NDC codes for medications administered as well as vital signs data such as height, weight, BMI, blood pressure, temperature, and heart rate, among others. As a result, researchers can directly utilize clinical terms to explore the MU i2b2 database. Current Procedural Terminology (CPT) codes are not currently available in the MU i2b2 database, but plans are underway to include those soon. For the 82 million

Table 1
Population characteristics

Total observations	81,859,529	*N/A*
Total unique patients	415,074	*N/A*
Gender		
Male	165.434	39.86%
Female	196,353	47.31%
*Unknown	53,194	12.82%
Age (mean)		
0-11	50,641	12.20%
11-20	48,601	11.71%
21 thru 30	65,562	15.80%
31 thru 40	43,077	10.38%
41 thru 50	39,943	9.62%
51 thru 60	45,223	10.90%
61 thru 70	35,210	8.48%
71 thru 80	21,121	5.09%
over 80	14,512	3.50%
Missing	51,137	12.32%
Marital status		
Single	179,881	43.34%
Married	110,614	26.65%
Widow	12,012	2.89%
Divorced	18,282	4.40%
Legally separated	2,930	0.71%
Missing	91,308	22.00%
Ethnicity		
Other	9,080	2.19%
Asian	5,944	1.43%
Native American	529	0.13%
Black	28,096	6.77%
Asian Pacific Islander	161	0.04%
White	282,786	68.13%
*Unknown	1,664	0.40%
Hispanic	2,422	0.58%
Missing	84,345	20.32%

**Unknown responses denote patients who chose not to disclose*

observations in Table 1, over 30,592 medical terms describe the data. In i2b2, medical terms are hierarchically grouped in various categories so that the users can easily navigate the terms. The ICD-9 codes are used for grouping diagnoses and procedures. The LOINC and NDC codes are used for grouping lab results and medications, respectively. Table 3 presents the top 10 data categories among unique patients per data domain.

Table 2
Visit/Encounter Type Overview

	Unique encounters	
	N	%
Outpatient	8,911,464	85.33%
Outpatient (general)	8,457,336	80.98%
Community	181,278	1.74%
Day surgery	82,599	0.79%
Observation-short	105,586	1.01%
Observation	26,456	< 1%
Specialty	44,962	< 1%
Surgery	13,247	< 1%
Missing	1,109,284	10.62%
Emergency	282,334	2.70%
Inpatient	130,367	1.25%
Newborn	9,493	< 1%
Preadmission	350	< 1%
Hospice	74	< 1%

The top five most common diagnosis categories among unique patients are vehicle accidents (13.7%); neuroses, personality, and other non-psychotic mental disorders (13.1%), metabolic and immunity disorders (11.7%); hypertensive disease (10.2%); and health hazards related to personal and family history (10.1%; see Table 3). Other notable diagnosis categories include acute respiratory infection (7.2%), rheumatism (7.0%), and chronic obstructive pulmonary disease (5.9%). Common procedures include: other non-operative procedures (5.1%) (e.g. injections, vaccinations, and blood transfusions); incision, excision, and anastomosis of intestine (4.1%); operations on skin/subcutaneous tissue (2.6%); diagnostic radiology/related techniques (2.0%); and repair and plastic operations on joint structures (1.8%; see Table 3).

Laboratory and medication data also are well represented within the MU i2b2 database. The most common lab test categories are hematology, mineral, bone, joint, connective tissue, and electrolytes, as well as gas- and acid- based tests; nearly 30% of all unique patients had those lab tests The most common medication categories within the database include analgesics (26.4%), intravenous nutritional products (21.4%), antiemetic/antivertigo agents (18.9%), anxiolytics, sedatives, and hypnotics (18.3%), and local injectable anesthetics (16.2%).

Table 3
Top 10 Data Categories per Data Domain

Diagnosis categories	N	%
Vehicle accidents, not elsewhere classifiable	56,753	13.7%
Neurotic/personality disorders, non-psychotic disorders	54,180	13.1%
Other metabolic disorders and immunity disorders	48,711	11.7%
Hypertensive disease	42,152	10.2%
Potential health hazards to personal/family history	41,796	10.1%
Arthropathies and related disorders	35,440	8.5%
Acute respiratory infections	30,006	7.2%
Rheumatism, excluding the back	29,054	7.0%
Dorsopathies	28,730	6.9%
Persons with condition influencing their health status	27,038	6.5%
Procedure categories	**N**	**%**
Other non-operative procedures	21,067	5.1%
Incision, excision, and anastomosis of intestine	16,791	4.1%
Operations on skin and subcutaneous tissue	10,877	2.6%
Other diagnostic radiology and related techniques	8,257	2.0%
Repair and plastic operations on joint structures	7,499	1.8%
Incision, excision, and occlusion of vessels	6,266	1.5%
Non-operative intubation and irrigation	5,587	1.4%
Incision and excision of joint structures	5,387	1.3%
Reduction of fracture and dislocation	4,822	1.2%
Physical and respiratory therapy, rehabilitation	4,490	1.1%
Laboratory test categories	**N**	**%**
Hematology	127,562	30.7%
Mineral, bone, joint, connective tissue	122,675	29.6%
Gases and acid/Base	122,182	29.4%
Electrolytes	120,373	29.0%
Protein	114,071	27.5%
Sugars/Sugar metabolism	77,502	18.7%
Analytes	74,354	17.9%
Endocrine	73,400	17.7%
Drugs	72,213	17.4%
Microorganism	63,441	15.3%
Medication categories	**N**	**%**
Analgesics	109,364	26.4%
Intravenous nutritional products	88,885	21.4%
Antiemetic/Antivertigo agents	78,372	18.9%
Anxiolytics, sedatives, and hypnotics	75,925	18.3%
Local injectable anesthetics	67,218	16.2%
Antiarrhythmic agents	59,756	14.4%
Minerals and electrolytes	52,839	12.7%
General anesthetics	46,639	11.2%
Antihistamines	46,620	11.2%
Adrenal cortical steroids	44,546	10.7%

Discussion

The theorem of biomedical informatics by Friedman (2009)[13] stipulates that a person assisted by informatics tools performs better than unassisted.[13] The mission of every health care provider is to provide high-quality patient care. On the other hand, the mission of every clinical and translational researcher is to advance medicine through better research. The use of EHR systems enhances patient care, and at the same time, leveraging secondary use of EHR data through informatics tools can enhance clinical and translational research.[14] As of September 2014, the MU integrated clinical data repository contained more than 400,000 patients with about 82 million observations. A trustworthy access management policy was developed in collaboration with the MU IRB. Our future goals include the development of an informatics framework to facilitate automatic patient registration in research registry databases for particular diseases and to contribute to the regional and national data sharing networks.

Data query tools such as i2b2 have several benefits. First, from a research perspective, i2b2 allows researchers to make educated determinations as to whether their institution would be a good candidate to host and/or participate in clinical trials or research. Second, one of the major challenges clinical and translational researchers face is the lack of timely access to "research-grade" data. The i2b2 system aims to optimize access to clinical data in a secure, HIPAA-compliant manner. The system facilitates the extraction and analysis of data and, consequently, the acquisition of new knowledge which ultimately will benefit the healthcare community and society. Third, the system allows providers and researchers to identify patients who meet criteria for specific, potentially beneficial, interventions and/or clinical trials.

The effort required to develop this system is worthwhile if researchers can successfully use it to conduct research efficiently. Danciu et al (2014)[14]

emphasized that investigators at academic medical centers are often unaware of the availability of informatics systems for research, and human support is necessary in order to promote their use. The MU-iCATS offers monthly training in efficient use of the self-service data query and retrieval tool. The MU-iCATS also provides the "honest broker" service for extracting identified data and delivering the data in a secured repository (e.g. REDCap).

The secondary use of clinical EHR data faces several challenges, largely due to the use of disparate data sources and multiple data processing steps. In particular, three of the most challenging tasks associated with i2b2 are extracting data from a "live" clinical environment, integrating data, and validating clinical data. First, in order to extract clinical data from the EHR, the implementation team must extract as much data as possible without overloading the system. Overloading the EHR system may result in poor performance for providers working within the clinical environment. Second, raw data from disparate sources are often incomplete, inconsistent and inaccurate;[15,16] data must be cleaned and integrated before they can be used for research. Third, because the i2b2 is comprised of multiple disparate data sources, carefully crafted queries must be used to validate clinical data within the i2b2. These queries must account for any data manipulation or restructuring that may have taken place during the ETL process. Fourth, i2b2 is maintained by Partners HealthCare System, which provides all system updates for the i2b2. Therefore, there is limited availability for customization of front-end user tools.

Conclusion

In this article, the implementation of an integrated clinical research data repository using i2b2 was described. The data repository contains approximately 400,000 patients and 82 million observations and is growing daily. A trustworthy access management protocol was developed in order to comply with regulatory requirements for human subject research such as the IRB and HIPAA. The system will facilitate the secondary use of EHR data in order to enable data-driven clinical and translational research at MU, while working toward the ultimate goal of providing better healthcare through research.

Acknowledgment

The authors would like to thank Win Phillips and Cynthia Haydon, University of Missouri School of Medicine, for their critical review of the manuscript.

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Disclosure

None reported.

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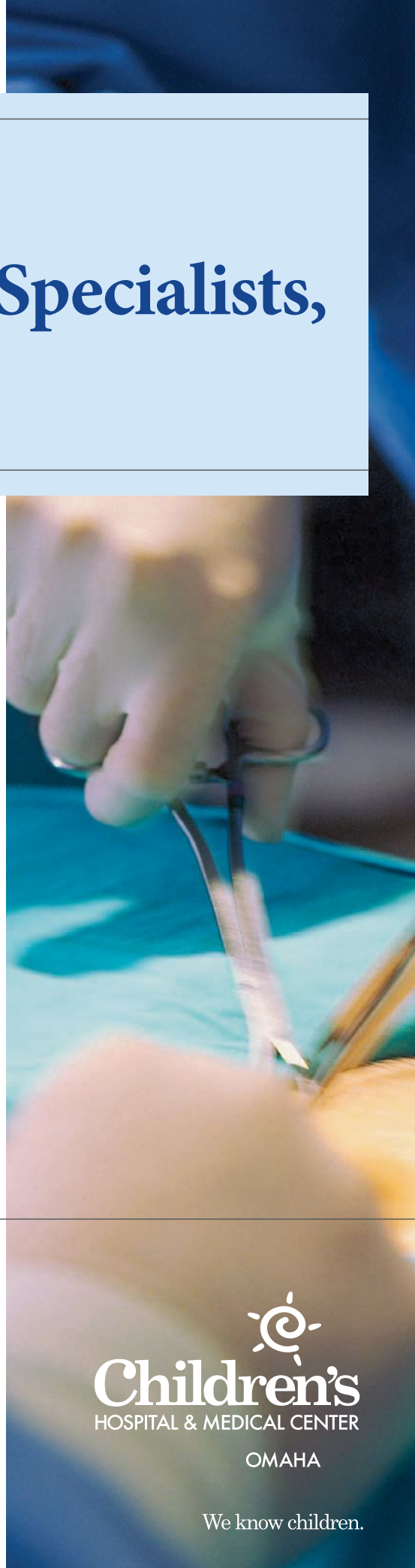
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