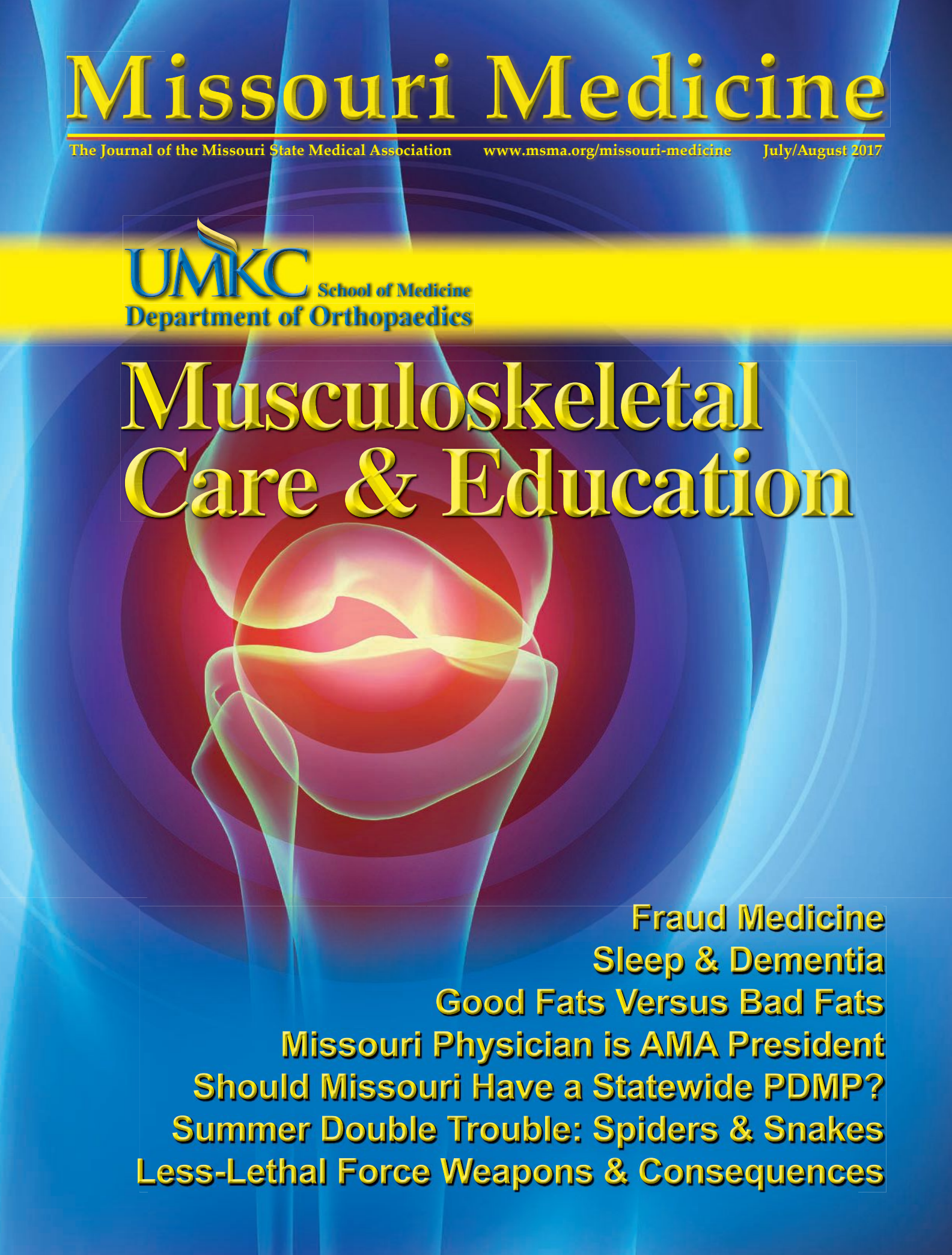
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The Journal of the Missouri State Medical Association www.msma.org/missouri-medicine July/August 2017

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King Canute's Court

by Charles Van Way, III, MD

As the story goes, Canute, king of England and Denmark around 1035 AD, had a sizeable court. Now, that wasn't unusual. Court functionaries were the bureaucrats of medieval kingdoms, and actually ran the place while the king did… well, kingly things. But Canute's courtiers, in the manner of government functionaries hangers-on today, thought that the king could do virtually anything. And of course, each courtier wished to have that supposedly vast power used to benefit his particular concerns. Tiring of their flattery and demands, Canute moved his throne to the edge of the sea, and commanded the tide to hold where it was, and not to advance. Of course, his shoes were shortly very wet. He then pointed out that he had no power over nature, that only God was all powerful. It is not recorded whether this silenced his courtiers.

The story was told by Henry of Huntingdon, a 12th century historian of Anglo-Saxon-Danish England. It may even be true. But true or apocryphal, it contains a lesson for today.

For the last ten years, we have been engaged in a national effort to re-configure the health care system. We are now entering a new phase of that effort. Let me say that the effort has achieved some worthy goals, particularly by decreasing the numbers of uninsured citizens. But nobody seems very happy. Rural hospitals are closing in large numbers, doctors are discouraged, medical practices are snarled in red tape, and costs are continuing to rise. Patients are covered, but the premiums and co-pays continue to rise. The public seems to be ambivalent at best, and hostile at worst.

The health care system isn't precisely like the tide coming in, though. It is, after all, a human system. One can certainly argue that if people put the thing together, other people can take it apart and fix it. Really? Let's see. During the Progressive Era, Prohibition was the Right Thing to do. Recall how well that worked? It was a disaster. Other than giving secure employment to a brigade of FBI agents, of course. More recently, remember the War on Poverty? Well-intentioned, perhaps even helpful. But poverty remains stubbornly with us. Just because people can create a problem is no reason to assume that people can un-create it, or even change it.

Indeed, once a system becomes sufficiently complex, changing it may be akin to changing the tides. For the last 50 years or so, the march of globalization has promised to make nation-states irrelevant. But recent events here, and in Britain, and across Europe, express a contrary opinion. Human institutions are constantly in a dynamic balance among many forces, pulling them in differing directions. Changing that balance is not carried out by the wave of a pen, whether the pen is wielded by a king, or a President, or even (gasp!) Congress.

So, the relevant question is, just how much power does the government have over the practice of health care? The



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assumption has been that by providing insurance coverage and tweaking the rules, we can re-order the health care system to our liking. But… are we really accomplishing something, or are we just watching the tide come in?

Health care is a bit large for a short essay. So, let's focus on one aspect. Take the Electronic Health Record. (Please!) We have all been subject to Meaningful Use requirements to incorporate the EHR into our practice. And we now know from a number of surveys, notably one by the Rand Corporation, that the EHR is a major source of dissatisfaction for physicians.[1] How did we get here?

Between 10 and 20 years ago, a number of people, inside and outside of health care, began a major push to bring information technology into health care. Advocates saw no downsides. Other than initial expense and maintenance, putting patient information into electronic form would streamline health care, cut costs, improve quality, and provide portability and transparency of health records. The Leapfrog Group, a consortium of major companies, was especially vocal. It may be worth noting that of the 150 members of the Leapfrog Group at that time, about 50 were information technology companies. Anyway, based on the hope that IT would improve health care, the Health Information Technology for Economic and Clinical Health Act (HITECH), was passed by Congress as part of the American Recovery and Reinvestment Act in 2009. The CMS created rules, and thus we wound up with Meaningful Use.[2] It was supposed to be introduced in three phases starting in 2011, leading to greatly improved outcomes by 2016.

Now, it's 2017. Meaningful Use has been abandoned. More precisely, it is now folded into MACRA and MIPS. MACRA is the Medicare Access and CHIP Reauthorization Act (MACRA) of 2016.[3] The idea was to manipulate reimbursement rates for Medicare patients, in order to encourage the use of EHRs. MIPS, or Medicare Incentive Payment System, is supposed to do the manipulation, financially rewarding good physicians, and penalizing bad physicians. And of course, the insurance companies are expected to line up behind the Center for Medicaid and Medicare Services (CMS).

What about all of those objectives? Well, most of them are pretty much abandoned, as well. CMS is now just into penalizing physicians if they don't meet a laundry list of requirements, without much regard for whether those requirements will improve outcomes or not. We should give credit here to the AMA, whose negotiations with CMS have considerably moderated the requirements and reduced the penalties. But the requirements and penalties still exist, and our government is counting on them to change our practices.

Meanwhile, EHRs have become a major problem for physicians. The Rand survey of 2013 showed that the EHR was a major source of dissatisfaction, entirely aside from the other aspects of increased paperwork and surging bureaucracy. The Physician Foundation's biennial Physician Survey of 2016 noted that the EHR was number three on the list of things that physicians found least satisfying about practicing medicine. (In case you were wondering, number one was regulatory and paperwork burdens.) That same survey showed that 52% of physicians were pessimistic about the current state of health care, and 63% about its future. Personally, 47% planned to accelerate their retirements.[4]

The Federally-mandated drive to bring the wonders of information technology to health care has resulted in widespread dissatisfaction and disillusion among physicians. More physicians than ever are planning to retire early, and more of them limiting their practices. Granted, we do have a lot of EHRs available. But they haven't produced the wonders that were anticipated.

Managing information in the health care system is difficult, and simply cannot be reduced to computer-friendly algorithms. We can track inventory, do accounting, and generate bills. Past those, we're into territory that is considerably more hostile than was ever dreamed by the Leap Frog Group. The same treatment doesn't produce the same result in a different patient. Or, often, in the same patient at a different time. An abnormal lab test may be important, unimportant, irrelevant, or wrong, depending on circumstances. Many things are time-sensitive, many are not. Some systems promote transparency, some advertise their proprietary nature as enhancing security. For that matter, we can't even agree on whether we want transparency or security of our data. Requiring the use of computer systems in this environment has become an exercise in futility. Except, of course, inside the Beltway and in most state legislative chambers.

It's safe to say that the king's shoes are pretty well soaked, the hem of his robe is sopping, and his throne is becoming waterlogged. King Canute was wise enough to know his limitations, and to stop ordering the tide to halt. Our present leaders, evidently, are not. Canute is dead, but the descendants of his couriers are alive and well today.

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PRO CON

Should Missouri Have a Statewide Prescription Drug Monitoring Program?

On July 17, 2017, Governor Greitens issued Executive Order 17-18 in response to the opioid epidemic. Although many press reports have concluded that this order establishes a Prescription Drug Monitoring Program (PDMP), it actually only allows the state to more closely observe prescribing practices. Inappropriate opioid prescribers identified by this new system will be turned over to law enforcement and licensing boards.

What the new program does not do is allow physicians to access the prescribing and dispensing data of their patients - a necessary component of all PDMPs. This information assists prescribers in identifying, treating, and preventing addiction. In the absence of a statewide in Missouri, St. Louis County launched its own in May of this year. A growing number of other counties and municipalities have joined that effort as subscribers, and many more are considering it.

Missouri is the only state without a PDMP. MSMA will continue to advocate for a statewide PDMP that offers physicians the clinical tools they need to fight the opioid epidemic.



What follows is a discussion for and against a statewide Prescription Drug Monitoring Program by MSMA members Sam Page, MD, St. Louis, and John Lilly, DO, Springfield.

PRO CON

PRO

The Case for a PDMP in Missouri

by Sam L. Page, Jr., MD

The most widely attributed writing declaring opioid analgesics as risk free of addiction is a 1980 letter to the editor in the *New England Journal of Medicine.* Dr. Hershel Jick and his graduate assistant, Jane Porter, wrote that in 39,946 hospitalized patients, 11,882 received at least one narcotic. They reported only one instance of major addiction and four cases total of addiction in patients who did not previously have documented addiction. They concluded that the widespread use of narcotic drugs in hospitals was unlikely to lead to addiction in medical patients, and the risk of addiction was indeed rare.[1]

The letter was frequently cited to advocate for the widespread use of opioids in outpatient settings, and was widely used to create momentum for the establishment of pain as the 5th vital sign. Until almost ten years ago, physicians were frequently taught to treat inpatients without fear of opioid addiction. Now, however, physicians and the medical community have spent the last decade fighting the tsunami of the opioid epidemic and its concomitant addiction, overdose, and death.

All MSMA members know that Missouri remains the last state in the United States without a state-run prescription drug monitoring program (PDMP). This article will outline how a PDMP is an important part of the physician and medical community's response the opioid epidemic sweeping our state.

Why does this matter to Missourians?

According to the Missouri Department of Mental Health, from 1999 to 2014, opioid-related death rates in Missouri increased:

- 7.6 times for females
- 3.8 times for males
- 5.9 times for Caucasians
- 2.6 times for African Americans
- 7.2 times for young adults age 25 to 34
- 3 times for adults age 35 to 44
- 6 times for adults age 45 to 64

As if to underscore the point, the *St. Louis Post-Dispatch* recently described how St. Louis County has had to resort to creating temporary morgues with mass-casualty refrigerated trucks to manage overdose victims.[2] Narcan is now available to first responders and is often prescribed by physicians for patients or their families to have on hand in the event an overdose requires resuscitation. But even with Narcan readily available – and many successful interventions – opioid-related deaths in Missouri are skyrocketing.

This is everyone's problem. It is especially our problem because we are a critical piece of the prescribing pathway. Public health data has shown several critical areas that need our attention. Among them are young people, who often get their first exposure to opioids from sports injuries and dental procedures – both of which have good data demonstrating successful treatment with NSAIDs and acetaminophen. The picture is even more challenging for those with chronic pain.

Opioid abuse is a major public health epidemic that demands a paradigm shift in the medical community's approach to chronic pain, and the creation of several tools to help physicians make good patient care decisions. A PDMP is the simplest and most widely accepted tool to fight narcotic addiction and diversion. There are many other resources, such as an Opioid Risk Tool (https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf)[3], disease-specific functional assessment tools, urine drug testing, medication management agreements, and opioid treatment guidelines. But without a well-run and functioning PDMP, these other tools become part of a treatment chain with a critical missing link.

A PDMP is simple. It's an electronic medical record, accessed by confidential user ID and password. It pools information from all area pharmacies to determine if narcotic prescriptions have been dispensed. It's well known that a prescription is not always filled, perhaps due to such issues as insurance co-pays and deductibles or the availability of that prescription at pharmacies. Patients may read something on the Internet or hear something from



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a friend or family member and decide a medicine is not right for them. Many of our older patients are unclear about their medications and don't realize they already have a prescription for an opioid or other substances that may interfere with opioids. There is also a subset of patients who have true addiction issues, or even a smaller subset who are diverting medications for sale.

It is essential that physicians address the correct diagnoses and use other interventions prior to starting a trial of opioid analgesics. It is critically important to ensure that the patients are not receiving opioids or other narcotics from other physicians. Other prescriptions do not necessarily mean the patient is not a candidate for opioids, but it does mean that a conversation is required to determine why they received those other medications. That may affect the treatment plan, and if addiction or other mental health disorders are also present, it would require appropriate intervention.

State-run PDMPs are well-established systems that function as a shared-pharmacy electronic medical record. No longer is a concerned physician relegated to calling pharmacies around town to check on the medication history of a patient who raises concerns. Prescribing data is merged into the database from all pharmacies, and often will include data from PDMPs in surrounding states. Physicians and other prescribers simply log on to this database for patients under their care, or have a designated and trained member of their team access the database to check the opioid prescriptions filled for a particular patient. Ideally, as with the St. Louis County PDMP, all narcotics (Schedule II-IV) for the past two years are contained in the database.

PDMPs are a demonstrably effective tool to reduce opioid diversion and identify and refer for treatment patients with opioid misuse syndrome. The PDMPs work for patient populations currently under the care of a physician, and for decisions regarding a trial of opioid analgesics for chronic pain.[4] In border state medical communities, PDMP interconnectivity is proven to reduce abuse and diversion of controlled substances.[5] Missouri is a health care export state, providing medical care to many residents of neighboring states. One of the most prevalent complaints in our neighbor state medical communities is the absence of a PDMP in Missouri and the doctor shopping tourism that allows patients to come to Missouri for narcotics and return home undetected. The St. Louis County PDMP can be accessed in large metropolitan regions in border states, but it is not yet universally available.

Emergency room physicians are especially plagued by a subset of patients seeking opioids for various ailments; some legitimate and some questionable. A PDMP helps these physicians make more informed decisions. One study in Ohio emergency departments showed a 41% decrease in opioid prescriptions with PDMP use.[6]

Opioid misuse falls into three primary groups: (1) Those with under-treated symptoms, including those who use pain medication for sleep or anxiety; (2) those who demonstrate addictive behavior; and (3) those who divert their prescriptions. Some patients take medication faster than prescribed, from multiple sources, or without a benefit that exceeds the risk of opioid-related side effects.

Physicians are trained to be compassionate and to seek to relieve pain whenever possible. Reflexively, we often err on the side of accepting patient's presentations and complaints and giving them the benefit of the doubt. We also understand that addiction, especially involving opioid medications, is powerful.

What are the concerns about PDMPs? Electronic information is certainly at risk to be breeched. Based on the experience of the other 49 states with a database, the incidence of unauthorized access is very rare. This information is protected by the same HIPAA rules that govern all other protected health information.

Also, prescribers are at risk for prosecution. The rules for governing PMDPs can be designed such that law enforcement cannot access the prescriber information without a warrant. Lawsuits are arising against prescribers who are not aware of overlapping prescriptions. Recently a case in St. Louis resulted in a very large settlement to a plaintiff who claimed to have been negligently prescribed pain medications for chronic pain that resulted in addiction.

There are concerns that prescribers will find a PDMP too difficult to use and quit prescribing pain medications to patients in need. Systems are now able to integrate with existing EMRs, and PDMP rules can allow a designee to access the database on your behalf. Finally, we are still governed by our goals of good clinical care for patients, and that will guide us in the best method for prescribing by treating physicians.

As a temporizing measure in the absence of a state-run database, Missouri counties are finding their own way to a regional PDMP. As of this writing, fully 27 counties and municipalities are participating in the St. Louis County PDMP, covering well over half of the population in Missouri. St. Louis took the lead to establish this system but has structured it in a way that adding counties can be done through local ordinances. This is a first class program initiated by a law that I sponsored and passed as a member

of the St. Louis County Council in March 2016. It is been live and functioning since May 2017. The program is run by Appriss, a company that operates prescription drug monitoring programs in 25 other states. And any licensed physician in Missouri or a neighboring state may visit https://missouri.pmpaware.net and register for access.

Unfortunately, many rural counties have not yet joined the Missouri effort, and remain at risk for continued issues. Ideally, the state legislature would enact a strong statewide PDMP that allows physicians to take good care of their patients regardless of the county in which they practice. Many physicians and other advocates worked very hard to get a statewide effort passed this year. As listed on the SafeandStrongMO.com website, a coalition of 33 health care providers and associations (including MSMA), 11 law enforcement agencies, 38 drug abuse prevention advocates, and 26 major Missouri employers has endorsed a statewide PDMP, and worked to pass enabling legislation. Unfortunately, PDMP opponents in the 2017 General Assembly managed to alter the original legislative language in a manner that made the proposed system ineffective for both providers and patients. And the amended version ultimately was opposed by MSMA and others for that reason. The objectionable changes included mandatory use of the system for all prescriptions, regardless of clinical indications and including patients in the hospital (with licensure penalties for failure to comply); mandating that only the physician could check the PDMP (no nurse or office staff delegation); limitation of the data to only 90 days of prescription history; and preemption of the higher functioning and much more effective and user-friendly regional PDMP database.

As the last state to have a functioning PDMP, the thirst for this information is extraordinary and no one expects the PDMP to be underused when appropriate. A poorly conceived mandate that paralyzes physician offices is punitive and runs counter to providing good medical care based on clinical decisions by the treating physician. To date, no PDMP has mandated physician usage prior to testing and validation.

A PDMP with streamlined data into individual patient electronic medical records would improve care for patients receiving opioid analgesics. Allowing delegated users to access the database on behalf of physicians and provide that information as part of the normal workflow in the office setting is good public health policy.

Addiction affects patients from all walks of life and demographic groups – from those in poverty to the most affluent members of society. Physicians have a responsibility to properly diagnose and treat these patients, either in our own practices or referral to the proper specialists. One important tool to aid the decision-making is easy access to a PDMP and the information it contains.

Throughout history, physicians have struggled with various epidemics and faced community opposition to health policy and interventions. Quarantines have been argued as a violation of individual rights and liberties. The December 30, 2016 issue of *The Atlantic* described concerns that civil liberties could be violated with new CDC rules issued to manage the Ebola virus outbreak.[7]

Requirement of immunizations to attend public schools has been argued as a violation of individual rights and liberties and has been a public health vs. individual liberties argument as well. But a century old United States Supreme Court decision recognizing the public health benefit of immunizations was upheld in 2015, by the U.S. Court of Appeals for the Second Circuit.[8]

Not only is adoption and widespread use of a PDMP the right decision from the standpoint of organized medicine, a wide and deep collection of nearly every health policy interest group in America has joined in advocacy. The AMA and MSMA have been advocates for this legislation for more than a decade.

A well-functioning PDMP provides the tool for physicians to make more informed clinical decisions. I join the coalition of physicians and community leaders calling for a well-designed state-run PDMP, like the one sponsored by State Representative Holly Rehder. In the meantime, I ask you to lend your voice to this effort for the 2018 session of the Missouri General Assembly. I also encourage you to lead your county to join in the efforts spearheaded by St. Louis County. We are both entrusted with and empowered to work for the safety and wellbeing of the good people of Missouri.

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CON Prescription Drug Monitoring Program: Useful Tool or Government Control?

by John D. Lilly, DO

To quote one of my business school professors, "The pleural of anecdote is anecdotes, not data." Public policy must be based on data, not anecdotal evidence. The proponents of the Prescription Drug Monitoring Programs (PDMP) use personal stories at legislative hearings and no valid evidence that the PDMPs work to decrease prescription drug deaths.

A National Institute on Drug Abuse report shows the number of deaths caused by all prescription drugs for the entire country has increased from 7,885 in 2000 to 29,728 in 2015, and the number of deaths per 100,000 population, age adjusted, has increased from 2.81 in 2000 to 9.23 in 2015.[1] About 75% of the deaths are due to opioids, and 25% of the deaths are due to benzodiazepines.

Almost all to the research on PDMPs have been limited studies in order to show some minimal success. Using the same ICD-10 codes used by the National Institute on Drug Abuse in the CDC Wonder database website for every state from 2000 to 2015, will show an increasing overall death rate.[2] In 2000, 16 states had an operational PDMP. That number increased to 21 by 2005 and to 34 by 2010. In 2014, 49 states had an operational PDMP. The exception was Missouri (See Figure 1). Does this look like the PDMPs are working?

If the PDMPs worked to reduce the number of deaths, then Missouri should be at the top of the list. The number of deaths per capita in Missouri for 2015 was 9.76. Missouri was 22nd in descending order for all of the states and the District of Columbia (DC). West Virginia had the highest death rate in 2015 at 35.20 (See Figure 2). In 2015, eight states that had an operational PDMP before 2000 had a death rate higher than Missouri. That is evidence that the PDMPs are ineffective. So why don't they work? The proponents claim the purpose of the PDMP is to eliminate "doctor shopping" which is the practice of one patient going to two or more physicians to obtain prescription drugs and having the prescriptions filled at two or more pharmacies in order to sell or abuse the medication.

The U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services, Administration Center for Behavioral Health Statistics and Quality performs an annual National Survey on Drug Use and Health.[3] This survey is the primary source of information on the use of illicit drugs, alcohol, and tobacco in the civilian, non-institutionalized population of the United States aged 12 years old or older. In the 2015 survey, table 6.56B on page 1873, shows the source where pain relievers were obtained for the most recent misuse among past year users aged 12 and older. The percentage of prescriptions from more than one doctor was 1.7%. This table also showed the percentage (40.5%) if the primary source was from a friend or relative for free. The survey then asked where the friend or relative obtained the pain medication using the same questions. Table 6.57B on page 1875, shows the source where pain relievers were obtained among past year misusers aged 12 or older who obtained the most recently misused pain relievers from a friend or relative for free in past year. The percentage of prescriptions from more than one doctor in table 6.57B was 1.4%. The total percentage of prescriptions from more than one doctor was 2.3% (1.4% x 40.5% = 0.6% + 1.7% = 2.3%). The survey started asking the "from more than one doctor" question in 2011. The percentage from more than one doctor increased incrementally each year from 3.6% in 2011 to 3.7% in 2012 to 4.3% in 2014 to 4.8% in 2014. The decrease in 2015 was due to a change in the question asked in the survey from lifetime misuse to misuse in the past 12 months.[4] Even when almost every state had a PDMP, the programs still could not stop doctor shopping.

Clearly, doctor shopping is not the problem. In the 2015 survey, 85.8% obtained the pain medicine from one



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doctor either directly or from a friend or relative. 11.9% stole it from a clinic or hospital, bought it from a stranger or off the internet, or some other way (See Figure 3). The real problem is the 97.7% that got the pain medicine from a source other than doctor shopping. The PDMPs will never catch the 97.7%. Is it any wonder that the programs don't work. I have yet to see this survey referenced in any published research on PDMPs.

Let's evaluate the death rate of the states that have a PDMP. By calculating the slope of the line of the number of age adjusted deaths per 100,000 population each year for each state starting with the year the PDMP became operational or the year 2000, whichever comes later, one will find that forty-three states had a positive slope indicating the death rate was increasing, and six states had a negative slope indicating the death rate was decreasing. Of those six, five had some annual increases and some annual decreases over the last three to four years. Only one state, Washington, had a consistent annual decreases over the last four years. How can anyone claim the PDMPs are succeeding when the per capita death rate is increasing in forty-three states. When only six states show a decreasing death rate and only one of those states showed a consistent decrease in the death rate over the last four years after the PDMP became operational, that is not an example of success. That's called normal variation or random chance. In fact, if one tabulates the slope of the lines in 0.5 increments and throws out the top outliers the resulting curve looks like a normal distribution curve.

Proponents of PDMPs are now pushing for real time programs claiming that is what will make the difference. Currently, only Oklahoma has a real time

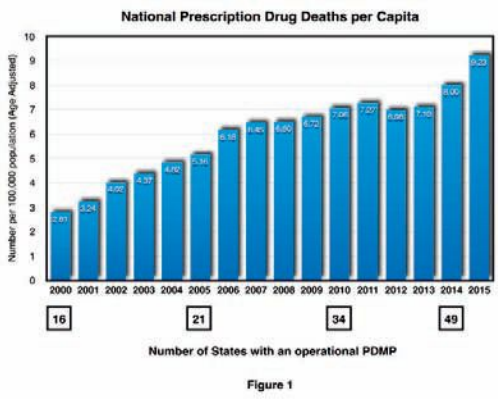


Figure 1

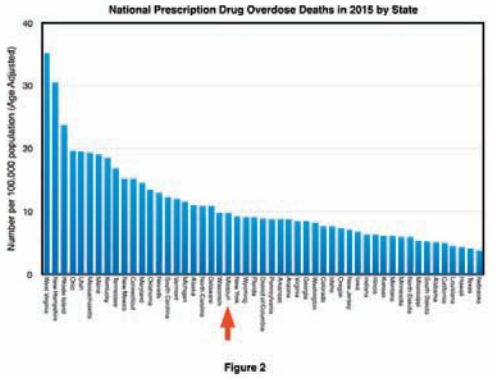


Figure 2

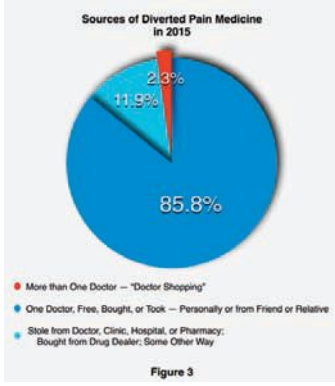


Figure 3

system. Twenty-nine states and DC have a reporting system of 24 hours or one business day. Fifty states and DC have a maximum of 7 days. Only Alaska has a monthly reporting period. A real time system is only beneficial the very first time a person is entered into the database. From then on, a real time system is meaningless. If I fill a prescription at one pharmacy and another prescription at another pharmacy the same day, the PDMPs that are not real time will not catch that. But that only applies to the very first time I try to fill a prescription. After one day, twenty-nine states will know what I am trying to do, and after one week, all of the states except Alaska will know. The real time systems are an improvement only on the very first day in ones life that one ever tries to fill multiple prescriptions. After that one, single day, it's unnecessary.

Private insurance companies and government programs like Medicare, Medicaid and the Veterans Administration have prescription databases. When you sign up for the insurance policy or the government program, you agree to become part of their database. The PDMP is completely different. It is a mandatory, involuntary database which makes it unconstitutional. It violates Article I, Section 15 of the Missouri Constitution which states, "That the people shall be secure in their persons, papers, homes, effects, and electronic communications and data, from unreasonable searches and seizures; and no warrant to search any place, or seize any person or thing, or access electronic data or communication, shall issue without describing the place to be searched, or the person or thing to be seized, or the data or communication to be accessed, as nearly as may be; nor without probable cause, supported by written oath

or affirmation." The electronic data and communications language was added in 2014.

Do I blame physicians for wanting this? Absolutely not. It would benefit my practice. I blame the politicians for passing the legislation. Their job is not to make my job easier. Our legislators primary job is protecting our liberty, not trying to correct the problems of individual citizens. The Missouri Constitution is very clear. Article I, Section 2 states, "That all constitutional government is intended to promote the general welfare of the people; that all persons have a natural right to life, liberty, the pursuit of happiness and the enjoyment of the gains of their own industry; that all persons are created equal and are entitled to equal rights and opportunity under the law; that to give security to these things is the principal office of government, and that when government does not confer this security, it fails in its chief design." The legislators in all of the states that have passed a PDMP are failing in their primary mission, which is maintaining the liberty of the citizens.

Clearly, doctor shopping is not the massive problem the proponents of PDMPs would have us believe. It was only 2.3% of misused pain medicine in 2015. Furthermore, the PDMP could not even stop the tiny amount of doctor shopping that does occur despite almost all of the states spending hundreds of millions of dollars to try to stop it. The real problem is the 97.7% which will never be caught by a PDMP. All of the talk about doctor shopping and saving lives is not the real goal. The real goal of those pushing the PDMP is a de facto national prescription database. The real goal is not fixing problems. The real goal is controlling people. Unfortunately, we are almost to a national prescription database. Forty-six states plus DC share the information on their databases.[5] If Missouri passes a PDMP bill, it will be number 47. The citizens are slowly losing their republic.

What is the American Medical Association's (AMA) policy concerning PDMPs?[6] The AMA House of Delegates has passed several resolutions since 1981. The following statements are part of these resolutions:

- The AMA supports permanent authorization of and adequate funding for the National All Schedules Prescription Electronic Reporting (NASPER) program so that every state, district and territory of the US can have an operational Prescription Drug Monitoring Program (PDMP) for use of clinicians in all jurisdictions;
- The AMA supports the voluntary use of state-based prescription drug monitoring programs (PDMP) when clinically appropriate;
- The AMA supports the ability of physicians to designate a delegate to perform a check of the PDMP, where allowed by state law; and
- The AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances.

All of that sounds fine to physicians, but let's look at what we are really saying when we translate these policies into the language of liberty.

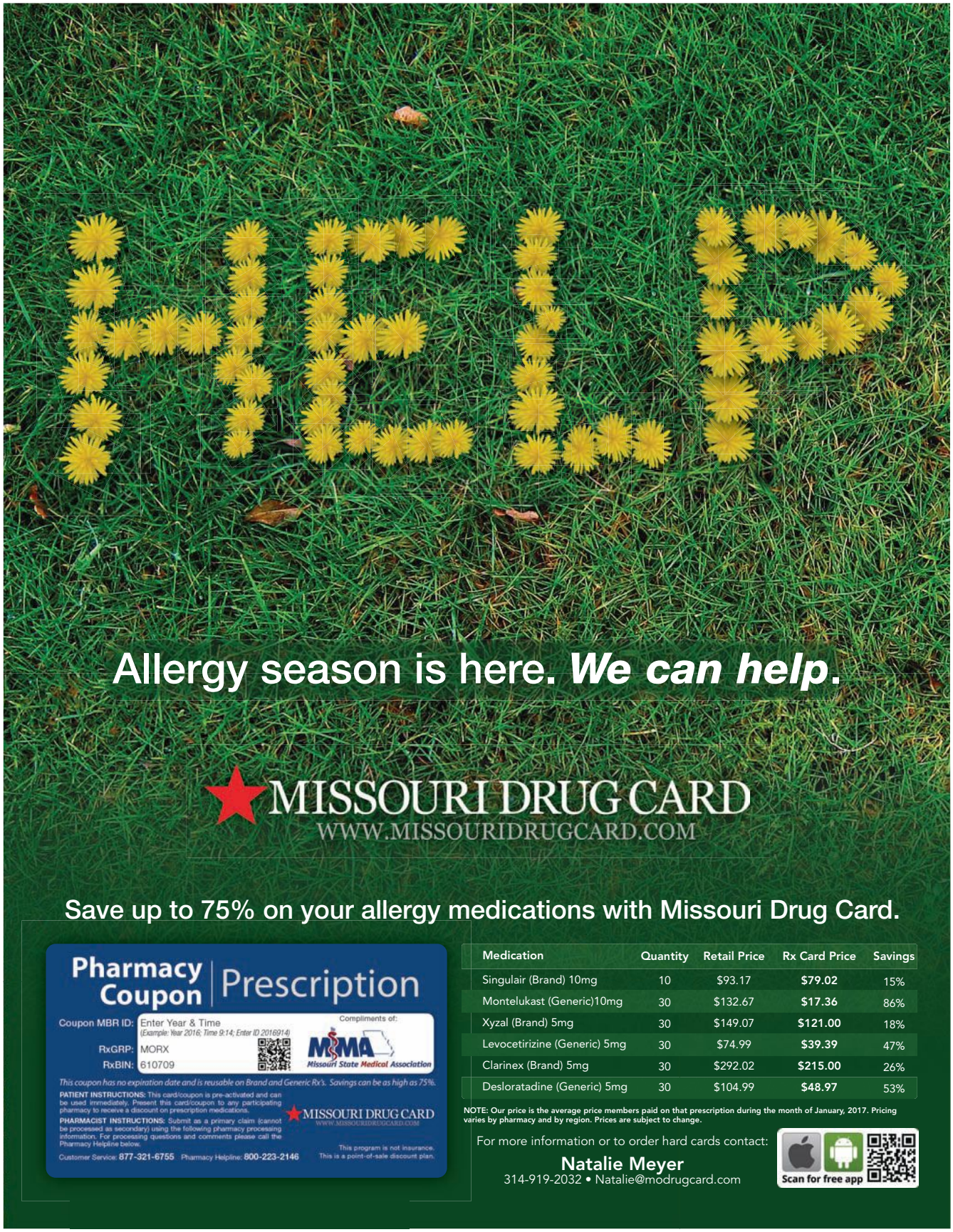
- "I want to use the police power of government to force other people, including my patients, to do something that will make my job easier."
- "I want someone else to pay for a program that will make my job easier."
- "I don't want to be held accountable for my actions."
- "I want to be able to appoint someone else to do my job."
- "I don't care if my actions trample on the liberties of my patients."

What if we were forced to disclose this to our patients prior to an office visit? How many of us would be proud to make these statements? When we look at these policies through the patient's eyes using the language of liberty, it is not flattering and does not conform to the oaths we took upon graduation. Is this really what we want for a national policy?

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Close Examination of a ZYTO Electrodermal Screening System

by Stephen Barrett, MD

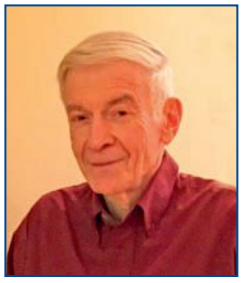
Abstract

Electrodermal screening" ("EDS") devices are claimed to use galvanic skin responses to identify health problems and corrective actions. Thousands are being used to persuade people to buy dietary supplements, diet programs, and other offerings. This study, which involved self-testing with a leading EDS device 43 times in 10 days, found that its assessments and recommendations were preposterous and potentially dangerous. The sale and clinical use of EDS devices should be banned.

Introduction

ZYTO Technologies Inc., of Lindon, Utah, claims that its device systems are useful for determining health problems throughout the body and how to fix them. According to its web site, "Just like a doctor uses a stethoscope to listen to a child's breathing, ZYTO 'listens' to the body's subtle galvanic skin response" and suggests corrective measures.[1]

This use of galvanometric device systems to guide practitioners is commonly referred to as electrodermal screening (EDS). EDS devices are said to detect and respond to skin resistance to the passage of low-level electrical current. At least 40 such devices have been marketed.[2]



Stephen Barrett, MD, a retired psychiatrist who lives near Chapel Hill, North Carolina, has achieved national renown as an author, editor, and consumer advocate. In addition to heading Quackwatch.com, in 1984, he received an FDA Commissioner's Special Citation Award for Public Service in fighting nutrition quackery.
Contact: sbinfo@quackwatch.org



Figure 1
The Zyto hand cradle.
To conduct the test, the device is attached to a computer and ZYTO software is run while the client's palm and fingers rest on six corresponding electrodes.

Early ones displayed skin-resistance measurements as numbers on a gauge or computer screen for the practitioner to relate to the health of the body's organs. Current devices are bundled with software that generates elaborate charts, pictures, and lists of body areas, symptoms, diseases, and corrective measures.

ZYTO Technologies appears to be the leading marketer of EDS systems, with thousands currently in use. EDS users include chiropractors; naturopaths; acupuncturists; massage and colon therapists; "holistic" dentists; veterinarians; physicians who purport to practice "integrative" or "complementary" medicine; and unlicensed "nutritional consultants," "wellness consultants," "health coaches," and distributors for multilevel marketing companies that sell dietary supplements and/or herbs. Many of these providers recommend that testing be done periodically.

ZYTO Systems

ZYTO systems have two components: a hand cradle (See Figure 1) and software that interprets the electronic signals generated by the device.

ZYTO says that its software sends "digital signatures" (unique code numbers) to the body and determines "the body's degree of preference" for measures that will make the body most "biologically coherent."

To run the test, the cradle is connected to a USB port on the practitioner's computer and the patient's hand is placed with the palm and fingers touching the corresponding points on the device. The practitioner then launches the software program and selects the type and scope of test from a sequence of menus that appear on the computer screen. The software then generates numbers and graphics that supposedly indicate (a) whether the function of various organs and body parts are "in range" (favorable) or "out of range" (unfavorable) and (b) which products, procedures, and/or dietary measures show the most "coherent responses" (those that will bring the values "within range"). Changes in skin resistance are said to trigger what gets matched.

To have their products considered during the test process, manufacturers submit them to the company, which creates a "library" of "digital signatures" for each product plus a brief description of what the product can do. ZYTO software also encodes the minimum usage age for the product, the suitability for male or female test subjects, the dosage, yes/no values for the practitioner's favorite product(s), and a few other values that guide the display of the data in the final report. The software is also said to contain "digital signatures" that represent the condition of various organs, teeth, and spinal segments—all of which, the company claims, are connected through "energetic channels" called "acupuncture meridians."[3]

During the scan, ZYTO software takes baseline measurements of the galvanic resistance to low-voltage electricity through the palm and fingers of the test subject and sends product codes to the hand cradle so the body can supposedly respond to product "signatures" as though the test subject had ingested the products. The system re-measures the galvanic resistance of the test subject and then calculates the difference between the "baseline" and second measurements. This process is repeated over and over again through the product line(s) selected by the practitioner. ZYTO states that the system processes over 100 "virtual items" per minute. The apparent goal of the test is to match the supposed characteristics of the patient to the products, services, and/or dietary advice that the practitioner can provide. The length of the test—typically 2 to 20 minutes—depends on how many parameters are chosen. The content of the reports also depends on the parameters selected.

The ZYTO Corporation web site currently offers "libraries" for the products of more than 200 companies. Its lowest-priced system, the ZYTO Compass, sells for $399 plus a $39.95 monthly subscription fee, and includes one library and measurement of 76 "biomarkers." ZYTO's high-end systems, which cost $9,750 or $14,750 plus $50 per month, assess 1,500+ "biomarkers" and provide access to as many libraries as the practitioner wants. Most libraries contain several hundred products. The monthly fee gives access to the password-protected portion of the company's web site, which provides training and marketing materials and enables practitioners to upload their test reports into their individual accounts.

Testing can be done in the presence of the practitioner or done remotely though the internet by hooking a purchased or borrowed hand cradle to the client's computer. The internet-advertised prices of scans run from $10 to $250, but the recommended products often cost hundreds of dollars more. Many practitioners aim to scan everyone who consults them. One provider in Virginia, who has no relevant license but offers remote testing throughout the world, states that he has done more than 20,000 scans.

My personal investigation—the first of its type ever published—examined whether ZYTO testing could produce consistent results, valid diagnostic findings, and rational recommendations.

Study Design

Last year, when presented with an opportunity to operate a ZYTO device with high-end software (Elite 5.0), I ran three series of tests on myself. The first was a basic scan that supposedly evaluated my organs and advised what products would bring them back "in range." The other two were nutritional "biosurveys" to determine what foods I should or should not eat.

The basic scan is said to determine whether "biomarkers" are in or out of range for 20 organs:

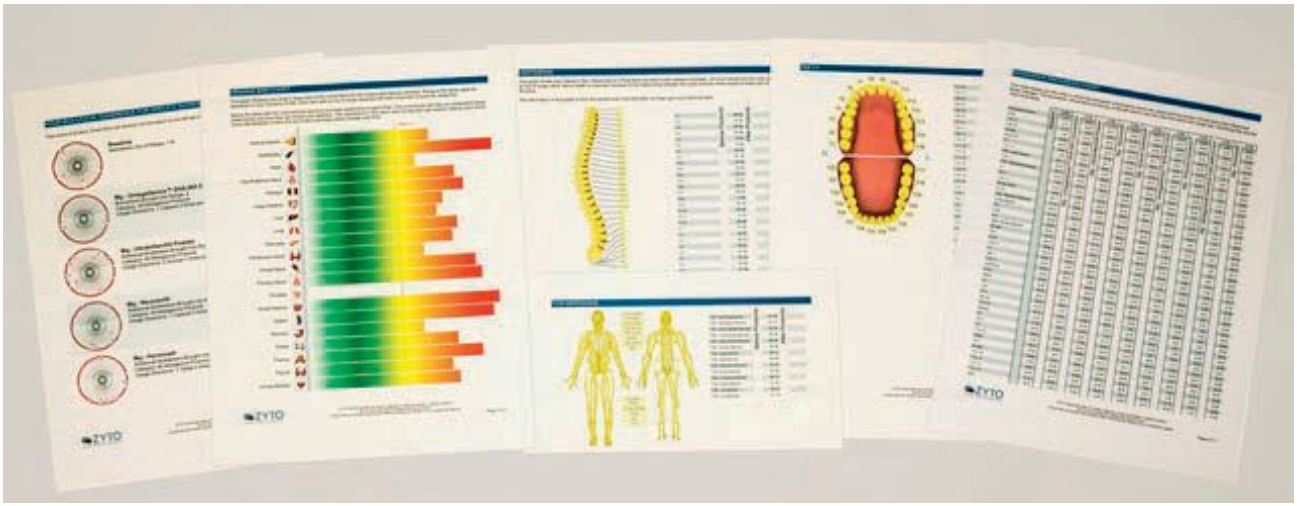


Figure 2
Selected pages from a ZYTO report
The bar graph purports to show whether biomarkers for each of 20 organs are "out of range." The other pages indicate which spinal segments, acupuncture meridians, or teeth have relevant problems and which products can correct the alleged problems. The greater the supposed problem, the longer and redder the bar that crosses the vertical "range line" in the middle of the bar graph. Most scans have a bar for every organ, but this one failed to detect the author's adrenal glands, prostate, and testes.

adrenals, bladder, gallbladder, heart, hypothalamus gland, kidneys, large intestine, liver, lung, pancreas, parathyroid, pineal, pituitary, prostate, small intestine, spleen, stomach, testes, thymus, and thyroid. My basic scans generated reports that were 8–13 pages long. Figure 2 shows portions of six pages from one of my reports. The findings for the organ biomarkers are displayed with a colorful full-page bar graph and as positive or negative numbers elsewhere in the reports.

ZYTO's marketing materials have stated that its nutritional surveys can determine "which foods and supplements are right for you."[4] The reports themselves describe the purpose this way:

> "This Food Biosurvey tests your body's Galvanic Skin Responses to Virtual Items that represents a particular food. Your response to each food Virtual Item is scored with a positive or negative number, and your most extreme responses will be shown on this report. Even though this is NOT a food allergy test, you may wish to avoid the Virtual Items with a negative response, and include in your diet the Virtual Items with a positive response."

The test reports can be configured to assess food categories, "top negative foods," and/or "all positive in-range foods." The food categories are additives, beans/legumes, beverages, dairy/egg, fat/oils, fish/seafood, fruits, grains, meats/poultry, miscellaneous, nuts/seeds, spices/seasonings, sugars/sweeteners, and vegetables. I did one series of tests that assessed the fourteen food categories and two others to assess individual foods. The resultant reports were 2–4 pages long.

My Test Results

Table 1 shows the results of sixteen basic scans, with four done within an hour on each of four consecutive days. These scans found means of 69.2 (SD, 31.9) biomarkers and 11.4 (SD, 5.4) organs that were "out of range," but the organs specified and the supposedly corrective products—a mean of 5.3 (SD, 2.6) per scan—varied considerably from one test to another. The organ with the highest "out-of-range" score, positive or negative, also differed from test to test. Four reports highlighted my adrenal glands, three chose my small intestine, two chose my heart, two chose my thymus, and the other six tests each identified a different, supposedly problematic, organ. Only four of the sixteen scans had any organs "within range."

Even though I have no gallbladder, this organ was reported to be positively "out of range" four times, negatively "out of range" 4 times, and "within range" eight times. I have benign prostatic hypertrophy, but my

Table 1. Summary of basic scan results.

Test Date	July 2, 2016				July 3, 2016				July 4, 2016				July 5, 2016			
"Range" Value	66	37	.01	.01	22	22	22	22	54	54	54	54	55	55	55	55
Adrenals	±47	70	-47	17	-142	±6	34	44	**107**		**107**	**143**	-82	69	**81**	-58
Bladder	±36	-52	64	-28	-168	±18		52		110		57	254			
Gallbladder	±48	-53	-20	**-51**	±0	±17			57	69	-60		164	74		
Heart	±30	±5	**92**	10	51	±18	-31	-34				-92	180	**125**		
Hypothalamus	86	53	-46	30	±6	±10	26	44				80	-120	116		-55
Kidneys	±42	52	-21	-35	-107	**-46**		26		85			139	57		
Large Int.	±48	±6	58	24	257	±18	-36	-58				120		-116	-58	
Liver	±65	**76**	51	20	±13	±6	44	37					-125	94		
Lung	±8	-67		-31	-131	-30		29		96		128	154		-78*	
Pancreas	±49	±9	35	28	113	±21	-37	-60						-108		
Parathyroid	89	60	48	12	79	23	**54**	27	-55		100	96	-115	110		
Pineal	±26	-48	49	39	-144	-35		27		111		129	175		-61	
Pituitary	±40	±6	17	43	177	±16		**-66**		-54		-66		-105		
Prostate	82	51	-51		104	±8	24	29	-63		62	-80	-116	103		
Small Int.	±47	-70	37	**-51**	-151	±17	-36	32		**117**		113	**283**	70		62
Spleen	83	±7	28	48	247		-39	-56		-60				-70	70	
Stomach	114	55	-73	-11	35	±8					58	-110	-100	94		
Testes	±8	-50	76	-28	-119	-27		34		101		121	210			
Thymus	±45	±11	10	41	**275**	±4		-58			-59			-111		**-63**
Thyroid	**135**	70	47	-25	±6	±10	24		-67		67	-99	-96	124	-66	
# of Biomarkers "out of range"	57	74	119	119	101	55	82	94	25	56	36	84	87	82	19	17
# of Organs "out of range"	6	14	19	19	16	5	11	17	6	9	7	14	15	16	6	4
# of Products	6	8	5	4	8	5	8	8	3	2	2	6	8	8	1	2

Table 1
The numbers are said to represent the body's response to code numbers that represent the organs listed in column 1. The software determines a range (baseline) value, compares the response numbers with that value, determines whether "biomarkers" are within that range," and recommends products that supposedly will bring "out of range" biomarkers back "in range." ZYTO reports list the "out-of-range" numbers in a table. The numerical value of the "in range" numbers can be derived by measuring the bars in the bar graph, but their direction is not specified, so they are listed here as "±" numbers. The furthest out-of-range numbers (displayed here in bold-face type) are said to require the most attention. If a table cell is empty, no organ response was reported. All numbers are rounded to the nearest integer.

prostate did not show up in one scan (Figure 2) and was reported to be positively out-of range in 7, negatively out of range in 4, and within range in 4.

To explore how the food biosurveys work, I conducted 12 food-category tests and 15 individual-food assessments. The food-category tests were completed within one hour. As shown in Table 2, the test reports recommended avoiding a mean of 6.4 (SD, 2.4) categories per test, but not necessarily the same ones. Ten of these tests recommended avoiding grains, nine recommended avoiding nuts and seeds, and eight recommended avoiding fruits, and vegetables. Five recommended avoiding all fruits, vegetables, and grains. One recommended only sugars/sweeteners; one recommended only beans/legumes; and one recommended only beverages, fish/seafood, meats/poultry, and spices/seasonings.

The food-category scores disagree so much from test to test that Cohen's kappa is zero (complete randomness). Some numbers in Table 1 are unspecified, but if the "±" numbers are eliminated, its kappa is 0.02, which is nearly random.

The individual-food tests were done in two groups. First there were ten tests that assessed common foods. Two days later, five tests assessed a larger food list. Both groups took less than an hour to complete. As with the basic scans, the individual-food scores were wildly inconsistent, with many foods scoring "positive" (recommended) on one test and "negative" (not recommended) on another administered a few minutes

Table 2. Results from the 12 food-category biosurveys.

Food category	Avoid	1	2	3	4	5	6	7	8	9	10	11	12
Additives	7	-11	-26	-36	-4	-23	19	21	-11	49	39		-18
Beans/Legumes	8	28	-35	-17	-35	-21	-43	28	-32	-33	79	8	-46
Beverages	4	6	38	33	30	28	-13	-71	72	7	-28	-107	
Dairy/Egg	6	-22	1	-20	-9	-14	51	58	-8	41	-36		-11
Fat/Oils	8	32	-30	-7	-33	-23	-44	-2	-26	-36	78	-79	-47
Fish/Seafood	3	9	33	41	43	45	-9	-56	48	5	-26	-118	
Fruits	8	-21	-10	-17	-5	-28	59	66	-31	38	-36		-21
Grains	10	19	-43	-34	-44	-27	-51	-22	-8	-46	78	-41	-60
Meats/Poultry	5	14	43	49	37	34	-11	-19	36	-5	-35	-89	
Meats/Poultry	5	14	43	49	37	34	-11	-19	36	-5	-35	-89	
Misc.	6	-39	-7	-9	3	-16	73	53	-43	61	-57		-8
Nuts/Seeds	9	25	-45	-31	-26	-14	-52	-30	21	-50	84	-41	-57
Spices/Seasonings	5	-6	39	48	37	40	-6	-30	38	7	-22	-95	
Sugars/Sweeteners	3	-26	11	-14	4	-15	65	72	-29	46	-67		11
Vegetables	8	28	-27	-31	-37	-15	-39	-41	21	-57	77		-53

The numbers are said to quantify the body's response to code numbers that represent the listed food categories. The positive numbers are food categories that should be included in your diet. The negative numbers represent the "top negative foods" that should be avoided. The "Avoid" column is the number of times the "top negative" list included the group. All numbers are rounded to the nearest integer.

later. For example, pineapple and red potatoes were listed seven times among the top negative foods and three times among the most positive foods.

Discussion

The claim that ZYTO scanning can provide clinically useful information is preposterous. To demonstrate that a device is capable of measuring something, it is necessary to validate its accuracy and consistency with repeated tests. My basic scan results were so inconsistent that they could not possibly be clinically meaningful.

In addition to being inconsistent, my food-category biosurveys recommended excluding so many foods that the resultant diets could be extremely unhealthful.

To demonstrate that a device can detect organ pathology, it is necessary to do controlled studies of people who have that condition and people who do not. To demonstrate that administering a product or procedure can improve outcome, it is necessary to study whether people who are treated do better than similar people who do not. A Medline search for "ZYTO" in the title yields no relevant publication. Proponent Web sites cite only one small unpublished study that looked for correlations between "organ stress results" reported with a four-minute ZYTO test and organ systems diagnosed as dysfunctional by a medical team.[5] Although the investigators considered the results promising, the data actually show marked discordance.

ZYTO Technologies has not explained how it can construct or validate its organ assessments or product libraries without any underlying clinical studies. Nor is there any logical reason to believe that skin resistance is related to organ health or what people should eat. But even if magical explanations were found, the ZYTO system's moment-to-moment variability would still render its findings useless.

Electrodermal screening tests are also potentially harmful. In addition to money wasted on the test and useless products, the harm can include (a) needless

There is no scientific evidence or logical reason to believe that galvanic skin response testing can determine a person's health status or strategies for health improvement.

worry about nonexistent medical problems suggested by the test reports, (b) the cost of medical care involved in seeking reassurance, (c) failure to seek appropriate medical care for real problems, and (d) the consequences of malnutrition due to excessive dietary restrictions.

Government Regulation

There are two major processes by which medical devices requiring FDA review come to the American market: premarket notification and premarket approval. Premarket notification—described in section 510(k) of Federal Food, Drug, and Cosmetic Act—is commonly referred to as the "510(k) process." A successful 510(k) submission results in clearance to market the new device. Clearance merely requires that the new device be "substantially equivalent" to a device that was previously cleared or approved. It is not the same thing as approval, which requires that clinical trials demonstrate safety and efficacy for its intended purpose. Some device manufacturers skirt the law by obtaining 510(k) clearance for one purpose when the device is actually used for another.

In 2011, the FDA cleared the ZYTO hand cradle for sale as a galvanic skin response measurement device (product code GZO).[6] Because moistness of the skin affects the ability of the skin to conduct an electrical current, a few devices in category GZO have legitimate medical use in the management of sweat-gland disorders. Aside from this, however, galvanic skin resistance has no proven or logical relationship to the diagnosis or management of any medical problem. ZYTO's software is separately registered as a medical device data system (product code OUG) that stores, controls, and/or transfers medical device data. Devices in this category are not legally authorized for patient monitoring.[7]

ZYTO devices are not FDA-approved. They were cleared because their 510(k) application and software registration did not indicate how practitioners would use them.

ZYTO's marketing materials state that its devices are "not intended to be used in the diagnosis, cure, treatment, mitigation, or prevention of any disease or medical condition." However, "intended use" is based on the context in which a device is used and is not necessarily changed by the use of disclaimers or contrived terminology.

In 2015, the FDA[8] warned ZYTO Technologies Inc. that, "The promotion of the ZYTO Hand Cradle for use in diagnosing a disease or condition, predicting biological responses to a wide range of virtual stimuli including drugs and nutritional supplements . . . fall outside of the device's cleared intended use to measure galvanic skin response and constitutes a major change or modification to the device's intended use." The marketing language to which the FDA objected included these claims:

- Clinical studies have compared ZYTO scan reports with results produced by generally accepted diagnostic methods.
- The hand cradle measures your body's galvanic skin response. ZYTO's various software offerings take this input and interpret it in terms of what we call your biological preference.
- Biological preference simply means those stimuli your body responds most favorably to. Using this information, you and your healthcare provider can decide on a clinical strategy developed specifically for you, based on your body's responses.
- ZYTO's technology measures your body's responses to a specific library of nutritional products, asking your body which it prefers.
- When your scan is complete, a report is generated that provides you and your healthcare provider with helpful information that was obtained. This report may provide insights that will prompt a closer look at specific organs and body systems, and explore your biological preference for medicine,

nutritional supplements, and treatments you could benefit from.

- General nutritional assistance biosurveys will help to identify your patient's biological preference for the products you sell. Other biosurveys may provide you with information specific to disease, toxins or organs and body functions.

In 2016, presumably as a result of FDA pressure, ZYTO Technologies announced a voluntary recall of 1,252 ZYTO Select and Elite software programs due to "claims exceeding the 510(k) clearance."[9] ZYTO has modified some of its marketing language, but there is no reason to believe this will influence how its EDS devices are used.

In 2017, the Federal Trade Commission obtained a consent agreement with the marketers of the NutriMost Ultimate Fat Loss System, which was developed by a chiropractor and franchised to other chiropractors.[10] The 40-day program, which included a very-low-calorie diet (only 600 to 800 calories per day) and supplement products, typically cost from $1,995 to $2,300, depending on the payment plan chosen. Advertisements claimed that the ZYTO scan would be used to create a "personalized and customized plan that will address your body's top organ stressors as well as finding the best products to balance those stressors." The supplement products were claimed to have been imprinted with "energetic resonant frequencies" that provide "information to your body's cells about how to more effectively detoxify."[11] In 2017, NutriMost redesigned its approach along more standard lines, abandoned use of the ZYTO device, and promised the FTC that any future weight loss and health claims would be supported with competent and reliable scientific evidence.

The use of EDS devices by practitioners is subject to regulation by the states. In 2015, the Arizona State Board of Chiropractic Examiners ordered three chiropractors to stop using ZYTO bioscan technology, and the Texas Medical Board reprimanded a physician for making improper advertising claims that included some about the ZYTO. I am not aware of any other ZYTO-related disciplinary actions.[12]

Conclusion

There is no scientific evidence or logical reason to believe that galvanic skin response testing can determine a person's health status or strategies for health improvement. All such devices and associated software that are used for these purposes should have their FDA 510(k) clearance revoked and be removed from the marketplace.

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Membership Matters

by Warren C. Lovinger, Jr., MD

Membership is the lifeblood of any organization. The more participating members a group has, the stronger it becomes. The medical profession is no exception to this rule. However, the different types of potential members in the medical field is complex, as we include many specialties, practice types/locations, and levels of professional experience—from medical students, to residents and fellows, to seasoned graduate physicians.

It is the mission of the Missouri State Medical Association to bring together the interests, needs, and services of this vast group of physicians and physicians in training—now totaling almost 15,000 in Missouri. In order to successfully achieve this goal of professional advocacy, we need to have wide participation from physician members.

Currently, MSMA membership includes 930 medical and osteopathic students, 118 residents, 2,447 practicing physicians, and 406 retired doctors. We are constantly working to increase our membership at every level by enhancing relevance, participation, and cost effectiveness. The professional services, legislative advocacy, and CME opportunities provided by MSMA are important to every Missouri physician and physician in training.

Therefore, we should all respond to the opportunity for membership in the Missouri State Medical Association. You can't influence the future of our profession if you're not part of the process!



David Keuhn, MD, Family Practice (17 years), Marshall

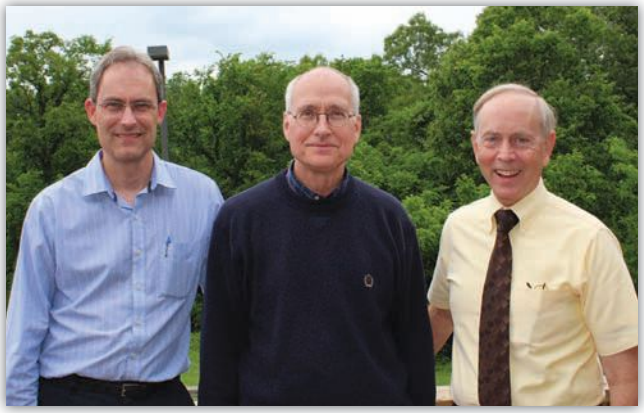
A special group of Missouri physicians are those who practice in the rural communities of our state. They have unique challenges and opportunities for service and leadership. I have personally experienced this for over 37 years as a solo practice Internist in Nevada, Mo. To emphasize the importance of our rural colleagues and their service, I have been traveling to each county in our state—currently having been to 67 of the 114 Missouri counties. During these travels, my wife, Marilyn, and I have had the pleasure of meeting with many MSMA member physicians—all of whom have expressed happiness in their rural lifestyle and medical practices. Several of these "Unsung Heroes of the Hinterland" are pictured here—with more to be featured in future issues of *Missouri Medicine.*



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Shelly Meents. MD, Obstetrics and Gynecology (12 years), Bolivar



Daniel Schmidt, MD, Family Practice (20 Years), and Barton Warren, MD, Family Practice (30 Years), Richland



Lirong Zhu, MD, Sleep Medicine (2 years), Rolla



Keith Ratcliff, MD, Family Practice (27 years), Washington



Stephen Williamson, MD, Occupational Medicine (8 Years), Waynesville



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Jeffrey Tedrow, MD, Family Practice (27 years), Bolivar

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Missouri Physician Installed as AMA President

by Charles W. Van Way, III, MD

David Barbe, MD, will lead the AMA in its advocacy and educational activities for the next year. During his inaugural address, he alluded to the many challenges to physicians in the current health care environment. He focused on the question, "What kind of leader do YOU want to be?"

David O. Barbe, MD, MHA, from Mountain Grove, Mo., was inaugurated as the 155th president of the American Medical Association on June 13 during the AMA's Annual Meeting in Chicago. Our state's last AMA President was 90 years ago. Dr. Barbe will lead the AMA in its advocacy and educational activities for the next year. During his inaugural address, he alluded to the many challenges to physicians in the current health care environment. He focused on the question, "What kind of leader do YOU want to be?"

Other members of the delegation had leadership roles. Edmond Cabbabe, MD, St. Louis, finished his term on the Board of the AMA Foundation and started a four-year term on the Council for Long Range Planning and Development. Rebecca Hierholzer, MD, Kansas City, chaired Reference Committee E on science and technology. Elie Azrak, MD, St. Louis, was a member of Reference Committee B on legislation.

The MSMA has lost one delegate and one alternate delegate because of decreasing AMA membership from Missouri. Lent Johnson, MD, and Warren Lovinger, MD, have left the delegation. At this meeting, there was further turnover. Ted Groshong, MD, Columbia, and Nathaniel Murdock, MD, St. Louis, retired from the delegation. They will be replaced. We urge all MSMA members to join the AMA, and help to maintain our voice at the national level.



Charles W. Van Way, III, MD FACS, FCCP, FCCM, MSMA member since 1989, Missouri/AMA Delegate, and *Missouri Medicine* Contributing Editor, is Director of the UMKC Shock Trauma Research Center.
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OSMAP, the Organization of State Medical Association Presidents, meets the day before AMA meetings, and is known for its programs presenting current and controversial topics. This year, the presentations concerned the proposed American Health Care Act, monitored injection centers, electronic participation in medical association decision-making, and the ever-unpopular maintenance of certification. Charles Van Way, MD, of Kansas City, was elected to a three-year term on the Steering Committee of OSMAP.

Opioid use remains a serious problem. A report on new and emerging drugs of abuse highlighted that narco-chemists are devising new drugs faster than law enforcement can deal with them. In the treatment area, the HOD wants to make it easier for physicians to prescribe buprenorphine, which is presently subject to onerous Federal restrictions. Supervised injection facilities were considered. While there is data in other countries that these can be beneficial, they are in a legal grey area in the U.S. The AMA will support trials of the concept. A report from the Board of Trustees (BOT) dealt with gaps in the prescription drug monitoring programs (PDMPs), and called for a literature review of the outcomes of PDMPs.

The BOT produced a bill of rights for physician medical staff members. These rights include self-government, advocacy for members without fear of retribution, participation in decision-making of the health care organization, and protection of professional autonomy. The use of screening tools addressing social determinants of health will be addressed by the BOT. Such tools are increasingly available and will be useful in the future, but there are questions about reimbursement, reliability, and integration into existing electronic health records (EHRs).

Controversy swirls around continuing medical education, life-long learning, and maintenance of certification (MOC). There is a strong movement to use life-long learning as a pathway to MOC. This would do away with mandatory objective tests, substituting practice-relevant CME and case reporting. The process would be

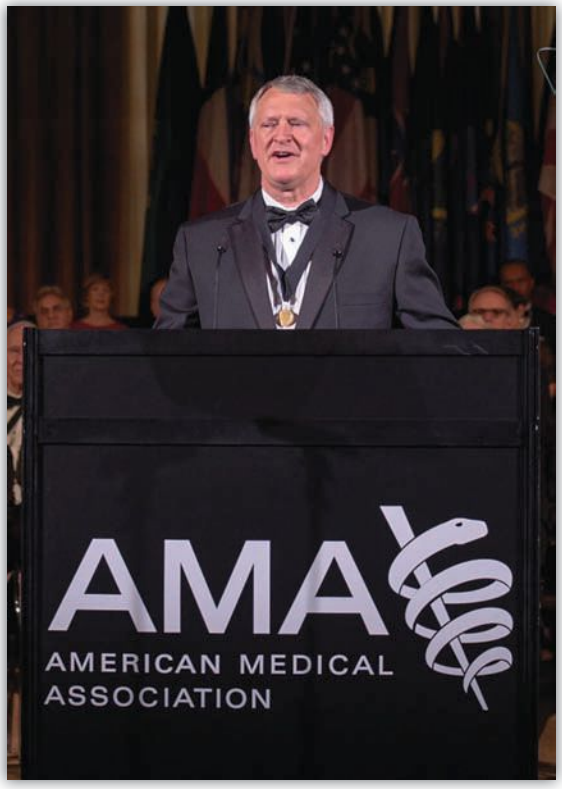
David Barbe, MD, Mountain Grove, Mo., Will Lead the Nation's Largest Physician Organization



A Mountain Grove, Mo., family physician was installed as President of the American Medical Association at its Annual Meeting on June 13.

David O. Barbe, MD, MHA, was first elected to the AMA Board of Trustees in 2009 and served on numerous AMA committees and task forces. He served as chair of the board from 2013–2014, as well as a member of its executive committee from 2011–2015.

Prior to his election to the AMA Board, Dr. Barbe was a member Council on Medical Service, an influential advisory committee of to the AMA, and served as its chair from 2008 to 2009. As a member of the council, Dr. Barbe participated in the development of AMA policy related to coverage of the uninsured, health care system reform, Medicare reform and health insurance market reform.



He has extensive experience as a medical society leader, serving as head of the governing board for the Missouri State Medical Association (MSMA) in 2003 and MSMA president in 2005. He was also a longtime member of MSMA's legislative committee and a board member of the Missouri Medical Political Action Committee.

Dr. Barbe received his bachelor's degree with honors in microbiology and his medical doctorate from the University of Missouri–Columbia School of Medicine. He completed his residency in family medicine at the University of Kansas affiliated program (now Via Christi) in Wichita, Kan. He also received his Master of Health Administration from the University of Missouri–Columbia.

Dr. Barbe has practiced family medicine in his hometown of Mountain Grove in rural southern Missouri for more than 30 years. After 15 years in independent practice, he merged his medical group with Mercy Clinic, Springfield, Mo., a 650-physician, multi-specialty integrated group. In his current role as vice-president of regional operations for Mercy, he is responsible for five hospitals, 90 clinics and more than 200 physicians and advanced practitioners. He also serves on the executive management team of Mercy-Springfield, which was ranked No. 1 in the nation in IMS Health's 100 Top Integrated Health Networks in 2012 and is one of Truven Health Analytics' top 20 large community hospitals.

managed by either specialty societies or existing specialty boards. The American Board of Medical Specialties strongly opposes the idea. The ABMS is of course simply protecting the interests of the public. Then too, objective testing is a multi-million-dollar business for ABMS member boards. There was a lot of passionate debate pro and con. Much of the support for changing MOC speaks to the lack of trust in bodies administering certification, notably the ABMS itself, the American Board of Internal Medicine, and the American Board of Pediatrics. Yet, there is real value in having an independent agency oversee the MOC process. Several of the certifying boards are responding positively to the objections. There is considerable distance to go, but progress is being made. Can the boards reform themselves?

This past year, Texas passed legislation to prevent health plans and licensing agencies from using MOC status in credentialing and licensing decisions. There is significant support for constructing model state legislation, and to implement such changes in more states. However, it will be vital to retain our ability to self-regulate our profession. There is a narrow line between using state law to control the use of MOC status, and using state law to control MOC itself. Some state legislatures will inevitably be tempted to cross that line. The old saying about letting the nose of the camel into the tent applies here. Other resolutions dealt with several different aspects of continuing education and re-certification. Stay tuned; there will be much more on MOC in the future.





Your Missouri Delegation to the American Medical Association: top photo, James Conant, William Huffaker, Ariel Carpenter, Edmond B Cabbabe, Rebecca Hierholzer, Ted Groshong, and guest Daniel Young. Bottom photo, Jared Lammert, Nat Murdock, Michael O'Dell, Betty Drees, and Charles Van Way.

Physician health and burnout continues to be a concern. There were resolutions protecting physicians who obtain mental health counseling or treatment from unfair treatment by licensing boards and hospitals. A resolution offered by medical student Ariel Carpenter, Columbia, called for studying burnout, depression, and suicide among medical students. Discussions on many other issues emphasized the effect on physician health.

A number of resolutions addressed alleviation of administrative burdens on physicians. For example, Samer Cabbabe, MD, St. Louis, introduced a resolution on easing the cost burden of interpreter services. It directs the AMA to advocate that payers, including Medicaid, reimburse for these services. Medical student Jared Lammert, Columbia, testified, as well. It passed easily. Several resolutions called for simplification of the Merit-based Incentive Payment System (MIPS), and other adjustments

to the regulatory burden. MIPS is misleadingly named. It is neither merit-based nor an incentive. Instead, it is a system of financial penalties for failing to adopt the reporting mandates of the Quality Payment Program (QPP). If this is gibberish to you, PLEASE refer to the AMA website on MIPS and QPP compliance: ama-assn.org/qpp-reporting.

Medical education was addressed. Several resolutions addressed the special issues of American graduates of foreign schools. Such students have increased financial burdens, they may not be eligible for Title IV funding, and their chances of going unmatched for residency positions is almost 50%. Other resolutions advocated the development of a diverse physician workforce, finding out why Native American applicants have declined, encouraging international graduates, and easing the burden of multiple examinations, particularly the pointless Clinical Skills Examination. The Council on Medical Education issued a report on education about obesity for students, residents, and practicing physicians. There was continuing concern about workforce issues, including a call for more accurate projections of the need for physicians into the future.

The Council on Science and Public Health produced a report on how to reduce the consumption of sweetened beverages. Strategies endorsed included taxation, school lunch programs, public education, and portion control. Resolutions supported healthier food in hospitals, healthier food in food banks, the SNAP program, and WIC. Others included access to treatment for prisoners with hepatitis C infection as well as better access for all such infected individuals. There was support for increased access to paid leave for child care. The phrase "gun violence prevention" is to be substituted for "gun control" in AMA policies. This is pretty much current policy, but is still a useful change. The AMA will review whether the CDC or other agencies should begin to track police-related injuries and deaths. There was a brisk discussion over vaping. While AMA policy has opposed e-cigarettes, there was support for using them as an aid to smoking cessation. But after debate, the matter was referred back to the Council. Lastly, a resolution from Shannon Tai, of St. Louis, called for limiting screen time for children to prevent myopia. It was adopted without debate.

In the legislative arena, health care and its financing were large items. There was great concern over Medicaid. Despite its well-publicized flaws, the AMA has been fiercely protective. There was much concern about plans to cap Medicaid expenditures. A Council of Medical Services report outlined a set of principles by which to evaluate proposed legislation. A core principle is protecting coverage to those currently under Medicaid. There was considerable discussion over whether or not these principles should be adopted and publicized. Many felt that the HOD should not place itself on record, or disclose its strategy to its opponents. In the end, the report was simply referred back to the Council to refine the principles. Both sides of this particular debate wanted to preserve Medicaid, and avoid caps, but were unable to agree on how best to do that. Strangely, both sides of this debate used the same arguments, but reached disparate conclusions. This debate was a testimony both to the difficulties of these issues and to the political polarization surrounding them.

Since health insurance reform may include cross-state insurance policies, the AMA is recommending that such policies should be compliant with the insurance requirements of all states in which it is being sold. As this would remove a major incentive for writing cross-state policies, this policy would in effect oppose most such policies. Nonetheless, protections for patients have been legislated in each state, often with strong support from state medical societies and the AMA.

Treatment of the homeless remains a problem in every part of the country. "Housing first" advocates want to provide shelter first, then treat mental illness and other illnesses later. The AMA supported the "housing first" principle, but recognized that this principle may not be effective in individuals with substance abuse. There were resolutions to improve veterans' health care both within and outside of the VA system. The HOD adopted a set of principles governing coverage of unanticipated out-of-network care. Drug pricing was addressed by resolutions calling for transparency in drug pricing, negotiated drug pricing, and limitations on annual price increases.

Barbara McAneny, MD, a medical oncologist from New Mexico, was elected President-Elect. She will succeed Dr. Barbe in 2018.

At this meeting, AMA dues were kept unchanged, as they have been since 1994. That's 24 years, a proud record of maintaining access to the largest medical organization in the United States. If YOU haven't joined – why not? You need an advocate at the national level. You may not care about politics. But politics cares about you. **MM**

A New AMA Policy – More Time Spent Outdoors May Reduce the Risk of Kids' Nearsightedness

by Shannon Tai

This resolution called for the American Medical Association to limit screen time and increase outdoor activity to prevent childhood myopia, authored by Shannon Tai, medical student at Saint Louis University, and Ingrid Hsiung, pathology resident physician at the Rush University Medical Center in Chicago. It was adopted as AMA policy by the House of Delegates at the 2017 Annual Meeting in Chicago.

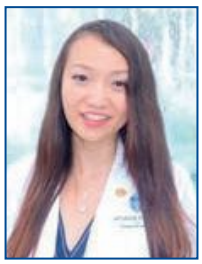
In the 21st century, children are leaving the playground behind to become digital consumers. From the time they can first grasp an object, children begin to play with their parents' phones or iPads and soon grow comfortable using tablets, TVs, laptops, and gaming systems. A national Kaiser Family Foundation survey found that 8-18-year-olds today devote an average of 7 hours and 38 minutes to using entertainment media across a typical day.[1] Furthermore, the post-millennial generation spends about half as much time outside as children did 20 years ago. This concurrent shift towards increased screen time and decreased outdoor play may raise the likelihood of developing myopia. It has long been thought that nearsightedness is mostly a hereditary problem, but researchers led by the *Journal of the American Medical Association*[2] (*JAMA*) and *Ophthalmology*[3] suggest that children's environment exerts a significant influence.

Myopia is the leading cause of visual impairment globally and will likely affect 50% of the world's population by the year 2050.[4] See Figure 1. It already affects 90% of children in Eastern Asia, predominantly in China, Korea, and Taiwan. Myopia's prevalence is an important healthcare concern, as afflicted patients report a lower quality of life and hefty financial consequences associated with a lifetime of refractive correction.[5] Growing up, we carried this burden and struggled constantly to get new contact lenses that could keep up with our ever-worsening myopia. Now, as grade schools begin implementing iPads as learning tools in class and require children to have a laptop for homework assignments, we worry that the educational system is inadvertently failing to address the health care consequences children may suffer.

This concern, in tandem with my interest in ophthalmology and intellectual attraction to medical advocacy sparked my initiative to combat childhood myopia. This then inspired us to write a medical policy to improve public health outcomes for children with nearsightedness.

During the research process for writing this policy, it was found that numerous studies showed increasing time spent outdoors may be a simple strategy to reduce the risk of developing myopia and its progression in children. These evidence-based guidelines had seen success and were already implemented in Chinese, Taiwanese, and Australian schools. For example, a randomized controlled trial published by *JAMA* showed that in six schools with children from grades 1-2, the addition of just 40 minutes of outdoor activity resulted in a reduced incidence rate of myopia by 9.1%.[2]

Our policy was titled, "Decreasing screen time and increasing outdoor activity to offset myopia onset and progression in school children." Myriad problems arise when screen time stymies physical activity and face-to-face social interaction outdoors. To those points, the American Academy of Pediatrics (AAP) recommends that parents limit the amount of screen time their children spend on electronic devices every day and ensure a minimum of 1 hour of physical activity.[6,7] Screen time can also potentially lead to eyestrain and problems as grave as myopia.



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Fortunately, our policy can build upon the foundation laid by the AAP and sharpen the scope to help reduce the prevalence and onset of childhood myopia.

It was truly an emotional and gratifying experience to help navigate this policy through the city, state, and national levels by way of the St. Louis Metropolitan Medical Society, Kansas City Medical Society, Missouri State Medical Association House of Delegates, and, finally, the American Medical Association House of Delegates. We would like to humbly thank Dr. Charles Van Way and the American Academy of Ophthalmology for their mentorship and guidance. Without the aforementioned parties, our dream of helping children avoid the burdens of myopia would not have become a reality. Ours has been a long journey, but thanks to the long hours we put into researching and writing this policy, we may help protect subsequent generations in a new, digital age. The final resolved clause is stated below:

"RESOLVED, That our American Medical Association support efforts to increase outdoor time and promote other activities that have been demonstrated to reduce the progression of myopia in children."

Figure 1

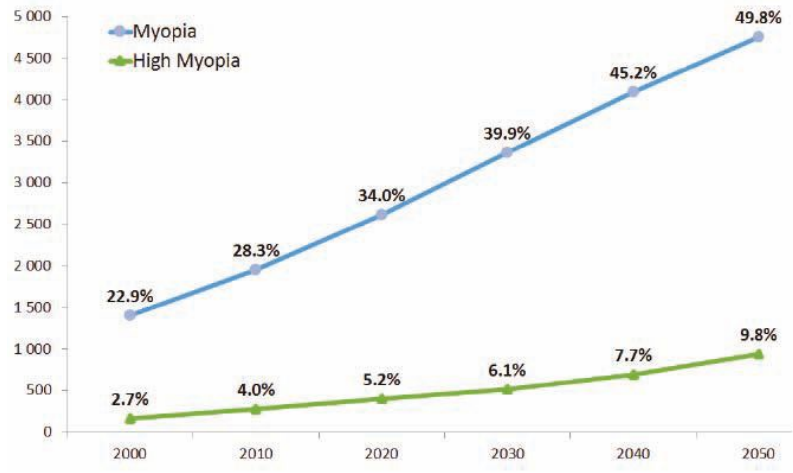


Figure 1 shows the number of people in millions estimated to have myopia and high myopia globally for each decade from 2000 through 2050. Myopia is projected to reach 4758 million people by 2050, 49.8% of the global population. High myopia is projected to reach 938 million by 2050, 9.8% of the global population.

Source: Franchi C, Longo A, Meslin D. High Myopia: the specificities of refraction and optical equipment. Points de Vue, International Review of Ophthalmic Optics. 2016; 73. Available at http://www.pointsdevue.com/article/high-myopia-specificities-refraction-and-optical-equipment#



Medical students at the AMA meeting, from left: Drew Garrone, Elliot Voss, Ariel Carpenter, Jared Lammert, David Barbe, MD, Scott Bernt, and Junaid Yasin.

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MM





Management of Missouri Snake Bites

by Brian Biggers, MD

Ophidiophobia or the fear of snakes, is common in Western civilization. Many stories mention snakes as evil and should be feared. The stories stretch from as back as the Old Testament when Adam and Eve were tempted by the snake all the way to current mainstream pop culture with examples of the famous fear of Indiana Jones of these creatures, to the film Snakes on a Plane. The fear continues to be perpetuated.

The topic of snake bites management in wilderness medicine is dependent on the location. There are approximately 3,000 different species of snakes. There are 375 species of venomous snakes in the world. Worldwide there are 20,000 deaths which occur every year. Most of the deaths are in sub-Saharan Africa and Asia.

The death rate in the United States is 14-20 per year. There have been five reported deaths in Missouri, 1933 by a Timber Rattlesnake, and two copperhead bites in 1965, a copperhead bite in 2014, and recently in 2015 from a cottonmouth. The last patient did not seek medical attention and had a reported lethal dose of oxycodone in his system as well as being legally intoxicated. In fact more people have been killed by dog attacks (32) and lightning (47) in the state during this time period.

In the United States copperheads, cottonmouths, coral snakes, and a variety of rattlesnakes are poisonous. None of the 10 most poisonous snakes live in the United Snakes. The most poisonous is the Belcher's Sea Snake (Hydrophis Belcheri), which resides in the Ashmore Reef in the Timor Sea off the northwestern coast of Australia. Other top snakes include the Inland Taipans, Common Indian Krait, Phillipine Cobra, the King Cobra, Russell's Viper, Black Mamba, Yellow Jawed Tommygoff, Multibanded Krait, Black Tiger Snake, and the Jararacussu.



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There are five poisonous snakes in the state of Missouri: the Osage Copperhead, Western Cottonmouth, Timber Rattlesnake, Eastern Massasauga Rattlesnake, and the Pygmy Rattlesnake. These snakes all belong to the family Crotalidae, also known as pit vipers. All pit vipers have common characteristics for identification:

- Triangular heads
- Fangs
- Elliptical pupil
- Heat sensing pit between eye and nostril

These characteristics allow differentiation between poisonous and non-poisonous snakes (See Figure 1).

Snake venom is used to mobilize prey as well as aid digestion. It is composed of numerous proteins and enzymes. Crotalidae venom is 90% water, 5-15 enzymes, and 3-12 non-enzymatic proteins. Enzymes of snake venom include:

- Proteolytic enzymes
- Arginine ester hydrolase
- Thrombin-like enzyme
- Collagenase
- Hyaluronidase
- Phospholipase A2
- Phospholipase C
- Lactate dehydrogenase
- Phosphomonoesterase
- Phosphodiesterase
- Acetylcholinesterase
- RNase
- DNase
- 5-Nucleotidase
- L-Amino acid oxidase

Identification

Identification is essential in treating snake bites. Location where the snake was encountered as well as identification of markings may help guide your treatment. Don't be surprised if the snake is brought to you by the patient or family for identification.

Missouri's Poisonous Snakes

Osage Copperhead (Agkistrodon contortrix phaeogaster)



This is the state's most common venomous snake. It is pink to orange in color with hourglass-shaped crossbands, which may be dark gray, brown, or reddish-brown. It is found in a variety of habitats ranging from prairies to rocky, wooded hillsides. The species will inhabit abandoned buildings and equipment.

Western Cottonmouth (Agkistrodon piscivorus leucostoma)



The snake measures 30-42 inches. It is black with a black/cream colored belly. This species is incredibly secretive and shy, but if confronted can be quite aggressive. It lives in cypress swamps, sloughs, drainage areas in the Mississippi Lowlands. Populations can also be in the Ozarks around small creeks and rivers.

Timber Rattlesnake (Crotalus horridus)



This is Missouri's largest venomous snake, measuring between 36-60 inches. It has a brown dorsal line, a black tale, a slate grey body with black side, and back markings. This species once inhabited the entire states, but now very rare. It is found in mature forests. Its den is often found on rocky, wooded, south facing hillsides, and bluffs.

Eastern Massasauga Rattlesnake (Sistrurus catenatus catenatus)



This snake is light to dark grey or brown in color. It has 28-40 black dorsal blotches. It is 18-30 inches in length. It is almost extinct in the wild due to habitat destruction and persecution. This species lives in the marches and moist prairies in Northern Missouri.

Pygmy Rattlesnake (Sistrurus miliarius streckeri)



It is small bodied (15-20 in). The body of the snake is grayish brown. It has brown dorsal stripe with black blotches on its back. It is found in glades, second growth forests near rock ledges, and in powerline cuts that are cut through dense areas of a forest.

Snakes from Surrounding States

The Texas Coral Snake (Micrurus tener) will grow to 24 inches (61 cm), but some can reach 40 inches (100 cm). Coloration is black, yellow, and red banding. The male are smaller than the females. There are four subspecies.

The Western Diamondback Rattlesnake (Crotalus atrox) can be found in the surrounding states of Oklahoma, Kansas, and Arkansas, as well as the Southwest. The color pattern consists of a dusky gray-brown, but variants including pinkish-brown, brick red, yellow, pinkish, and chalky white are also found. This color is overlaid with a series of dorsal body blotches which are dark gray-brown or brown in color. The tail has two to eight alternating bands of black and with white or gray. The males are larger than the females. They commonly grow to 4 feet (120 cm), but rarely grow up to 6 feet (180 cm).

The Prairie Rattlesnake (Crotalus viridis) is also known as the Hopi Rattlesnake, Western Rattlesnake, and the plains rattlesnake. Originally thought to have seven different subspecies, now it is thought that there are two clades, a western and eastern, with the Rocky Mountains the dividing line. They can grow larger than 3.3 feet (100 cm). The upper body is light brown to green. There are dark, light-bordered blotches along the back.

Which Snake Bit Me?

In treating snake bite patients in Missouri, we must remember that we are boarded by eight states. Identification is important as one may have a patient bitten by a snake not native to Missouri, though there is significant overlap of the species.

Arkansas poisonous snakes
- Osage Copperhead
- Western Cottonmouth
- Timber Rattlesnake
- Western Pygmy Rattlesnake
- Texas Corral Snake
- Western Diamondback Rattlesnake

Oklahoma poisonous snakes
- Copperhead
- Western Cottonmouth
- Timber Rattlesnake
- Massasauga
- Western Pygmy Rattlesnake
- Prairie Rattlesnake
- Western Diamondback Rattlesnake

Kansas poisonous snakes
- Prairie Rattlesnake
- Massasauga
- Timber Rattlesnake
- Copperhead

Illinois poisonous snakes
- Timber Rattlesnake
- Massasauga
- Cottonmouth
- Copperhead

Iowa poisonous snakes
- Timber Rattlesnake
- Massasauga
- Copperhead
- Prairie Rattlesnake

Nebraska poisonous snakes
- Timber Rattlesnake
- Massasauga
- Copperhead
- Prairie Rattlesnake

Kentucky poisonous snakes
- Osage Copperhead
- Western Cottonmouth
- Timber Rattlesnake
- Western Pygmy Rattlesnake

Tennessee poisonous snakes
- Osage Copperhead
- Western Cottonmouth
- Timber Rattlesnake
- Western Pygmy Rattlesnake

Management

Prehospital Care

Field care should adhere to the principles of ACLS, remember the ABCs. Monitor vital signs and establish IV access with one large-bore IV. Start crystalloid infusion. Start oxygen if available and monitor the airway. Restrict the person's activity and immobilize the affected area. This will most commonly be an extremity as most commonly the site on envenomation. The use of a proximal tourniquet is discouraged. This can lead to venous congestion and increased ischemia. No demonstratable benefit has been seen. Cryotherapy (ice packs) is also discouraged as this increased tissue ischemia. If negative-pressure suction devices are available they are beneficial if started within the first several minutes after the bite. Transfer to definitive facility. Do not administer antivenin in the field.

Emergency Department Care

The majority of snake bites are seen by physicians with little experience. If a regional center is available, the patient should be transferred to this facility. Surgical evaluation is recommended. In the emergency room review the ABCs and assess the patient for signs of shock (tachypnea, tachycardia, dry mucous membranes, mental status changes, and hypotension. Laboratory evaluation should include a complete blood count (CBC), Prothrombin time (PT), Partial thromboplastin time (PTT), Fibrinogen, and fibrin degradation products. Tetanus prophylaxis should be performed. Prevention of secondary infections is important. Systemic antibiotic therapy is commonly given to prevent infections of Aerobacter, Proteus, and Pseudomonas. There is debate of the efficacy and utility of antivenin therapy, but it remains the mainstay of significant envenomation.

Envenomation is graded and determines the need for the administration of an antivenin. The grading of pit viper bites is 0-4.

- Grade 0 – Visible bite but no envenomation
- Grade 1 – Minimal pain and edema less than 25 cm.
- Grade 2 – Moderate pain, edema 25-40 cm, systemic weakness and emesis
- Grade 3 – Severe pain, edema 40-50 cm, petechia, and systemic vertigo
- Grade 4 – Lethal envenomation, widespread edema, shock, seizures, coma, and renal failure

Antivenins

Antivenins are neutralizing antibodies. Two types of antivenin are available. One was first manufactured in 1956. It is derived from horse serum (Wyeth). The antivenin is purified but still contains other serum proteins that can be immunogenic. The latest version, approved by the US Food and Drug Administration (FDA) in 2000 (CroFab, Savage), is a monovalent immunoglobulin fragment derived from sheep proteins.

The old antivenin may still be available, but it is recommended to use the more specific and purified drug. Even with the newer agent, one must remember while the antivenin maybe life-saving, it also may lead to immediate hypersensitivity (anaphylaxis) and delayed hypersensitivity (serum sickness) reactions and must be used with caution. To achieve maximum efficacy, administer within 4-6 hours of the snake bite.

CroFab is made specifically from venom of the eastern and western diamondback snakes, Mohave rattlesnakes, and the cottonmouth/water moccasin snakes. The purpose of any antivenin is to bind the toxins in the venom and prevent both local and systemic results. Side effects occur in one-third are considered mild to moderate. These include utcaria, pruritus, and rash. Rare side effects include severe rash and uticaria and recurrent coagulopathy. CroFab has been used in Crotalid bites with good effect (reduced fasciotomy) and reductions in antivenin toxicity.

The initial amount of antivenin should correlate with the patient's presenting grade.

- Grade 1 – none
- Grade 2 – none
- Grade 3 – 2-4 vials
- Grade 4 – 5-9 vials
- Grade 5 – more than 10 vials

Prior to the administration of antivenin, the patient is tested for sensitivity to equine serum. Intradermal testing is given as 0.2 ml with a ratio of 1:10 or 1:100. A wheal within the first 15-30 minutes is considered a positive test. The patient can also be tested with two drops in the conjunctiva at a ratio 1:1000 ratio. The production of itching and erythema is a positive test. Each vial is diluted in 50 ml of saline and given over 15-20 minutes. Antivenin therapy is continued until progression of symptoms is stopped. Repeated dosing may be necessary.

Surgery is reserved for the development of compartment syndrome initially. Debridement of necrotic tissue may be needed several days after the original bite.

Walker et al. published in 2011 in the American College of Surgeon's on the management of Copperhead's specifically. In this article all snakebites from 1995-2010 were reviewed who presented to East Texas Medical Center, Crockett, a level III trauma center. A total of 142 snakebites were treated. Ninety-four were of the Agkistrodon species-contortrix contortrix (copperhead) or piscivorus leukostoma (water moccasin). Three were rattlesnakes, and three were from the Texas coral snake (Micrurus fulvius tener). Forty-two were unidentified pit vipers. The 88 copperhead bites were then reviewed.

Results from the study demonstrated that the most common presenting symptoms were pain and swelling. Eighty-five percent of the patients had grade 1 envenomations. Ten patients had laboratory abnormalities secondary to the snakebite. Forty-four were admitted for observation. The average length of stay for patients admitted was two days. No patients received antivenin, and no patients required surgical intervention. There were no deaths. One patient had edema and ecchymosis that persisted for more than 1 month.

The conclusion from the study was that accurate identification of the pit viper species involved in snakebites is essential. Although envenomation by a rattlesnake (Crotalus species) may require antivenin and uncommonly surgery, a bite by a copperhead (Agkistrodon contortrix) rarely requires any intervention other than observation. The unnecessary use of antivenin should be discouraged.

Conclusion

The treatment of snake bites is essential in wilderness medicine. It is important to follow the ABCs when managing these injuries. Identification of the snake is helpful. Remember that exotic snakes have been imported into the United States and could be the cause of the envenomation. In the case of Copperheads, identification may save the administration of antivenin. Stabilization and transfer for definitive treatment to the nearest medical facility is essential.

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MM





Clinical Experience With Management of 20 Brown Recluse Spider Bites: An Effective Treatment Regimen

by Troy Major, MD

The bite of a brown recluse spider is very toxic and thus needs a regimen that speeds recovery and minimizes tissue loss. To date, limited resources are known of any such successful regimen. I have constructed and have been using a regimen since 2010 that has proven to minimize and prevent tissue loss if implemented in the first 24 to 48 hours. I would not hesitate to use it as far out as even 96 hours or more. I would like to provide and share my knowledge and discovery of the results and success of this effective treatment regimen discovered for brown recluse spider bites so that others may benefit from it.

Exposures

Most of these observations and treatments prescribed were done in my office and some at Cox Hospital emergency room both which are in Springfield, Mo. It was a longitudinal, observational study using convenience samples of more than 20 patients with bites. A majority of the bites treated have had the spider recovered. A few did not, but those bites presented with actual punctum or double punctum and typical appearance. Some of the bites encountered and treated were severe with very large areas of erythema and swelling, some with lymphangitic streaking, widespread toxic rash, fever, and myalgias. Emphasis cannot be stressed enough that early initiation of treatment is critical!! It is also extremely important to not disturb the site with any type of surgical intervention (e.g. I and D, debridement, or drain placement). If wound breakdown should occur, usual wound care should be used.



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Design and Treatment

This regimen consists of the following: tetanus booster (if not up to date); gram positive antibiotic therapy (usually Cephalexin 500 bid); aspirin (1 full-strength/day) prednisone 80-100 mg/day as a single a.m. dose until bite area has lost the majority of its surrounding erythema and induration (usually 6-7 days), then drop down to 60 mg/day for a few days and gradually tapering off in about 3-4 weeks; gastric protection; and pain relief. Any patient medium-sized and up should start with the 100 mg (80 mg in very small people) dose of prednisone per day as a single a.m. dose. It is very important not to split doses. This dose is reduced to 80 mg/day as soon as toxicity clears (usually 2 to 4 days) and erythema is reduced. Further tapering is based on response.

Data and Patients

I have successfully treated over 20 patients that presented with brown recluse spider bites with this regimen when it was instituted in the time frame described without significant tissue loss. Minor bites were not included. I will present two patients in this article.

Patient 1 was a 38-year-old white male seen two days post-brown recluse spider bite on the left posterior thigh. He presented with a temperature 101, stated he felt "bad" with malaise. The site had the following characteristics: a 20 cm area of erythema and swelling, 10 cm induration, 4 cm bullous grey-white-blue center, 1 cm stab wound, (I and D attempt by walk-in clinic). The regimen for this patient consisted of the following: tetanus up to date,



cephalexin 500 bid, prednisone 100mg/day, one coated aspirin daily, Domeboro® compresses, Spandex/Telfa/Bactroban®, Prilosec OTC®. Followed up two days later (four days post-bite), and the patient was afebrile and felt fine, erythema and swelling were decreased, induration was 7 cm x 5 cm, bullous area unchanged, prednisone level was decreased to 80 mg/day with directions to go to 60mg/day in three days. Followed up nine days post bite, and the erythema and swelling were gone, 4 cm induration remained, central area was 2 cm, ½ cm of white/blue avascularity was noted, prednisone taper schedule initiated (serum AM Cortisol levels checked). Followed up 16 days post bite and found there was a 3 cm induration and a 1 cm ulcer (at stab wound site). The final result was complete healing with no tissue loss and minimal scarring

Patient 2 presented with a brown recluse bite on left anterior thigh three days post bite. (See photos, above.) Patient saw urgent care facility prior to seeing my office, and they treated the site with I and D with drain placement. The site had the following characteristics: 20 cm x 20 cm margin of erythema and swelling, 5 cm of induration, 3 cm of white-grey-bluish center with stab wound and drain, and lymphangitic proximal toxic streaking. The patient was afebrile but "achy". The regimen for this patient consisted of the following: tetanus up to date, prednisone 100 mg/day x 2, then 80 mg/day, one coated aspirin daily, Prilosec OTC®, cephalexin 500 bid, drain removal, Dome Boro/Bactroban. Followed up 10 days post-bite and found the erythema decreased in intensity to faint pink and swelling had decreased. There was a 5 cm x 4 cm whitish area centrally with 2 cm x 2 cm x 1 cm purpuric area containing the iatrogenic "wound". At this point, the prednisone was decreased to 60 mg/day. Followed up 21 days post-bite and found the erythema and swelling are gone, induration 3 cm x 2 cm, hypovascular area smaller, prednisone tapering initiated. Followed up five weeks post bite and found 2 cm x 1½ induration. On the 34th day post bite, a 4 mm ulcer remained. On the 55th day post bite, area was completely healed and only a tiny scar remains.

Conclusion

This appears to be one of the largest case reports of brown recluse spider bites in the literature. (https://www.uptodate.com/contents/approach-to-the-patient-with-a-suspected-spider-bite-an-overview accessed 7/20/2017) They were all managed by the author using the same treatment program outlined in the manuscript. The treatment regimen was well tolerated and rapidly ended toxicity. Relative predictors of tissue loss are size of area of induration, size of area of hypo-vascularity and the time between the brown recluse spider bite and this regimen being started. It is hoped that this treatment will be further studied and of help to physicians especially those who infrequently treat brown recluse spider bites. **MM**

When's My Doctor Coming In?

by Lauren Umstattd, MD

Despite the fact that more than half of all graduating medical students carry two X chromosomes, we as a culture still view physicians as traditionally male.

Another late night in the emergency department..... Shortly after being called by the Emergency Department (ED) physician to evaluate one of our postoperative pediatric patients, I quickly reviewed their chart, jumped in my car, and headed towards the hospital. The patient encounter was fairly typical. I introduced myself to the patient and his mother, sat down on the stool, and began asking questions about what prompted their trip to the ED. After I felt I had enough information, I asked the boy which game he was playing on his iPad and if he was winning. He smiled, put the game down, and was cooperative with my exam. After my history and exam was complete, I discussed my thoughts with his mother. I was comfortable with them leaving, gave her a few things to look out for at home, arranged for close follow-up, and ensured she had our contact information should any more questions or concerns arise. She seemed content with my assessment and agreed with the plan. I left the room, turned the corner, and sat down at a nearby computer to complete the note and orders for our encounter.

Soon thereafter, the patient's mother received a phone call, stepped out of the room, and began discussing her son's trip to the ED with what sounded like a family member. She went on to say they'd been seen by the Ear, Nose, and Throat (ENT) nurse, but no doctor from the team must have been available at 2:00 a.m. She summarized our discussion, hung up, and returned to the room to await discharge.

I have to admit I was upset. I, Dr. Lauren Umstattd, had attended eight years of post-high school education, accrued more than $200,000 in student loans, was working 80-plus hours per week as a surgical resident, intentionally wore a long white coat into the ED exam room, and introduced myself as "Dr. Umstattd, the ENT doctor on call," and was thought to be a nurse.



Lauren Umstattd, MD, MSMA member since 2011, is a Resident Physician, Department of Otolaryngology - Head & Neck Surgery, University of Missouri - Columbia.
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I had gotten out of bed in the middle of the night, given my undivided attention to the patient and his mother, and she didn't even think I was a physician. Granted, I'm only a second-year resident, relatively petite (compared to all my male surgical colleagues), and am often mistaken for younger than my real age...but c'mon. I was there as the specialist, called in by the ED attending, to evaluate this mother's son.

Now I have to pause here and say that I am thankful for all of my nursing colleagues. There's no doubt they are critical to all aspects of patient care. The same goes for mid-level providers, office staff, billers and coders, security officers, and the list goes on. We're each a piece of the giant health care puzzle, working together, with the ultimate goal of contributing positively to patient care.

I've lost track of the number of times I've been mistaken for a nurse, by the patient, their family, a nurse, or even another physician. It happens in the ED, on the inpatient units, in the intensive care, and in clinic. Even though I know there are no foul intentions that come with the misassignment, I can't help but wonder if they've taken my instruction, my assessment, or my questions as they would have had they known I was the providing physician. Does a patient put the same emphasis on an encounter when they think they're being seen by a nurse, rather than a physician?

And I've made the same mistake myself. I'll never forget the time I approached another female physician (unknowingly), asked if she was the nurse taking care of the patient I was getting ready to see, and felt humiliated when she politely responded, "No, I'm a new attending with Orthopedic Surgery."

Despite the fact that more than half of all graduating medical students carry two X chromosomes, we as a culture still view physicians as traditionally male. This cultural norm is even more obvious in the surgical arena, where far fewer providers are female. I'm not sure what the fix is. Or if we even need a fix. I suppose as a junior resident with a world of clinical, anatomical, and surgical knowledge to still accrue, solving society's deep-seated gender bias may not land at the top of my priority list...at least today. **MM**

Dangers of Falling

On June 25, 2017, I celebrated my 90th birthday. One of my primary concerns is to avoid a fall. So far I have been successful. I know of friends, younger than me, who have had serious falls resulting in concussion, fractured ribs, forearm fracture, subdural hematoma, and fatal intracranial hemorrhage. In 2000, there were 283,000 fall-related deaths in the US. Sixty percent of falls occur in the home, 30% in the community, and 10% in nursing homes. Most falls are on same level, standing height, related to tripping, slippery surfaces, poor lighting, or medication. Each year, 11 million seniors 65 and older, one in three, have a fall at a cumulative cost of $20 billion. The most common fall-related injuries are fractures of hip, spine, and forearm. Ninety percent of hip fractures are fall-related. Seniors 85-plus are 15% more likely to have a hip fracture than those age 60 to 65. Mortality of hip fractures reaches as high as 25%.

Now for the good news. There are ways of reducing the risk of falling. Osteoporosis, which increases the risk of fractures, is treatable. To make the home fall-resistant arrange furniture so a stable structure is within reach as much as possible. Install grab bars by toilet and in tub or shower. Have good lighting with a night light for bathroom and stairs. Your physical therapist can prescribe very important lower body and balance exercises, which I do at least daily. Walk like you are on a sailboat with one steadying hand on a chair, table, desk, or the wall. When you stand up after lying down or sitting beware of orthostatic hypotension by standing slowly using support. Wait one minute before walking. If you must walk without support have a stance wider than width of your pelvis. Take short steps, swing your arms, engage heel first, flex your toes. When using stairs, have one stabilizing hand on the rail, and do not carrying a heavy load. If there is no rail, use wall and walk sideways If no wall better crawl than fall. Getting out of a car open the door wide and use door and hand bars to exit and enter. Be careful with curbs and watch the ground in front of you for things that might make you stumble. If necessary get a cart when in a store. Use as a walker or cane if appropriate. Avoid ice and snow if possible. They make spikes for canes and walkers. Play romantic and take the hand of a spouse or friend. There is truth in getting by with a little help from your friends. You younger docs should save this. You will need it if you are lucky to live as long as me. Hopefully you will follow my advice and join the no-fall group.

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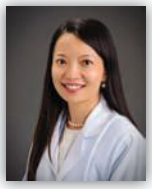
MSMA Members in the News

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

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



John B. Holds, MD, FACS, MSMA member since 1991, is a Clinical Professor of Ophthalmology and Otolaryngology/Head and Neck Surgery at Saint Louis University, and a former president of the Missouri Society of Eye Physicians and Surgeons. He is the new Ophthalmology member replacing Charles Lederer, MD, who is retiring and who has served on the board since 2001.



Kan N. Huang, MD, PhD, MSMA member since 2017, Hematology/Medical Oncology, is an Assistant Professor of Clinical Medicine at the University of Missouri - Columbia. She replaces Daniel Kingsley, MD, who has served on the board since 2016, and is leaving the state to practice in Tennessee. *Missouri Medicine* thanks both Drs. Lederer and Kingsley for their years of service.



Missouri Medicine and the Department of Obstetrics & Gynecology, Washington University School of Medicine, St. Louis, wish to thank their faculty member Andrew E. Galakatos, MD, Professor of Clinical Obstetrics & Gynecology and MSMA member since 1977, for his superb work in coordinating the department's May/June 2017 theme issue "Women's Reproductive Health."

Thank you, Deans of the Missouri Schools of Medicine, for your support and membership in MSMA: Kevin Behrns, MD, Saint Louis University; Darrin D'Agostino, DO, Kansas City University; Patrice Delafontaine, MD; Paula Gregory, DO, Kansas City University – Joplin; Steven Kanter, MD, University of MO – Kansas City; David Perlmutter, MD, Washington University; and Margaret Wilson, DO, AT Still University/Kirksville College of Medicine.

MSMA commends Jim Blaine, MD, for his service to the Springfield community, for having started the OTC Health and Wellness Center, and for his work with the American Heart Association and Million Hearts. MSMA appreciates his support as a member since 1984.





An MSMA member since 2006, Aron Burke, MD, recently merged his practice with Community Hospital-Fairfax.



MSMA is happy to welcome Darrin D'Agostino, DO, to the position of executive dean of the College of Osteopathic Medicine and vice president of Health Affairs for Kansas City University of Medicine and Biosciences, and equally as thrilled to have him as a new MSMA member.



William Dailey, MD, MSMA member since 2010, now practices in Clinton, in addition to seeing patients in Windsor.



Christopher Jung, MD, has been an MSMA member for more than 40 years. Congratulations on joining the new Cape ENT Group.



Nicholas T. Kouchoukos, MD, of St. Louis, was awarded the 2017 A.N. Bakoulev prize from the Russian Association of Cardiovascular Surgeons for outstanding contributions to the development of cardiovascular surgery.

Drs. David and Joel McKinsey, brothers, now provide treatment for infectious disease in Clinton and through telemedicine. They have been MSMA members for a combined 45 years.





Mary Jo Middleton, MD, of Kansas City, was the featured speaker at the first annual Stroke Reunion hosted by Cameron Regional Medical Center on May 22. She's been an MSMA member since 1994.





Congratulations, Terry Morris, MD, MSMA member since 1979, on joining St. Mary's Medical Center in Blue Springs.



Inderjit Singh, MD, of St. Louis, was named a Fellow of the National Kidney Foundation. He's been an MSMA member since 2013 and serves as MSMA District 3 Vice Councilor.



Robert L. Sweeten, Jr., MD, member since 2010, has opened a new practice in Neosho.



MSMA is pleased to have Irena Vitkovitsky, MD, back in Missouri and as an MSMA member again. Congratulations on your work in St. Louis and Kansas City.

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

MPHP Announces New Medical Director



The Missouri Physicians Health Program announces Lisa Thomas, MD, MA, MSMA member since 2005 and Fifth District Vice Councilor, will serve as its new Medical Director. She is a graduate of the University of Missouri where she completed a residency in Psychiatry followed by fellowships in Child/Adolescent and Forensic Psychiatry. She also earned a Master of Arts in Clinical Psychology from Washington University in St. Louis.

She replaces Charles Sincox, MD, FAAFP, MSMA member since 1977, as Medical Director. We thank Dr. Sincox for his many years of dedicated service. He will continue to serve as a Medical Director Emeritus and as a member of the Physicians Health Committee.

Dr. Thomas has worked in the private sector as well as for the state and the federal government. She has experience with inpatient, outpatient, and residential treatment settings. Most recently, Dr. Thomas spent nearly nine years as a staff psychiatrist at the Veterans Hospital in Columbia, Missouri.

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Sept. 16	Determination of Death by Neurologic Criteria
Sept. 23	Fetal Cardiac Screening: A Practical Approach
Sept. 29	Evaluation & Management of the Pulmonary Nodule
Oct. 5-6	Annual Symposium in OBGYN
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UMKC Health Sciences District: An Innovative Enterprise to Advance Health and Health Care

by Steven L. Kanter, MD

UMKC Health Sciences District will pursue a mission based on the core goals of "Vital Directions for Health and Health Care," an initiative recently launched by the National Academy of Medicine.

The University of Missouri-Kansas City (UMKC) School of Medicine is the anchoring institution for an exciting new endeavor in which a dozen of Kansas City's health care institutions that coexist in an area known as Hospital Hill (just south of downtown Kansas City) have agreed to align as the UMKC Health Sciences District.

The leaders of these institutions gathered on May 19, 2017 for the formal announcement of plans to develop the UMKC Health Sciences District as an innovative enterprise that brings together a university with local, county, and state health care organizations.

These organizations include the University of Missouri-Kansas City and its schools of Medicine, Nursing and Health Studies, Pharmacy, and Dentistry; Truman Medical Centers and University Health; Children's Mercy Hospital; the Kansas City, Missouri, Health Department; the Missouri Department of Mental Health's Center for Behavioral Medicine; the Jackson County Medical Examiner; Diastole Scholars' Center; and the Ronald McDonald House of Kansas City.

The collective efforts of these health care institutions will stimulate new opportunities for biomedical research, health professions education, community initiatives, and innovative approaches to the well-being of the more than 16,000 individuals who come every day to work and learn in the Health Sciences District. And it will make UMKC School of Medicine an even stronger academic institution and a better partner to Saint Luke's Hospital of Kansas City, the Kansas City Veterans Affairs Medical Center, and Research Medical Center, all long-time affiliates.



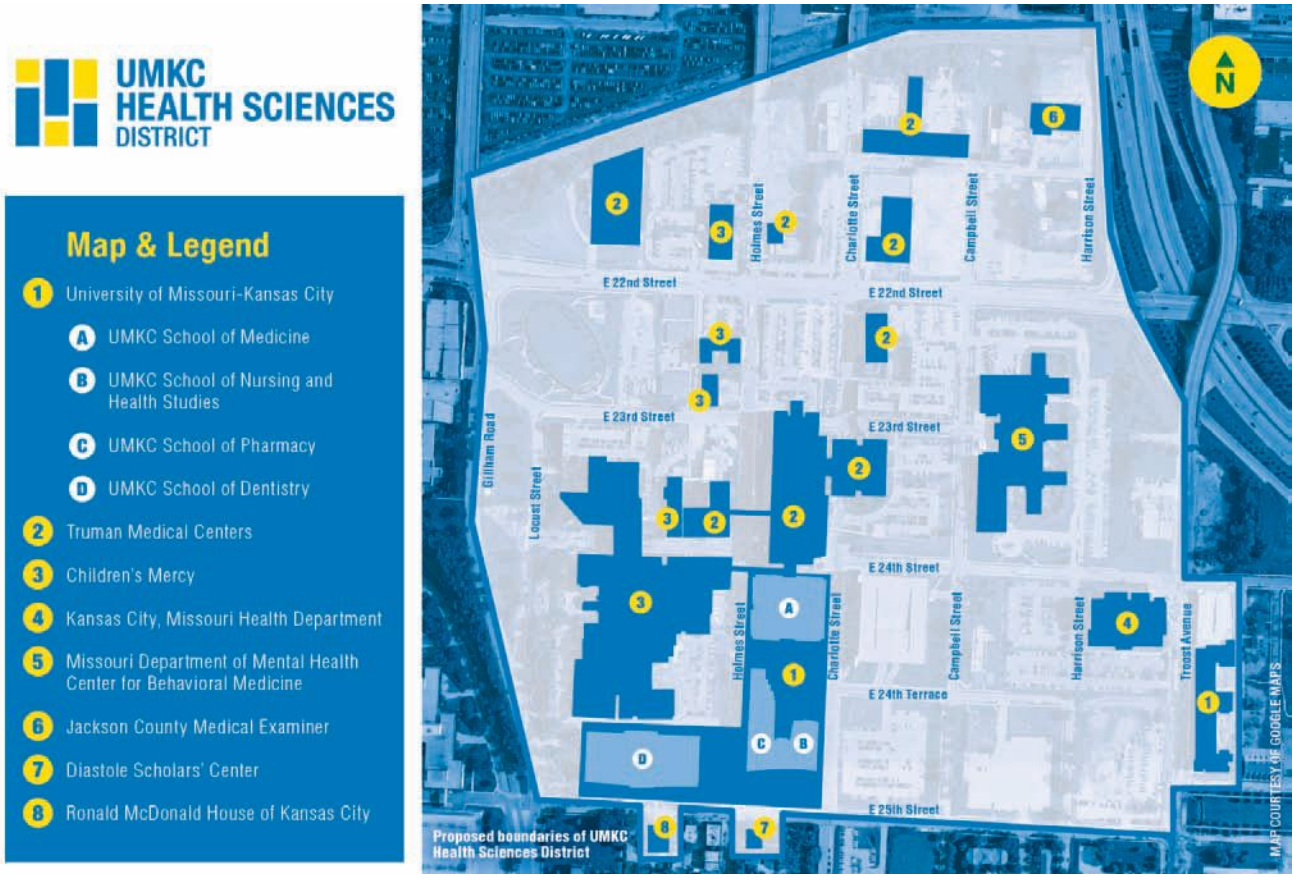
Steven L. Kanter, MD, MSMA member since 2015, is a neurosurgeon, and Dean, University of Missouri - Kansas City School of Medicine.
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An academic health center generates value by fostering a culture of learning and inquiry, by creating feedback loops to use what is learned in the scientific laboratory to advance health and health care, by providing that health care to the sickest patients with the most complex illnesses and to society's most vulnerable individuals, and by educating the next generation of health care professionals to ensure an adequate workforce well into the future. All of these essential endeavors require health care professionals and biomedical scientists who work in highly-functioning, multidisciplinary, multi-professional teams. UMKC Health Sciences District will be a catalyst for developing the most effective teams through an intentional process of collaboration and shared initiatives.

Furthermore, the District has the potential to help attract new talent to the Kansas City region, recruit high-caliber clinician-scientists, move discoveries to the marketplace, develop new approaches to interprofessional education, create jobs, stimulate economic growth, create shared opportunities around employee health and wellness, and coordinate parking, transportation, and security services.

UMKC Health Sciences District will pursue a mission based on the core goals of "Vital Directions for Health and Health Care," an initiative recently launched by the National Academy of Medicine. The core goals are better health and well-being, high-value health care,

UMKC
School of Medicine



and strong science and technology. The District will add health advocacy to fully leverage and integrate its significant expertise in public health, population health, and community health.

Academic health centers create social structures to catalyze communication and intellectual cross-fertilization (e.g., interdisciplinary research conferences, learning communities that comingle professions and disciplines to leverage shared knowledge, multi-professional clinical teams) and physical structures that bring people together to stimulate conversation and new ideas (pedestrian bridges, shortcuts, and walking paths). The institutions that compose the Health Sciences District all exist on a single, walkable campus and, thus, are ideally-situated to pursue these opportunities.

Robert Brook, in his book published by the RAND Corporation in 2015, Redefining Health Care Systems, wrote about three models for producing health: the medical model (i.e., elements of the current health care system including health care professionals, hospitals, long-term care facilities), the public health model (i.e., food and water safety, preventing and controlling epidemics and pandemics, disaster preparedness), and the social determinants of health model (i.e., the effect on health of education, wealth, social status, and other social factors). UMKC Health Sciences District brings together a set of institutions that collectively possess the expertise and resources to integrate all three models for producing health and to apply them in creative and innovative ways to improve health and health care in Kansas City and beyond. **MM**

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Providing Musculoskeletal Care and Education in Kansas City

by Mark Bernhardt, MD

The Department of Orthopaedic Surgery at Truman Medical Center and the University of Missouri—Kansas City (UMKC) School of Medicine has entered a new and exciting era. The newest addition to the Hospital Hill Campus is the University Health Ambulatory Care Center, where the Orthopaedic Surgery Department's clinicians provide the majority of our outpatient musculoskeletal care. This state-of the-art facility is downtown Kansas City's only outpatient clinic and surgery center.

The Department is pleased to provide a variety of articles which we think are of interest to physicians in this edition of *Missouri Medicine*. As the Chairman of the Department of Orthopaedic Surgery, I am proud to showcase our outstanding faculty and some of our medical student and orthopaedic residency registrants. The topics include a small "biopsy" of our faculty's many clinical and academic interests.

Akin Cil, MD, is an Associate Professor at UMKC and the Vice-Chairman of the Department of Orthopaedic Surgery at Truman Medical Center (TMC). Dr. Cil is the Director of Shoulder and Elbow Surgery at TMC, a faculty member in the UMKC Orthopaedic Sports Medicine Fellowship, the Franklin D. Dickson Professor of Orthopaedic Research, and collaborates with the mechanical engineers at UMKC on the Volker Campus, where he holds an adjunct faculty appointment. Dr. Cil and I collaborated with Richard Butin, MD, Department of Internal Medicine at TMC and UMKC, in describing the many adverse effects of smoking on the musculoskeletal system and its repair. All physicians and patients are aware of the negative health effects of smoking on the pulmonary and cardiovascular systems in our bodies. Most patients and many physicians, however, are not aware of the significant adverse health effects of smoking on the musculoskeletal system. In another article Dr. Cil, the immediate past-president of the Missouri State Orthopedic Association, and I and colleagues summarize the results of a survey of Missouri orthopaedic surgeons, showing the tremendous economic impact of orthopaedists in the Show-Me state.



Mark Bernhardt, MD, is the Rex L. Diveley Professor and Chairman of the Department of Orthopaedics at the University of Missouri – Kansas City School of Medicine and University Health Orthopaedics.
Contact: BernhardtM@umkc.edu

James Bogener, MD, Associate Professor at UMKC, is the UMKC Orthopaedic Surgery Residency Program Director. Dr. Bogener is also the Director of Foot and Ankle Surgery and the Director of the Franklin D. Dickson Laboratory at TMC. Dr. Bogener and colleagues review the changing "landscape" of surgical training, from its beginnings in America with William Halsted, MD, to the creation of the Accreditation Council for Graduate Medical Education (ACGME) and to the current requirements of the Next Accreditation System (NAS), with a shift from process-based to outcomes-based education and important emphases on patient safety and measurement of clinical competencies of trainees.

Jonathan Dubin, MD, is an Assistant Professor at UMKC, an Associate Program Director of the UMKC Orthopaedic Surgery Residency Program, and the Director of Musculoskeletal Trauma at TMC. Dr. Dubin and coauthors review the process of device regulation by the FDA. It is important to understand this regulatory process so that we can advocate for our patients and advise them about the safety and efficacy of the implants which are used in their care.

Suhel Kotwal, MD, Associate Professor at UMKC, is a specialist in Musculoskeletal Oncology and Hip and Knee Arthroplasty at TMC and the Director of Joint Replacement at TMC-Hospital Hill. Dr. Kotwal and colleagues present a systematic approach to the successful evaluation and management of a common problem for clinicians, the assessment of the patient with a "lump or bump" on the body.

The Director of Hand Surgery at TMC is Amelia Sorenson, MD, an Assistant Professor at UMKC. Dr. Sorenson and coauthor discuss the pervasive problem of osteoporosis and describe the elements of a Fracture Liaison Service, a multidisciplinary effort and cost-effective way to identify patients at risk, work them up, and manage and follow these patients in order to prevent "the next fracture."

Christopher Shaw, MD, is an Assistant Professor at UMKC and faculty member in the UMKC Orthopaedic Sports Medicine Fellowship Program. Dr. Shaw shares with us his special interest and expertise in the evaluation and management of femoral-acetabular impingement, a common and probably underrecognized disease.

Drs. Jordan Barker, Dane Church, Madelyn Lauer, John Krumme, Joanne Marasigan, and Kirsten Norrell are current UMKC orthopaedic surgery residents and helped author these works. Sean Bonanni, Abhishek Kantamneni, Mitchell Solano, and Belal Tarakji are current or former UMKC medical students who also participated in these academic projects.

We hope you enjoy reading this issue of *Missouri Medicine* as much we have enjoyed contributing to it. **MM**

Adverse Effects of Smoking on Musculoskeletal Health

by Belal Tarakji, BA, Akin Cil, MD, Richard E. Butin, MD & Mark Bernhardt, MD

Smoking has been demonstrated to compromise the quality of bone healing resulting in nonunion, malunion, and increased complication rates after surgery.



Belal Tarakji, BA, Akin Cil, MD, and Mark Bernhardt, MD, (above), are in the Department of Orthopaedic Surgery, University of Missouri—Kansas City School of Medicine, and Truman Medical Center. Richard E. Butin, MD, MSMA member since 1987, is in the Department of Internal Medicine, UMKC, and Truman Medical Center.
Contact: BernhardtM@umkc.edu

Abstract

Smoking remains a prevalent part of present day society, with over 42 million Americans who continue to use cigarettes. Smoking is strongly associated with a variety of conditions that result in increased morbidity and mortality. Research also indicates that smoking has an adverse effect on surgical outcomes. Its effect on the musculoskeletal system is evident and results in postoperative complications such as infection, nonunion, and malunion. These complications also come with a price, as there are severe economic implications of smoking. Patients who smoke may benefit from a period of perioperative cessation to help diminish some of these negative outcomes. It is the physician's duty to educate patients preoperatively about these outcomes and the potential benefit of smoking cessation.

Introduction

This past year marked the 50th anniversary of Surgeon General Luther L. Terry's first report on smoking and health on January 11, 1964. His report aimed to bring to the forefront an issue that had been largely ignored by society: the ravaging effects of smoking on the body. The report was the first step of many that paved the way for crucial laws such as the Federal Cigarette Labeling and Advertising Act of 1965 that required health warnings on cigarette packages etc. More than 50 years later, a great deal of progress has been made towards limiting the toxicity of tobacco on the health of the American public. Despite the positive steps taken towards raising public awareness on the disastrous effects of smoking, there remains much work to be done as the epidemic continues. Over the past 50 years, the smoking rate in U.S. adults has been reduced by 50 percent; nonetheless 42 million people continue to smoke. It is estimated that more than 20 million Americans have died as a result of smoking, and 2.5 million of those deaths were due to diseases related to second hand smoke. Furthermore, almost half a million Americans die prematurely each year from smoking. It is estimated that the fiscal impact due to smoking is approximately $300 billion dollars annually with $130 billion of those dollars being attributed to health care costs.

Cigarette smoke has over 7,000 chemicals, 250 of which have been found to be toxic including ammonia, cyanide, as well as carbon monoxide. There have been at least 69 chemicals identified in cigarettes that are carcinogenic. These chemicals have been found to have a profound effect on surgical outcomes. According to the American Society of Anesthesiology, smoking increases mucus secretion meanwhile decreasing ability of the lungs to clear secretions. Furthermore, it narrows the bronchioles and makes them prone to collapse, resulting in increased pulmonary complications as well as increased susceptibility to infection.[5] The American College of Surgeons recommends smoking cessation at least four weeks prior to surgery and cessation of smoking for an additional four to eight weeks postoperatively can decrease the incidence of wound complications by 50%.

Fifty years after the first Surgeon General's report, there continues to be new evidence published each year linking tobacco to a variety of conditions. This alone is perhaps the most telling sign of the debilitating effects of tobacco use.

This review will attempt to further highlight and discuss the detrimental effects of cigarette smoke particularly as it pertains to the musculoskeletal system, especially in the perioperative period.

Cellular Effects of Smoking

It is important to understand what happens at the microscopic level in order to better comprehend the ramifications of smoking on the body. On a cellular level smoking has been shown to decrease tissue oxygenation.[1] Nicotine, the primary addictive component of cigarettes, has several physiological effects that negatively impact wound healing. These effects are partially mediated through the peripheral vasoconstrictive effects of nicotine. Carbon monoxide binds to hemoglobin 200 times stronger than oxygen, displacing the oxygen dissociation curve to the left. This further interferes with the transport of oxygen molecules to tissues and contributes to tissue hypoxia.[1,2] In one study, smoking was found to decrease subcutaneous blood flow by approximately 50%.[1] Furthermore, smoking for merely ten minutes was found to decrease the oxygen tension for approximately one hour afterward. Hydrogen cyanide found in cigarette smoke primarily affects wound healing by impairing oxidative metabolism and oxygen transport.[3]

Smoking also has been found to induce platelet aggregation and subsequently produce microvascular occlusion, further compounding the detrimental effects on microperfusion.[3]

On a soft tissue level, smoking has repeatedly been shown to impede several steps in the wound healing process. The initial step of wound healing involves the formation of granulation tissue. This stage involves several key mediators including fibroblasts, growth factors, as well as appropriate blood flow via capillaries. Fibroblasts interact with growth factors secreted by macrophages to produce and lay down crucial components of the granulation tissue including fibronectin, collagen, and elastin. Nicotine in cigarette smoke has been found to decrease the proliferation as well as impair the migration of these cellular components.[3,4]

The immune and inflammatory response is the key cog behind the impediment of disease processes as well as resistance to infections. Cigarette smoke has long been documented to impair wound healing and to be the primary cause behind several diseases via its detrimental effects on the immune system. Reduction in blood flow hampers delivery of leukocytes to infected areas and decreases oxygen delivery to leukocytes; these effects combine to contribute to the overall decreased resistance to infections.[5]

Effects of Smoking on Bone Metabolism

The various aforementioned cellular effects on soft tissues also play a role in perpetuating the harmful effects of smoke on bone metabolism. Diminished vascular supply and the resultant thrombosis have been thought to play a role in osteonecrosis. Hirota and colleagues studied the association of smoking with femoral head necrosis and found that smokers had a four times increased risk of developing osteonecrosis.[6]

Another study concluded that the effects of nicotine on bone metabolism are dose-dependent. In low doses, nicotine was found to have a stimulatory effect on osteoblast cells. However in higher concentrations, similar to the exposure in a heavy smoker, nicotine was found to exhibit inhibitory effects on osteoblast proliferation and bone metabolism. [7]

Iqbal and coinvestigators demonstrated that in addition to its inhibitory affects on osteoblasts, smoke toxins also play a role in osteoclast activation. These authors found that benzo(a)pyrene (BaP) and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) found in cigarette smoke interacts with aryl hydrocarbon receptor to induce osteoclastic bone resorption. [8]

Calcium and vitamin D, critical components of bone formation, are also affected by cigarette smoke. Vitamin D3 normally acts via the RANKL receptor to increase calcium and phosphate levels promoting bone formation. The Minos study in 2002 examined 719 patients and the effects of smoking on overall bone mineral density.[15] Smokers were found to have decreased vitamin D and increased PTH. Compared to patients that had never smoked, former smokers were also found to have decreased bone mineral density, comparable to that of current smokers.[9]

Several studies demonstrate an association between postmenopausal smoking and the development of osteoporosis.[10] Daniell studied the effects of smoking and lack of obesity on cortical bone loss. Postmenopausal smokers were found to have an average cortical bone loss of 1.02% per year versus 0.69% in nonsmokers. The rate in smokers increased to 1.19% per year in nonobese postmenopausal women indicating that body weight also plays a role in the development of osteoporosis. In a review of 3,617 hip fracture cases, smokers (n= 467) were younger, suggesting that smoking results in hip fractures at a younger age.[11]

Impact of Smoking on Fracture Healing

Smoking has been demonstrated to compromise the quality of bone healing resulting in nonunion, malunion, and increased complication rates aftef nonsmokers. Overall, the study also showed that smokers had more outpatient visits and required more antibiotics compared to the patients that did not smoke, further indicating that smoking increases the overall rate of postoperative complications.[12]

Humerus fractures comprise 5-8% of fractures overall. Although uncommon, nonunions of the humerus are difficult to manage and thus risk factors must be minimized. Smokers have been found to have an increased rate of nonunions and complications in such fractures. In a study of patients with proximal humerus fractures, smoking was found to be a significant risk factor for complications and often resulted in revision surgery.

The Lower Extremity Assessment Project (LEAP) prospectively studied the time to union, development of infection, and osteomyelitis in 268 unilateral open tibial fractures treated operatively.[13] Patients were divided into current smokers (n=105), previous smokers (n=82), and never smoked (n=81). The study enrolled patients over a

40-month period and they were followed for 3, 6, 12, and 24 months postoperatively. Smokers and previous smokers were 37% and 34% more likely to develop nonunion respectively. Smokers were also found to have an increased infection rate, were twice as likely to develop an infection, and 3.7 times as likely to develop osteomyelitis. Previous smokers were also more likely to develop osteomyelitis. Furthermore, current smokers were found to have slower fracture healing with 24.1% being unhealed at 24 months compared to 9.9% in nonsmokers.[13]

The effect of cigarette smoke on the outcomes of spinal surgery has also been well established.[14] Pseudoarthrosis of spinal fusion surgery is a common complication in smokers. Brown in an early study retrospectively studied 100 patients who underwent a two level laminectomy and fusion. Forty percent of smokers (20 of 50 patients) developed pseudoarthrosis and overall were five times more likely to develop nonunion compared to nonsmokers.[23] In an animal study of the effects of nicotine on spinal fusion, rabbit models exposed to systemic nicotine were found to have a nonunion rate of 100%. In another a study examining 50 patients with spondylolisthesis treated surgically, all instances of pseudoarthrosis (n=6) were found to be in smokers.

Cobb and colleagues examined the relationship between smoking and nonunion in ankle arthrodesis.[15] They found that smokers had a 3.75 times increased risk of nonunion. Assous and Bhamra examined 40 patients with intrarticular calcaneal fractures, fractures with poor functional outcome. They found that 70% of patients that smoked (9 of 13) went on to develop a deep tissue infection versus 15% of nonsmokers (4 of 27). They questioned whether smokers should be treated operatively as smoking significantly impairs wound and bone healing and placed patients at increased risk of surgical complications.

Operative treatment of nonunions has also been shown to have a higher failure rate in smokers. In a 2006 study of patients with established nonunion of the scaphoid bone, patients who smoked had a significantly lower surgical success rate (40% compared to 82.4%) than nonsmokers.[16]

Mallon and colleagues in a retrospective study showed that smoking has also been shown to negatively impact rotator cuff repairs.[17] Patients were divided into two groups: smokers with at least a 40-pack year history and all others who were considered non-smokers. The results showed significant postoperative benefits in the non-smokers in terms of outcomes, which were measured by the UCLA assessment; this included function, pain status, strength, and range of motion. By this measure, non-smokers had significantly better outcomes than the smokers in this study and they did significantly better postoperatively. The investigators and other authors hypothesize that because the rotator cuff is primarily made of type 1 collagen, toxins from cigarettes likely had an effect on its deposition in some way, especially during wound healing. Smokers were found to have 1.8 times less mature collagen in surgical wounds post operatively. A second possible explanation could be attributed to the hypovascularity caused by the nicotine from cigarettes. Limited vascularity could have a direct negative impact on healing, possibly leading to the negative outcomes found.[17,18]

Several studies have been performed examining the benefits of smoking cessation on postoperative complications. Mills and coworkers performed a large meta-analysis looking at 21 studies that attempted to determine the effects of smoking cessation on postoperative complications.[19] Fifteen observational and six randomized trials were included in the criteria. In looking at the pooled data, cessation resulted in a 41% reduction in risk of postoperative complications (with a 95% confidence interval); cessation of at least four weeks preoperatively resulted in the most positive effects when compared to shorter cessation periods. Those postoperative complications included pulmonary complications, wound healing problems, duration of hospital stay, and mortality.[19]

Additional studies have better highlighted the postoperative complications of smoking.[20-21] Warner established criteria for post-operative complications, ranging from wound healing, cardiopulmonary, renal, and neurological complications to increased hospital stay. After defining criteria of complications, a control group and a test group of patients were organized to compare whether smoking cessation had any significant effects on the extent and severity of postoperative complications. Several studies have found that a 50% decrease in cigarette consumption showed a significant reduction in the post-operative complications studied.[20-21] Furthermore, it was found that at least 3-8 weeks of preoperative cessation of smoking had significant positive benefits postoperatively.[20] Length of hospital stay post-operatively is one the most significant criteria evaluated by these studies; the ramifications of these criteria are significant because of the effects on patient health, cost and mortality.

Another use explored by a few of the studies, is the ability to use the preoperative smoking cessation as a "teaching moment" to convince long-term smokers to stop permanently. Though tentative, the benefits were seen in some studies and listed as areas of future exploration.[20-21]

From an orthopedic perspective, Nasell and coauthors looked at patients with upper or lower extremity fractures that required surgical intervention.[22] The complications criteria were determined by one of the following effects/consequences: a need for additional medical or surgical treatment within 6-12 weeks of post operatively, a prolonged hospital stay, extra imaging, or unscheduled outpatient follow ups. This randomized, controlled trial was able to determine the significant effects of smoking cessation which they achieved by enrolling patients in an education program, designed to reduce or stop smoking completely, for at least six weeks after emergency fracture surgery. The investigators found that the odds of having a complication were 2.51 times lower than when smoking was continued.[22]

While numerous studies have been conducted with regards to wound healing and perioperative smoking cessation, very few studies have considered the relationship between bone healing and smoking cessation. Truntzer and coworkers demonstrated that there was a significant benefit in bone healing at the four

week point of preoperative smoking cessation. Cessation four weeks preoperatively was also stressed to have a significant benefit in minimizing complications post operatively.[23]

Cost and Economics of Smoking

In addition to the perioperative effects, the impact of smoking has profound economic implications as well. In a cost analysis of surgical site infections, Urban found that the cost could vary from $400 per case to more than $30,000 depending on the severity of infection (superficial versus deep, etc.). There have been very few studies highlighting the economic benefits of preoperative smoking cessation on fracture surgery. However, Hak and coworkers found the average cost of nonunions to be significant, approximately $11,333 per case.[24] In a prospective study comparing patients with periprosthetic joint infections to noninfected cohorts at a tertiary center, Kapadia and colleagues found the infected group to have longer hospital stays, more readmissions, and increased clinic visits.[25] This amounted to a higher mean annual cost for the infected group at $116,383 compared to $28,249 for the noninfected group.

Discussion

Over the course of the past 50 years, cigarettes and smoking have been implicated in many adverse health effects. Numerous studies demonstrate that tobacco is a toxic product. Smoking has been shown to affect nearly every organ in the body and is a major cause of cardiovascular disease, a variety of malignancies, as well as many adverse musculoskeletal effects. Nevertheless, clinicians continue to see many patients who smoke. From a surgical standpoint, the detrimental effects of smoking can be reduced through intervention. Preoperative cessation has been shown to improve outcomes and help facilitate healing postoperatively. Education of patients and raising physician awareness of this issue is essential to diminish the overall incidence of tobacco-induced diseases.

Given the myriad adverse effects of smoking (nonunion, malunion, delayed fracture healing, etc.), some surgeons have advocated withholding elective surgeries to those patients who smoke. Physicians must uphold a moral obligation towards patients. Principles such as patient autonomy, physician autonomy, and nonmalificence are important considerations. According to the AMA's Principles of Medical Ethics, a physician is free to choose the environment in which he/she provides medical care. This may encompass mitigating surgical risk factors, including smoking, in order to ensure that the best care possible is provided. Ultimately, the decision for surgery is a joint one made by the patient and surgeon after an informed consent discussion of the risks, potential benefits, and alternatives. Patients who smoke pose an additional surgical risk and their outcome may be compromised when compared to nonsmokers. The medical establishment has provided a strong push for risk factor modification over the past several decades to prevent and decrease the incidence of death by largely preventable diseases. It is time to view smoking as a modifiable risk factor in the surgical world. It is the physician's duty to optimize the conditions for surgery and medical studies have repeatedly shown that quitting smoking saves lives and prevents surgical complications.

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Disclosure

None reported. **MM**

The Economic Impact of Orthopaedics in Missouri

by Abhishek Kantamneni, Akin Cil, MD, Brian Treece & Mark Bernhardt, MD

After examining the data, it is clear that orthopaedic-related services make up a profound portion of the healthcare related economic output not only within the state of Missouri, but nationwide as well.



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Abstract

Orthopaedics contributes a significant benefit to the Missouri economy. Economic modeling and data quantified the direct and indirect impact within Missouri. Multipliers were applied to direct expenditures to calculate the indirect impact attributable to initial spending. Nearly $1.8 billion can be attributed to the output of orthopaedic related services. The related physical therapy industry increases this figure to nearly $2.3 billion. It is clear that orthopaedics benefits Missouri with both medical services and economic growth.

Introduction

In 2010, over 5.5 million operations were performed on the musculoskeletal system throughout the United States.[1] These procedures included reduction of fractures, total joint replacement, and discectomy, among many others. This figure comprises more than 10% of the total number of procedures completed during that year, clearly proving the evidence that orthopaedic surgery makes up a significant portion of procedural medicine in the United States. As the population ages and as obesity epidemic continues to lead to medical comorbidities such as osteoarthritis, the need for orthopaedic care is projected to increase [2,3,4]. While the value of orthopaedic surgery in the quality of patient's lives and their level of physical function it is unclear what the economic implications of orthopaedic surgery are on the local economy.[5,6] Our goal was to quantify the economic benefit that is attributable to the practice of orthopaedic medicine in the state of Missouri.

Materials and Methods

The data for this study were collected by a consulting firm; Development Strategies at the request of the Missouri State Orthopaedic Association.[7] In order to discuss the metrics that would be followed, the staff of Development Strategies met with a representative from the Missouri State Orthopaedic Association. The American Association of Orthopaedic Surgeons (AAOS) Orthopaedic Surgeon Census for 2012 was consulted to understand the total number of orthopaedic physicians in the state. With this data, a confidential online survey was developed to gain insight into the operational spending and staffing patterns of practices throughout Missouri. This survey included questions regarding general background information such as type of practice and number of patients served annually, staffing information such as the number of physicians related to orthopaedic activity and number of support staff, and operational spending information such as average annual labor costs and non labor expenses. In order to compare the data more effectively, the two highest and two lowest values collected were omitted and reanalyzed. The complete survey can be found in the appendix by contacting Dr. Bernhardt.

Data from the U.S. Economic Census, Bureau of Labor Statistics and Bureau of Economic Analysis was obtained in order to estimate the jobs supported by orthopaedic related activity within the state, along with the direct wages attributed to orthopaedic care. Additionally, multiplier coefficients were obtained for the state of Missouri from the U.S. Department of Commerce, Bureau of Economic Analysis [7]

The multiplier coefficients are obtained from the U.S. Department of Commerce and it's Regional Input-Output Multiplier System (RIMS-II).[7] The RIMS-II forms multiplier coefficients based on data reported by businesses, individuals, and government agencies to the corresponding state and federal governments. The data are representative of geographic areas that are made up of one or more counties. The multipliers were designed to demonstrate the indirect economic effects of direct expenditure on household earnings, employment, and output defined as the total new or added economic activity at all points of the production process. The hospitals' multipliers are then applied to the direct non-labor expenditures for all orthopaedic entities including, but not limited to, private practitioners, academic institutions, orthopaedic centers, and hospitals. However, as the employees of these orthopaedic entities spend their wages differently, distinct household multipliers are applied to the estimated annual payroll expenditures.

The study examined both direct and indirect multiplier economic impacts on the state economy. Direct impacts were defined as the amount of money spent to operate orthopaedic related care at orthopaedic centers, hospitals, academic institutions, and private practices. Direct costs were further divided into labor costs and non-labor expenses such as equipment and utilities. The multipliers were applied to the direct annual expenditures to calculate the indirect economic activity that is attributable that initial spending.

The indirect economic effects are the result of the aforementioned multiplier effects imposed on the direct expenses of orthopaedic related activity. In order to operate an orthopaedic center, for example, the center must purchase medical equipment and routine supplies, pay for utilities, and contract with security personnel. The businesses that provide these goods and services take the direct expenditures spent by the orthopaedic center and invest it in various economic.[8]

The direct fiscal benefits derived from the practice of orthopaedic related care are calculated using assumptions based on actual tax revenues collected by the state government. To determine the likely tax benefits for the state, the taxation rates are applied to the estimated annual wages of employees. The total taxation benefits to the state were calculated using a combination of the employees' individual income taxes derived from direct wages from orthopaedic entities, corporate income taxes, sales and use taxes generated by spending of the household wages at retail outlets, and other miscellaneous state taxes.

The orthopaedic industry was defined for this study using the North American Industry Classification System (NAICS).[9] This is the primary classification system utilized by the businesses and governments in the United States to classify economic activity based on business type. A two-digit code describes economic sectors in more general terms, with six digit codes used to classify more specific activity. Using data from the Bureau of Labor Statistics, Bureau of Economic Analysis, and U.S. Economic Census, economic metrics including, but not limited to, GDP, employment wages, revenue, and spending could be quantified.

Results

The practitioner survey provided valuable information regarding the demographics of the orthopaedic related care industry within Missouri. There are an estimated 491 practicing orthopaedic physicians within the state. Of the 436 practitioners that were contacted by email, there were 20 responses that comprised approximately 44 percent of the orthopaedic practitioners in Missouri. These responses were used to form reasonable assumptions about average staffing and spending patterns by orthopaedic practices across the state. The results of this survey are summarized in Table 1.

Based on the results of the economic impact study conducted by Development Strategies, the orthopaedic care industry generates nearly $1.8 billion dollars in output for the state of Missouri. The direct expenditures by orthopaedic entities made up of the labor and non-labor expenses contributed $633.6 million to this total figure. The remainder of the economic impact can be attributed to the indirect effects of this primary expenditure. The multiplier coefficients described earlier are applied to the primary expenditure in order to calculate the total economic impact that can be attributed to the initial spending. A multiplier of 2.158 can be applied to the direct operational expenditures of $374,469,000. This leads to an additional $808,590,000 in economic spending within the state. This trend is seen again when examining the funds spent on employee compensation. The direct

Table 1 describes the responses to the Orthopaedic Practitioner Survey from practicing orthopaedic surgeons throughout Missouri. It aims to clarify the demographics of orthopaedic providers within the state.

TABLE 1 Missouri Orthopaedic Practitioner Survey Results

Patients per Orthopaedic Physician	Low	High
Min Response	125	188
Max Response	5,400	6,000
Average	2,087	2,620
Median	1,167	1,667
Patients per Orthopaedic Physician + Staff	Low	High
Min Response	13	19
Max Response	931	1,034
Average	374	478
Median	253	323
Referrals per Orthopaedic Physician	Low	High
Min Response	29	36
Max Response	4,000	4,600
Average	784	1,014
Median	321	507

Number of Staff per Orthopaedic Physician	
Min Response	1.0
Max Response	9.3
Average	5.3
Median	5.0

Occupational Breakdown	Min	Max	Average	Median
Nursing	4.6%	40.0%	25.8%	25.0%
Admin	12.0%	69.2%	43.9%	45.8%
Technicians	4.0%	40.0%	16.6%	16.7%
Other	0.0%	44.6%	10.0%	0.0%
Other	0.0%	22.9%	2.5%	0.0%

Proportion of Non-Labor Spending to Wages	
Min Response	9.9%
Max Response	64.0%
Average	42.9%
Median	45.2%

impact attributed to employee wages was $258,880,000. After applying a 1.360 multiplier to this value, there is an additional $351,999,000 in economic output related to employee wages. In total, the data show that the indirect economic impact is nearly double the direct expenditures that it is derived from. This is supported by the calculated multiplier rate of 1.832 within the state of Missouri. The total economic impact determined by the summation of these values reaches approximately $1.8 billion.

Statewide economic impacts also come in the form of taxation. The data for taxation revenue can be found in Table 2.

Using the data for average annual payroll assumptions within the industry, it is estimated that the total payroll is $272,505,000 in 2013 dollars. This estimate is decreased by 5% to account for employees that reside outside the state of Missouri to achieve the estimated direct employee wages described above. Based on the taxation specifications within the state, the direct earnings for Missouri workers generate $12.4 million in fiscal benefits. Additionally, the indirect earnings for Missouri are estimated at $341,306,000 in 2013 dollars. By applying the same taxation rate, these earnings generate an additional $15.6 million in tax benefits for the state. As a result, the employee earnings derived from work within the orthopaedic industry adds over $28 million in taxes to the $1.8 billion in combined economic output.

The survey results indicate a very wide range of physical therapy referrals per physician ranging from 29 to 4,600, leading to low average of 723 and a high average of 940. When excluding the bottom two and top two responses, the low average becomes 371 and the high average decreases to 571. Therefore, there are an estimated average of approximately 500 referrals per orthopaedic practitioner, resulting in an estimated average referral number of 245,500 per year.

The physical therapy industry is also a contributor to the economic output of orthopaedic related services in Missouri. The data collected describe only the economic impact as a direct result of orthopaedic referrals. The results examining the average annual economic impacts of physical therapy practices supported by orthopaedic referrals are summarized in Table 3.

Additionally, there are $7,956,000 in state tax revenues that can be attributed to the direct and indirect earnings of workers in the physical therapy industry. In total, the combined economic output of the orthopaedic industry and the physical therapy industry is nearly $2.3 billion.

In addition to the economic impacts of patient care related services, there are economic benefits caused by the construction of orthopaedic related care centers. Since 2004, the construction of these orthopaedic related facilities has led to an estimated investment of $222.5 million within the state. This sum can be divided amongst five projects, the most recent being the Mercy Orthopaedic Hospital in Springfield, Missouri opened in 2013. Using economic modeling similar to what utilized for the analysis of care related services, the construction of this facility led to a combined direct and indirect economic output of $173,090,000 and tax revenues of $2,160,000 within the state. The data summarizing the investments made by the construction of these facilities can be found in Table 4.

Table 2 aims to quantify the total economic benefits that can be attributed to orthopaedic related services in the state of Missouri.

TABLE 2	Average Annual Direct and Indirect Fiscal Benefits from the Orthopaedic Industry on the Missouri State Treasury		
	From Direct Earnings for Missouri Workers	From Indirect Earnings for Missouri Workers	Totals
Multiplier Earnings ($)	$272,505,000	$341,306,000	$613,811,000
Estimated Taxes based on Direct/Multiplier Earnings			
Individual Income Taxes ($)	$7,203,000	$9,022,000	$16,225,000
Corporate Income Taxes ($)	$594,000	$744,000	$1,338,000
Sales and Use Taxes ($)	$3,608,000	$4,519,000	$8,127,000
Other Taxes and Fees ($)	$1,057,000	$1,324,000	$2,381,000
Total ($)	$12,462,000	$15,609,000	$28,071,000

Table 3 quantifies the economic benefit of the orthopaedic referral based physical therapy industry in the state of Missouri.

TABLE 3	Average Annual Economic Impacts of Physical Therapy Practices Supported by Orthopaedic Referrals on Missouri, in 2013 dollars		
	Operational Expenditures	Employee Compensation	Total
Direct Spending ($)	$99,059,000	$69,819,000	$168,878,000
Multipliers			
Output	2.088	1.36	1.787
Earnings	0.763	0.357	0.595
Employment	16.636	11.02	13.917
Added Economic Impact on Missouri			
Output ($)	$206,825,000	$94,933,000	$301,758,000
Earnings ($)	$75,532,000	$24,939,000	$100,471,000
Indirect Jobs Held by Missouri Residents	1,500	700	2,200
Total Economic Impact on Missouri			
Output ($)			$470,636,000
Earnings ($)			$170,290,000
Direct Jobs Held by Missouri Residents			1,200
Total Direct and Indirect Jobs Held by Missouri Residents			3,400

Discussion

Orthopaedic surgery makes a significant impact on the Missouri economy. The data show that nearly $1.8 billion can be attributed to the output of orthopaedic related services within the state. This figure becomes is put into perspective when examined in the context of the total impact of healthcare in Missouri. A report prepared for the American Medical Association in 2014 noted that the total direct and indirect economic output of physicians in Missouri was $20.3 billion.[10] The orthopaedic related care industry makes up nearly 10 percent of the total healthcare output in the state.

Similar comparisons can be made when examining the output of healthcare entities within the state of Missouri. A report compiled by the University of Missouri Health System described a total economic output of approximately $2.4 billion based on annual expenditures totaling over $1 billion.[11] The statewide economic output of only orthopaedic related care nearly equals the combined economic output of the entire University of Missouri healthcare system.

Not only does orthopaedic related care make up a significant portion of the state's healthcare related output, this trend continues at the national level. A survey

Table 4 quantifies the economic benefit secondary to the construction of the Mercy Orthopaedic Hospital in the state of Missouri.

TABLE 4	Average Annual Economic Impacts of Mercy Orthopaedic Hospital Construction on Missouri, in 2013 dollars		
	Non Labor Expenditures	Employee Compensation	Total
Direct Spending ($)	$46,000,000	$10,925,000	$56,925,000
Multipliers			
Output	2.202	1.36	2.041
Earnings	0.692	0.357	0.628
Employment	17.432	11.020	16.202
Added Economic Impact on Missouri			
Output ($)	$101,310,000	$14,855,000	$116,165,000
Earnings ($)	$31,823,000	$3,902,000	$35,725,000
Indirect Jobs Held by Missouri Residents	751	113	863
Total Economic Impact on Missouri			
Output ($)			$173,090,000
Earnings ($)			$46,650,000
Direct Jobs Held by Missouri Residents			$224
Total Direct and Indirect Jobs Held by Missouri Residents			1,087

conducted by Merritt Hawkins polled hospital chief financial officers to examine physicians' inpatient and outpatient revenue. The data showed that the average annual net inpatient and outpatient revenue generated by physicians for their respective institutions was approximately $1.4 million. However, orthopaedic surgeons generated nearly $2.7 million, almost double the average annual net revenue and over $500,000 above the next closest specialty.[12]

Upon comparison to other specialties, orthopaedic surgery continues to demonstrate a significant economic impact. In Missouri, family medicine physicians play an important role in the delivery of primary care throughout the state. A report prepared by the Robert Graham Center for Policy Studies describes the economic impact of family physicians throughout the United States. The data showed that on average, family physicians in Missouri generate a combined direct and indirect economic impact of $1,048,595 per physician.[13] In comparison, the data shows that orthopaedic surgeons within the state generate $1,290,374 in direct economic output per physician. If the indirect economic output is added on to this sum, the combined economic output per orthopaedic practitioner in Missouri swells to $3,654,099.

An even larger impact is noted when considering the additional impact of the physical therapy industry and its relationship to orthopaedic care. There is a direct relationship between the physical therapy industry in Missouri and the orthopaedic industry within the state. The Orthopaedic Practitioner Survey noted that there were an average of 500 referrals to physical therapy from orthopaedic practitioners. Using the estimate of 491 practitioners within the state, there are an estimated 245,500 referrals to physical therapy per year. Nearly $192 million in revenue, of which $73,494,000 is designated for payroll, can be attributed to these orthopaedic referrals alone. After applying the same economic modeling used to estimate the direct and indirect economic impact of orthopaedic practitioners, the physical therapy industry has a combined economic output of $470,636,000 in Missouri. Clearly, there is a positive economic and patient care relationship between the two groups of healthcare professionals.

While it is evident that orthopaedic related services lead to favorable economic impact on the state, the need for these services will continue to rise in the future. Conditions prevalent in society such as obesity are significant causes of orthopaedic comorbidity.[3] Data collected by the Centers for Disease Control found that 30.6% of obese individuals reported physician diagnosed arthritis, compared to 16% of normal and underweight individuals.[4] An estimated 67 million Americans will suffer from arthritis by the year 2030.[14] With this increase in disease prevalence, the healthcare

and societal costs of such ailments will rise in tandem. Using 1994 data, an estimated $3.9 billion in lost productivity was attributed to employees with body mass indices over 30. This is reflective of nearly 39.2 million lost days of work.[15] It is clear that the need for orthopaedic related services will continue to grow in the future. Not only can orthopaedic surgery have a positive economic impact, orthopaedic related services can lessen the negative economic implications of medical conditions such as obesity and arthritis.

The limitations of the study include the NAICS code system's inability to classify the orthopaedic industry accurately as a whole. This limited the scope of the study due to difficulties in describing the orthopaedic related services industry. The term "orthopedic" is found 30 times in the NAICS dictionary and is associated with eight unique six-digit codes. These codes include, but are not limited to, the manufacture of orthopaedic shoes, orthopaedic hospitals, and orthopaedic device manufacturers. As such, there was difficulty in accurately categorizing the orthopaedic related care industry. In order to address these issues, the industry categories themselves had to be examined in order to avoid double counting and subsequent overestimation of the multiplier effects. This limitation could be overcome with more specific NAICS coding designations. A second limitation is the incomplete response to the Orthopaedic Practitioner Survey. The survey is a snapshot of nearly half of the orthopaedic practices in the state of Missouri. The survey was sent to 436 of the 491 licensed orthopaedic practitioners in Missouri. Furthermore, there were 20 responses, which represented approximately 44% of the practitioners in the state. The data were then extrapolated using the information contained in the completed surveys. Additionally, certain practices reported significantly higher values than the rest of the responses. This could have been due to variation between the various practice types or simply confusion about the survey itself. As a result, these responses were not held to any statistical testing. This was addressed by reexamining the data after excluding the top two and the bottom two responses as described earlier. Had a larger proportion of the practitioners responded, a more complete picture of the Missouri orthopaedic industry could have been ascertained.

After examining the data, it is clear that orthopaedic related services make up a profound portion of the healthcare related economic output not only within the state of Missouri, but nationwide as well. Orthopaedic related services make a significant economic impact within Missouri. These services bring wages to employees, taxes to the state and federal budgets, and healthcare to the patients who need such care. Orthopaedic surgery benefits the state by providing life changing medical services and economic growth throughout the community.

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Disclosure

None reported.

MM

New Paradigms in Post-Graduate Surgical Education

by Kirsten Norrell, MD, Joanne Marasigan, MD & James Bogener, MD

In order to meet the demands from the public and from regulators, residency programs must respond to demonstrate we are generating safe and effective physicians and surgeons.



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Abstract

With a growing focus on patient safety and trainee education, the Accreditation Council for Graduate Medical Education implemented changes including work hour restrictions, focused clinical competencies, and the Next Accreditation System (NAS). The NAS poses initial challenges on residencies with the implementation of surgical simulation programs and defining resident competency. It is the hope that innovative training methods will allow for improved advancement of knowledge and surgical skills given the current direction of post-graduate surgical training.

Introduction

Medical education and surgical training has changed drastically throughout the past century. William Stewart Halsted, the "father" of American surgical residency system developed a residency program at John's Hopkins in 1889 with the following principles: knowledge of basic sciences, research and graduated patient responsibility.[1,2] These principles are still the focus of modern day resident education. Halsted's rigorous program had no definite length of training in which assistant residents underwent competition to advance. Halsted envisioned "a system…which will produce not only surgeons but surgeons of the highest type, men [and women] who will stimulate the first youths of our country to study surgery and to devote their energies and their lives to raising the standard of surgical science."[1]

In contrast, Edward D. Churchill of Massachusetts General Hospital greatly opposed Halsted's surgical training model due to the indefinite residency time. Churchill believed surgical training should be based on instructed knowledge and developed a five-year residency program in 1931-the rectangular model. He believed the competitive nature of the pyramidal model created too much pressure on the resident which distracted from their education.[2]

During this same time, the Clinical Congress of Surgeons, now the American College of Surgeons (ACS), formulated minimum requirements for surgical education in 1912 after the Flexner report exposed overproduction of physicians and inadequacy of medical training.[1,3] In 1937 the American Board of Surgery implemented the first examination to evaluate resident knowledge. Churchill's rectangular model gained popularity, while Halsted's principle of graduated patient responsibility was maintained to become what we now know as residency.[2]

Since Medicare and Medicaid were implemented in 1964, new challenges to resident education have arisen. Attending surgeon

presence was required for all procedural billing. Prior to Medicare, residents were often responsible for all aspects of care, including surgery as they received graduated responsibility. This system of patient care, a Halsted key principle, is today not as pronounced due to current social, ethical, political and economic climates.[2] In order to accomplish adequate residency training in the 21st century, when knowledge is vast and ever growing, standardized resident evaluation beyond test questions is needed.[1] Therefore the ACGME implemented the next accreditation system (NAS) in an attempt to institute standardized outcomes-based residency education with the goal of graduating competent residents.

The Next GME Accreditation System

The Accreditation Council for Graduate Medical Education (ACGME) was established in 1981 to address two major issues, the variability of resident education quality and formal subspecialty education. Today the goal of the NAS is to better prepare physicians to practice in the 21st century, accelerate ACGME accreditation based on educational outcomes, and reduce burden associated with site visits.[4] In addition to NAS, the Clinical Learning Environment Review (CLER) was developed in 2012 to address patient safety, resident and fellow supervision, health care quality, transition of care, duty hours and fatigue management, and institution professionalism. All of these changes represent a pivotal shift from process-based learning to an outcomes-based education.[5]

The NAS requires programs to submit resident milestone data every 6 months, which is then synchronized with residents' semi-annual evaluations.[4] These milestones are individualized to each specialty in order to fulfill the six core competencies: medical knowledge, patient care, professionalism, interpersonal communication, practice-based learning with demonstration of personal improvement, and systems based practice with system improvement.[6] The Residency Review Committee (RCC) for orthopaedics chose to divide medical knowledge and surgical competency into milestones based on core procedures. The RCC chose to base these milestones on 16 procedures thought to be representative of fundamental knowledge required for a successful orthopaedic career—a "biopsy" of the residents medical knowledge and patient care skills. In total, orthopaedics has 750 milestones that are reported to the ACGME every 6 months on each resident—the most of any specialty.[7]

By July 2014 all specialties entered the NAS. The hope was that data driven annual review of performance, rather than episodic site visits would help identify low-performing residency programs more quickly and the appropriate program support could be given before major issues arise. The NAS also allows the ACGME to extend site visits from 5 to 10 years for high functioning programs. In addition, with the frequency of data collections, a higher rate of turnover is possible for programs on probationary status. Early data from the NAS demonstrates that the number of accredited residency programs has gone from 9472, prior to the NAS, to 9793 in 2014-2015, after implementation of the NAS. Only 34 of the 328 programs on "Probationary accreditation" or "Continued accreditation with warning" did not progress to full accreditation. There were also 189 programs newly identified as needing a warning or probationary status.[4] This early data is evidence of the effectiveness of the ACGME's NAS.

Development of Objective Competency Measures

While the driving force behind the ACGME NAS is the competence of graduating residents, the ACGME does not clearly define competence. This is largely because clinical competence is an individual trait and the ACGME certifies programs, not individual residents. Therefore the milestones provide a framework for the knowledge and skills residents should achieve combined with a measurable tool to identify areas of improvement. These milestones assess what residents are doing in the clinical workplace, rather than how they perform on written and simulated examinations. With regards to surgical specialties, these skill evaluations are used to assess how well programs are meeting ACGME standards to provide adequate operative experience with sufficient exposure.

Competence, by definition, is subjective and dependent on the individual. Milestones are part of an attempt to objectively evaluate something that is

inherently subjective. This may be perplexing within surgical specialties because the ACGME Review Committee for surgery states that "Performance of this minimum number of cases by a resident must not be interpreted as equivalent to competence achievement." Therefore, it is still solely up to the individual program to appropriately identify residents that are not adequately meeting milestones as expected and create a plan for addressing deficiencies. In addition, competency is not a stable trait. Some who competently perform a procedure one day may not the next day or a decade later. Potts elegantly describes competency as something that is "usually easily recognized when it is observed and even more easily recognized in its absence… Competency is an ill-defined but observable task-specific and unstable condition of individuals."[6]

There are multiple barriers to true competency-based training described by Potts et al which are relevant to the challenges programs may face with the NAS. There is a need to educate faculty at the institution and all of the programs' associated hospitals on teaching, feedback and evaluation of competency. This requires both structural and educational changes which make a solely competency-based educational system difficult to implement under the current NAS.[6] For high performing programs, there may be opportunities to apply for experimental competency based curriculums. Even within the parameters of the NAS, residency programs are instituting novel training systems that embody this trend towards standardized competency-based evaluation.

Surgical Skills Training

Although there is currently no optimal method to measure surgical competency, the move of resident education from an apprenticeship model to a competency-based type has led to the implement of surgical "boot camps" across the nation.[9,10] With 80-hours per week duty hour restrictions, the variability of exposure to surgical procedures, and heightened concern of medico-legal consequences, training programs are attempting to give residents a solid set of surgical skills upon which to build. Current resident physicians are now expected to reach the same level of competency as their predecessors over a shorter amount of clinical hours. Therefore alternative methods for surgical training are becoming more appealing. Synthetic, animal, and cadaver models have been commonly utilized in surgical simulation training. While this training has been used for decades, these exercises have only recently been quantified by standardization and the development of goals and objectives for use in resident education.[11]

Surgical simulation has been influenced by long-standing models of technical education in other fields such as aviation, where simulation exercises encompassing various scenarios are a regular practice.[11] These exercises allow learning in a low-stress environment, have no patient risk, and give immediate feedback. In arthroscopic surgery, evidence indicates that virtual simulation decreases the learning curve for junior residents while allowing adequate transfer for skills to the operative room.[12] The decreased learning curve could lead to decreased operative time and possibly decreased patient complications. These results are promising for the orthopaedic field and have mirrored the laparoscopic studies in general surgery training programs. In 2009 the ACS became the first surgical field to require residents to pass a technical proficiency program in order to obtain board certification.[13]

At this time the American Board of Orthopaedic Surgery does not currently have a technical skills examination required for board certification, but it appears the field is moving in that direction. In July 2013 the ABOS and RRC introduced 17 surgical skills modules to be implemented in all orthopaedic surgery programs during the PGY-1 year.[15] This was an important step in orthopaedic training towards standardizing the evaluation of surgical skills. Many programs have implemented 1 month of basic skills training[9,10] whereas at our residency program, PGY1s spend 1 hour a week throughout the year in our orthopaedic surgical skills lab led by faculty. Much debate remains on the best way-longitudinal or clustered-for the training and retention of surgical skills.

Although numerous orthopaedic procedures may be simulated in a skills lab, ensuring the transition of these skills to the operating room is of critical importance. With the abundance of technological advances, there have been efforts to bridge this gap.

The University of Iowa has evaluated residents' real-life surgical experiences using a GoPro from a point of view perspective while Dartmouth is currently studying video-assisted feedback using Google Glass.[9,16] Due to the material cost and time constraints of video capture analysis, these innovative concepts are not yet a common practice in surgical assessment of residents.

While the goal of resident evaluation in the operating room to provide objective feedback, it remains a subjective assessment based upon the interaction of the supervising attending with the resident during each procedure. Attending assessments intra-operatively and post-operatively remain the predominant means of providing surgical evaluation. These evaluations become officially recorded as "the milestones" and are the current standard for assessing technical competency. To streamline milestone evaluations our program has utilized an online milestone tracking and reporting tool to make the process simpler. This novel online tool has easy milestone access, no lost paperwork, and allows immediate feedback to our program and residents to note strengths and weaknesses in education. Furthermore, the novelty of the program breaks the individual milestones down into "yes/no" questions the faculty answers to aggregate an overall milestone level. The "yes/no" evaluations are sent to the faculty by the resident on each case, and the faculty simply completes the "yes/no" evaluation on their smartphone.[7,17]

Training capable surgeons is the goal of all surgical residency programs but determining the methods that best support technical proficiency is still being studied. As surgical simulation research becomes more widespread, we anticipate accelerated resident progress that can be more objectively measured through milestones.

Discussion

The ACGME NAS is an attempt to standardize resident education using core competencies measures with milestones and ensure a safe working environment for both trainees and patients. While providing quality orthopaedic care for patients is of utmost importance, adequately training our future orthopaedic surgeons should be held in the same regard. Investing in the training of orthopaedic residents with quality intraoperative exposure will help ensure that orthopaedic surgeons are prepared to safely operate independently after completion of residency. Within the duty hour restrictions, residency programs must find more efficient ways to educate residents. Simulation allows mastering procedural steps prior to performing it and has been shown effective in decreasing the learning curve for techniques particularly in arthroscopy.[12] Dwyer et al showed when comparing junior residents after arthroscopy simulation to senior residents with no prior simulation experience, senior residents continued to perform superior to junior residents. This study demonstrated that although simulation is beneficial in initial learning, it is not a replacement for intra-operative and clinical experience.[18]

Simulation is an essential part of surgical training and is a worthwhile investment. Our simulation lab includes sawbones, wet labs, arthroscopy simulators and two haptic virtual reality computer-based simulators. In addition, industry sponsored surgical labs are provided quarterly and residents have the opportunity to attend 2 orthopaedic skills courses per year. The combination of these resources has become an essential adjunct to our residents' education.

Unlike the FLS required for the ACS, there is no standardized method for evaluating technical skills in orthopaedics at this time. Similar to FLS, a Fundamentals of Arthroscopic Surgery Training Program (FAST) may eventually be required in the future to demonstrate competency in techniques associated with arthroscopy.[7] Even with standardization, it is important to recognize that many residents will subspecialize and these requirements may not be applicable to all clinical practices.

Orthopaedics is a constantly evolving medical field. As subspecialization is becoming more widespread the medical knowledge to learn increases exponentially. In addition, the endless advent of new technology requires continual surgical training even after completion of residency. This requires residencies educate residents how to learn technical skills independently, such as with simulation, based on a foundation of fundamental skills. Surgical training modalities are currently geared towards resident education, but the use of these methods may prove beneficial in maintaining, improving, and

acquiring surgical skills for even established orthopaedic surgeons.

The goal of orthopaedic residency training is to graduate competent surgeons feasibly with the available resources at hand. While the ACGME NAS provides tools to measure residency programs' outcomes, the milestones are only a guide with which to identify the progress and deficits in a resident's training. Standardized testing provides a window into the breadth of clinical knowledge a resident may have, but may not elucidate the application of that knowledge in a clinical setting. Therefore determining how to adequately evaluate competency, particularly surgically, is still a dilemma orthopaedic training programs face.

Conclusions

A drastic paradigm shift is taking place within medicine which has greatly impacted the educational environment of orthopaedic residents due to the concern of quality of education, competency of graduating residents, and patient safety. The ACGME NAS is one of the many changes that residency programs have seen recently. The ACGME has provided milestones which give more specific expectations as well as a framework for identifying the progress or deficiency of residents, but they are only able to accredit programs and cannot determine the competency, including technical (surgical) ability, of individual graduates. Therefore it is up to each residency program and each specialty board to standardize and determine what represents a competent graduate.

Further work remains to be done in the translation of surgical skills learned in the lab to the OR, the best modalities for evaluation and simulation, and even the definition of competency itself. In order to meet the demands from the public and from regulators, residency programs must respond to demonstrate we are generating safe and effective physicians and surgeons. To do so, we must develop objective measures which are reliable and reportable, and the graduate medical education community is in the infancy of doing so.

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Disclosure

None reported.

MM

FDA Device Regulation

by Madelyn Lauer, MD, Jordan P. Barker, MD, Mitchell Solano, BA & Jonathan Dubin, MD

Tens of thousands of devices reach market annually in the United States, with each offering the opportunity to improve the quality of life for millions of patients.



Madelyn Lauer, MD, and Jordan P. Barker, MD, are orthopaedic surgery residents at the University of Missouri-Kansas City. Mitchell Solano, BA, MSMA member since 2012, is a medical student at the UMKC. Jonathan Dubin, MD, (above) is the Chief of Orthopaedic Trauma at Truman Medical Center and an Assistant Professor in the Department of Orthopaedic Surgery at UMKC.
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Introduction

The United States (US) is the largest consumer of medical devices in the world[1]. Responsible for assuring the "safety and effectiveness" of all medical devices, the Food and Drug Administration (FDA) regulates device manufacturers' ability to market devices within the US[2]. How the FDA carries out this task, however, is controversial. Consumer-protection advocacy groups demand tighter regulatory oversight, while businesses, many physicians, and some patient advocacy groups argue that the current bureaucratic regulations stymie innovation and hamper patient access to novel devices[3].

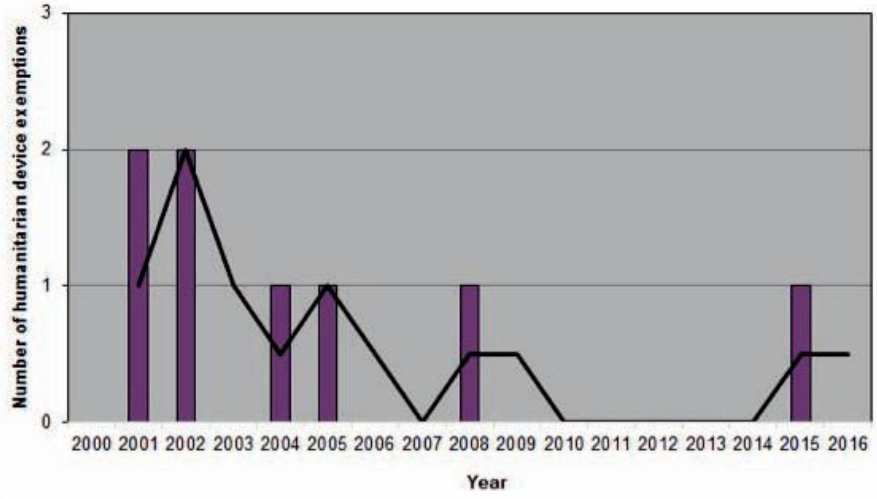
It is the authors' experience that many medical doctors understand FDA oversight of drug development, but most harbor little understanding of the regulatory process for devices. In fact, many erroneously believe the two to be alike. It is important, however, for all physicians to familiarize themselves with device regulation so that they can advocate for their patients and advise them about the devices they may be choosing to have implanted. This review will introduce to general physicians the vast and intricate process of device regulation, as well as highlight several controversies fueling recent debate.

History of FDA Device Regulation

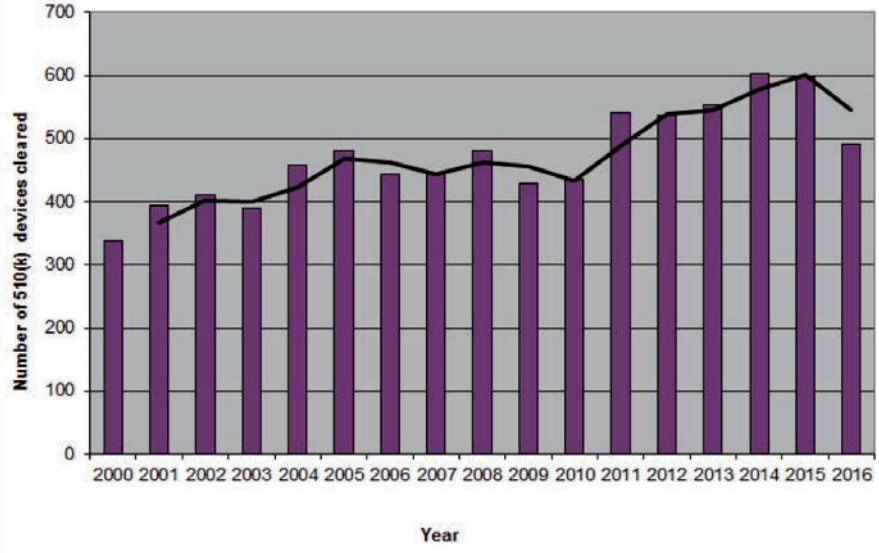
In 1938, President Franklin Roosevelt signed into law the Federal Food, Drug, and Cosmetic Act, which, for the first time, required manufacturers to prove the safety of the drugs they sold. While it also implemented limited oversight of device manufacturing, this pertained only to post-market intervention after damage had already occurred. In 1976, with congressional approval of the Medical Device Amendments Act (MDAA), the FDA finally received its jurisdiction to regulate devices prior to reaching market and authorize their use within the US. An integral forerunner of the MDAA was the Cooper Commission, a government-issued task force that reported over 10,000 documented injuries from medical devices, including 731 deaths. The findings of the Cooper report swayed public opinion and influenced congress to legislate new oversight of manufacturers, resulting in much of the FDA regulatory framework as we know it today[4].

To begin managing the vast array of new devices coming to market, the MDAA established a classification system that codified all novel devices into one of three risk classes. Devices already in use, by-and-large, required no further testing and ultimately

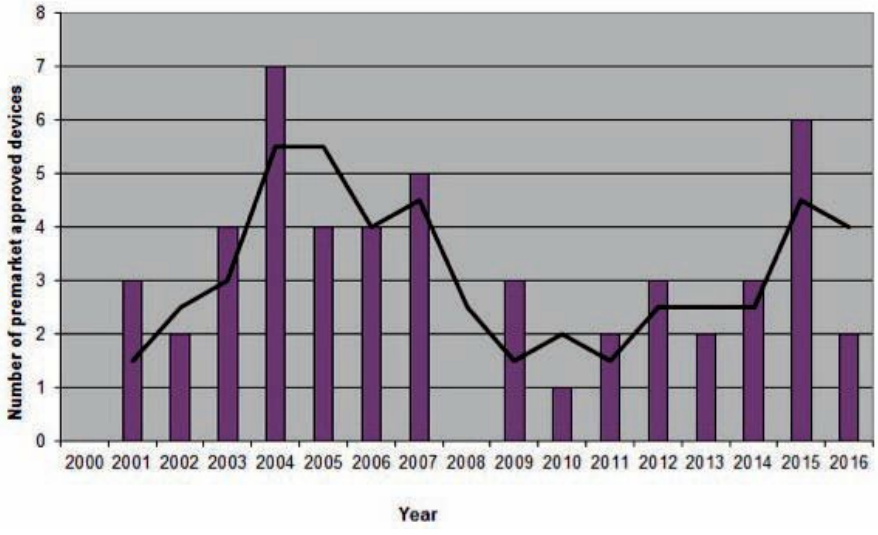
Figures 1a/1b/1c
Number of orthopaedic devices advanced to market between 2000-2016



1a. Humanitarian device exemptions
Data acquired from the Humanitarian Device Exemption Database found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm. Advisory Committee: Orthopedic. Accessed February 27, 2017. Each device was counted only once.



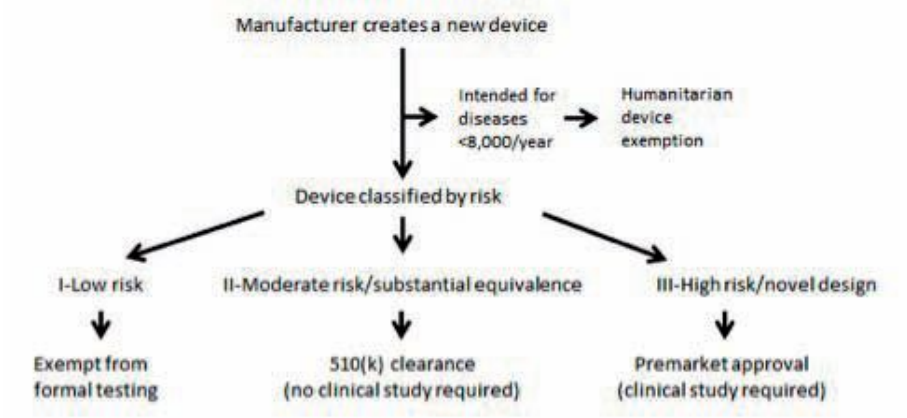
1b. 510(k) clearances
Data acquired from the 510(k) Premarket Notification Database found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Panel: Orthopedic. Accessed February 27, 2017.



1c. Premarket approvals
Data acquired from the Premarket Approval Database found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Advisory Committee: Orthopedic. Supplement Type: Originals Only. Accessed February 27, 2017.

forwent this system by receiving "pre-amendment" device status. Class I devices present minimal risk (i.e., nonpowered goniometer); Class II devices have moderate risk (i.e., intramedullary nails, screws, and most total joint arthroplasties); Class III devices carry the highest risk, represent a completely novel design, and/or support or sustain human life (i.e., intervertebral body fusion devices that include therapeutic biologics, metal-on-metal hip resurfacing, and cardiac ventricular assist)[4,5].

Figure 2
Common FDA pathways to market



Following passage of the MDAA, most changes to device regulation have revolved around less regulation in response to manufacturers' concerns about FDA costs and delays, and to promote the timely availability of new products. The most significant change was the passage of the FDA Modernization Act of 1997, which established the "least burdensome provisions." These mandated the FDA to require only the least burdensome amount of evidence that would result in a reasonable likelihood of device approval. For instance, the Act forbade the FDA from requesting a clinical study for class II devices when a benchtop study would likely result in clearance[6]. In the most recent effort to further limit regulatory oversight of novel devices, Congress reinforced the "least burdensome" principle in the 21st Century Cures Act, signed into law December 2016[7].

How Devices Reach Market

The majority of medical devices subject to FDA regulation progress to market via one of three pathways: Premarket Notification (commonly known as 510(k) Clearance), Premarket Approval (PMA), and Humanitarian Device Exemption (HDE) (See Figure 1). There are other pathways, such as the Breakthrough, Expedited Access, De Novo, and Investigational Device Exemption, however these are less frequently used and beyond the scope of this review[1,2,4,5,8].

510(k) Clearance, the most frequently utilized pathway, stipulates that a new device must demonstrate "substantial equivalence" to a device already approved or cleared by the FDA, or to a pre-amendment device that was in use prior to May 28, 1976. Manufacturers accomplish this usually without producing supporting clinical data, and instead rely on simpler bench-top biomechanical studies[2,5]. Premarket Approval, the most rigorous process, requires supporting empirical clinical data demonstrating safety and effectiveness, though the methodologic rigor of these studies has been called into question by multiple authors[5,9]. Humanitarian Device Exemption is a path exempt from clinical evidence of effectiveness, and is intended for devices that will be utilized for diseases found in no more than 8,000 patients per year (changed from 4,000 prior to the 21st Century Cures Act)[10].

The decision of which pathway a device must enter typically follows the aforementioned classification system related to perceived risk. Forty-seven percent of all medical devices are Class I, 95% of which are exempt from undergoing any formal clearance or approval, while other Class I devices, like Class II devices, require clearance through the 510(k)[11]. Class III devices undergo the more demanding PMA[2,5]. (See Figure 2) After initial evaluation, a device may be selected to undergo additional independent evaluation by the Medical Devices Advisory Committee, which consists of multiple medical specialty panels, each made up of FDA-designated experts in the respective specialty, though the decision to approve a device ultimately rests in the hands of the FDA[12].

Table 1
Comparison of device regulation in the United States and European Union

	United States	European Union
Title Granted	FDA Approval/Clearance	Conformité Européenne
Burden of Proof	Devices must demonstrate effectiveness	Devices must "function as intended"
Oversight	Manufacturers interact with single federal entity throughout process	Numerous (>70) private groups (Notified Bodies) compete in open market for opportunity to approve devices
Marketability	Available within US	Approval by one NB allows marketability in each member country
Time to Approval	3-11 months for 510(k), 9-54 months for PMA	For 510(k) and PMA equivalents, 4 and 11 months, respectively

Controversies in Device Approval

510(k) Overutilization

The 510(k) is by far the most commonly utilized FDA regulatory pathway. (See Figure 1) These devices never receive FDA approval, but rather clearance. Though subtle, the difference is significant as approval by the FDA implies certain protections, such as immunity from litigation in instances of harm directly related to the device. This statute was confirmed in the Riegel vs Medtronic court decision[3].

Furthermore, devices cleared by 510(k) most often do not require supporting empirical clinical research. While this simplifies, and cheapens, the process for a manufacturer, it diminishes "real-world" testing prior to wide spread dissemination and implantation of the product. The metal-on-metal DePuy ASR XL total hip replacement exemplifies the worst-case scenario of this policy. By claiming "substantial equivalence" to 95 different previously marketed devices, including pre-amendment devices in use prior to 1976, it cleared without any clinical evaluation in 2008. The ASR XL was recalled just two years later, at which time 100,000 devices had already been implanted and there was a reported 49% failure rate at 6-year follow-up[5,13,14].

As a result of this and other public controversies, the criteria for submission to and clearance by the 510(k) pathway have been called into question[5,15]. In 2011, the Institute of Medicine conducted a thorough investigation of the 510(k) process 35 years after its implementation. In their conclusion, they reported "the committee believes that a move away from the 510(k) clearance process should occur as soon as reasonably possible but recognizes that it will take time to obtain the information needed to design the new framework"[15]. To the authors' knowledge, the investigation has not amounted to any significant FDA policy change.

Comparison to European Device Regulation

Critics of the FDA often compare the US system of device regulation to that of Europe. (See Table 1). In their 2010 survey of over 200 medical device manufacturers, Makower, et. al. proffered a scathing analysis of the FDA[1]. They found that 76% of the responding companies believed the European process good or excellent, compared to only 16% expressing that sentiment toward the US system. In addition, they found the FDA to be much less efficient, which often led to US patients receiving innovative technologies nearly two years later than their European counterparts[1].

It is true that devices take longer to obtain approval in the US than Europe, but the actual discrepancy varies dramatically depending on the source. Manufacturers claim it takes 11 months for FDA 510(k) clearance and 54 months for PMA approval, whereas for the European equivalents, it takes only four months and 11 months, respectively. The FDA publishes three months for 510(k) clearance and nine months for PMA approval[1].

Yet, these comparisons may be flawed from the inception. The FDA emerged out of public health concern for consumer and patient protection with the intent to mitigate harm from untested devices[4]. The Conformité Européenne (CE) mark for medical devices, the European equivalent of FDA approval, stemmed from the New Approach Directives in the 1990s, which attempted to streamline innovation and create uniformity across the nations of the European Union (EU). Public health concerns in Europe largely fall within the purview of the Competent Authority of each individual country. This difference in founding principles allows for a burden of proof substantially weaker for European approval than that in the US. While both systems require some assurance of safety, within the EU a device manufacturer must prove only a

device "functions as intended," whereas in the US they must demonstrate effectiveness[8].

To carry this out, Notified Bodies (NB) formed as private, for-profit enterprises to evaluate novel devices and approve them for marketing within the European Union. With little central oversight, a manufacturer may seek approval from any NB within the EU and still be granted rights to market throughout the trading bloc. Multiple studies have pointedly shown enormous variation among the more than 70 NB across Europe. In essence, while a manufacturer may apply to only a single NB at a time, they can peruse the market for the most favorable NB, i.e., one that is faster, cheaper, and most likely to approve the device. Published in the British Medical Journal, Cohen described the process for obtaining approval for a made-up metal-on-metal hip replacement from a fictitious company, Changi. The dossier for the device included comparisons to two recalled devices, as well as serum metal ion levels known to be toxic. They presented their data to 14 different NBs across Europe, including one called Alberk, located "in an office above a garage in the back streets of Istanbul," and discovered devices rarely fail to obtain approval[16]. Each NB competes openly to obtain business from manufacturers, and tighter scrutiny drives away business[8].

Balancing Innovation and Regulation

An appropriate balance must exist between innovation and regulation to ensure patient safety. Multiple authors have called for more robust FDA checkpoints and supporting clinical data in order for devices to reach market[17]. Schemitsch, et. al. proposed a four-tiered system, similar to the pathway required in the more rigorous drug industry, involving multiple research trials[17]. Although such a change would potentially come with a substantial cost. The current cost for a single drug to reach market in the US is reported to be $350 million, and estimated up to $5 billion when taking into account multiple failed attempts that accompany the development of a safe and effective medication[18]. To bring a device to market in the US, on the other hand, currently costs roughly $31 million for 510(k) and $94 million for PMA devices[1].

Unlike the European market in, despite earlier approval, payors (notably, the government) control aggressive spread of costly and unproven technologies, in the US devices can integrate quickly to usher in staggering profits. A bone morphogenetic protein (BMP) product, Infuse Bone Graft, was approved in 2002 for single level LT-Cage lumbar fusion and in 2004 for use in open acute tibial shaft fractures treated with intramedullary nail fixation. Between 2002-2011, Infuse yielded over $4 billion in sales[19]. Despite multiple studies in peer-reviewed journals, including a dedicated exposé issue in The Spine Journal in 2011, outlining ineffectiveness, higher rates of complications, inappropriate disclosure of financial arrangements with the lead authors of the pivotal studies, as well as a Senate investigation into Medtronic's promotion of off-label use of BMP, the device still profited $471 million in the 2013-2014 fiscal year, an 11% decrease from the year before[20].

Similarly, hyaluronic acid (HA) injections (considered a device by the FDA) have yielded substantial profits that dwarf the investment costs for FDA approval. Eight HA injection products indicated for painful knee arthritis were premarket approved between 2001-2015. Among these, Synvisc-One alone accounted for $274 million in US sales in 2014[21]. Despite this staggering value, quality evidence supporting HA use is lacking. The original blinded randomized-controlled trial for Orthovisc, another HA injection approved in 2004, failed to show any significant difference between the investigational cohort and saline placebo. It instead relied upon a post-hoc analysis with altered endpoints[22]. Monovisc, a similar HA device, likewise initially failed to demonstrate significant improvement over saline placebo, but ultimately was approved on the basis of non-inferiority to Orthovisc[23]. This, among other evidence, has led the American Academy of Orthopaedic Surgeons to publish a strong recommendation against the use of HA injections for knee osteoarthritis[24]. Despite this expert recommendation, it remains unlikely that sales will subside in the near future.

The assumption that all novel devices are truly innovative is false according to the Institute of Medicine's definition of innovation: "Something that improves the quality of, efficiency of, or access to healthcare"[15]. Currently, there is no FDA requirement that a device must meet this standard to achieve approval or clearance. The current standard for high-risk devices seeking PMA, for example, often mandates

a non-inferiority research design, using an existing treatment as the comparator, such as proving that a novel lumbar or cervical disc replacement is not inferior to spinal fusion. There need not be an empirical demonstration of improvement, efficiency, or better access over the comparator.

Conclusion

Tens of thousands of devices reach market annually in the United States, with each offering the opportunity to improve the quality of life for millions of patients. This benefit, however, must be weighed against the potential for harm from devices lacking sufficient clinical testing prior to their widespread use. While we recommend strengthening the pre-market clinical analysis of devices by the FDA, there are pragmatic limitations such as cost, as well as concerns from industry of excessive regulation limiting innovation. As it stands now, the FDA and European governing bodies are trending towards following post-market surveillance techniques such as MedWatch and EudaMed, respectively[8,25]. While device manufacturers are required to report adverse events to the FDA, MedWatch is a voluntary reporting system that allows both consumers and providers to report device issues to the FDA[8,12,25]. The greatest contributors are nurses (25%), while physicians only contribute 8% of reports[8,12]. As we progress into an era that places more emphasis on post-market surveillance, it becomes ever more important for physicians to understand and participate in the process of device regulation.

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Disclosure

None reported. **MM**

Evaluating Soft-Tissue Lumps and Bumps

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The successful evaluation and management of soft tissues masses requires a systematic approach.



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Abstract

Patients presenting with soft-tissue lumps and bumps are commonly encountered by both primary care physicians and orthopaedic surgeons. Though common, the initial evaluation and management of a soft-tissue mass can be challenging for many clinicians due to the considerable overlap in the presentation of benign and malignant tumors. Furthermore, a myriad of conditions, ranging from infection to trauma, can present with a soft-tissue mass. Subsequently, the correct diagnosis is often delayed or missed which may ultimately lead to inappropriate treatment. The propose of this article is to review the fundamental elements of a successful soft-tissue mass work-up and to provide the clinician with a systematic approach to the evaluation, diagnosis and management of the patient with a soft-tissue tumor.

Epidemiology

Soft-tissue tumors are common; however, defining the true incidence of these tumors is difficult given that most go unrecognized or simply do not present for medical evaluation when the individual is unconcerned with the presence of an asymptomatic mass. Most soft-tissue tumors are benign, outnumbering malignant tumors approximately 150:1 with roughly 20 malignant soft-tissue tumors per 1 million people in the United States.[1] Although carcinomas can potentially metastasize to the soft-tissues and lymphomas may occasionally invade muscle plains, malignant or cancerous tumors of the soft-tissues are collectively referred to as sarcomas. Soft-tissue sarcomas can occur at any age, although the majority are seen in patients 40 years of age or older. When sarcomas occur in children, greater than 50% are Rhabdomyosarcomas. In young adults, synovial sarcoma and epithelioid sarcoma are the most commonly diagnosed. Sarcomas occur more frequently in the lower extremities than in the upper extremities by a 2:1 ratio.[2] Nearly one-third of sarcomas occur in the trunk and pelvis and 10% occur in the head and neck.[3]

Presentation and Evaluation

Patients with a soft-tissue tumor, whether benign or malignant, typically present with a painless, growing prominence. Subcutaneous tumors are often easily recognized, allowing the patient to isolate the exact location of the tumor and provide a detailed description of the nature and duration of their symptoms. In contrast, deep soft-tissue tumors located within the muscle or below the fascia may go unrecognized initially and are often not localized until the tumor has grown to a large size (> 10 cm). (Figure 1)[4]

History

Despite the overlapping clinical features of benign and malignant soft-tissue tumors, in general, an accurate differential diagnosis can be formulated after a thorough history and physical exam has been performed. History taking should include questions



Figure 1
Benign soft-tissue mass of the arm.
(Murphy MD. Imaging of Soft Tissue Tumors. 2014.)



Figure 2
High-grade undifferentiated sarcoma in the wrist.
(Murphy MD. Imaging of Soft Tissue Tumors. 2014.)

designed to determine how long the mass has been present as well as the nature and duration of any associated symptoms. Any changes in the size or growth rate of the mass should be noted, as well as any prior history of cancer. Antecedent trauma should be noted as a history of trauma suggests the presence of a hematoma or possibly myositis ossificans. An abscess rises in the differential if the patient complains of constitutional symptoms in the setting of a slow healing wound or a rapidly enlarging, red, warm and tender mass. Crystalline or inflammatory arthropathy, including Gout or rheumatoid arthritis, can also produce a red, warm and tender soft-tissue tophus or nodule.

A common misconception is that patients with a malignant soft-tissue tumor will appear ill, as is often seen in patients with disseminated non-musculoskeletal malignancies. A lack of co-existent constitutional symptoms such as fever, chills, night sweats or unintentional weight loss, should not lower the clinician's index of suspicion for malignancy. Such symptoms are rarely present, even in patients with metastatic disease.[16] A slowly growing mass suggests a benign nature, whereas, rapid growth over a period of weeks to months is concerning for a malignancy. A mass with a "waxing and waning" size suggests the presence of a ganglion cyst or hemangioma, but it is not typically a characteristic of a sarcoma.

Many practitioners mistakenly believe that there is no need for concern unless a mass is painful, when in fact, most malignant lesions are asymptomatic early on. When symptoms do present, they are typically due to the size of the tumor causing mass effect on surrounding structures. When a benign tumor reaches a large size, it may result in the compression of vessels, nerves or vital organs. Thus, a benign tumor can be characterized as a "locally aggressive" tumor despite its inability to metastasize. In addition to localized pain, patients may experience neurogenic symptoms such as referred pain, paresthesia or a focal neurologic deficit if the mass compresses or incorporates a peripheral nerve.

Physical Exam

Distinguishing features that can aid in narrowing the diagnosis of a soft-tissue mass are the size, depth, consistency, and mobility of the mass. Typically, masses that are superficial and less than 5 cm in size tend to be benign, whereas, masses that are greater than 5 cm or found deep to the fascia have a higher likelihood of being malignant. However, one-third of sarcomas will present as a superficial mass.[7] (Figure 2)[4] A firm, fixed mass suggests a sarcoma or an underlying bony origin, although a desmoid tumor can present in this way as well. Benign masses are often soft and mobile, as is typical of a lipoma. In adults, most small superficial soft-tissue tumors are lipomas, whereas, in children most are hemangiomas.

Superficial bruising or ecchymosis is seen with a

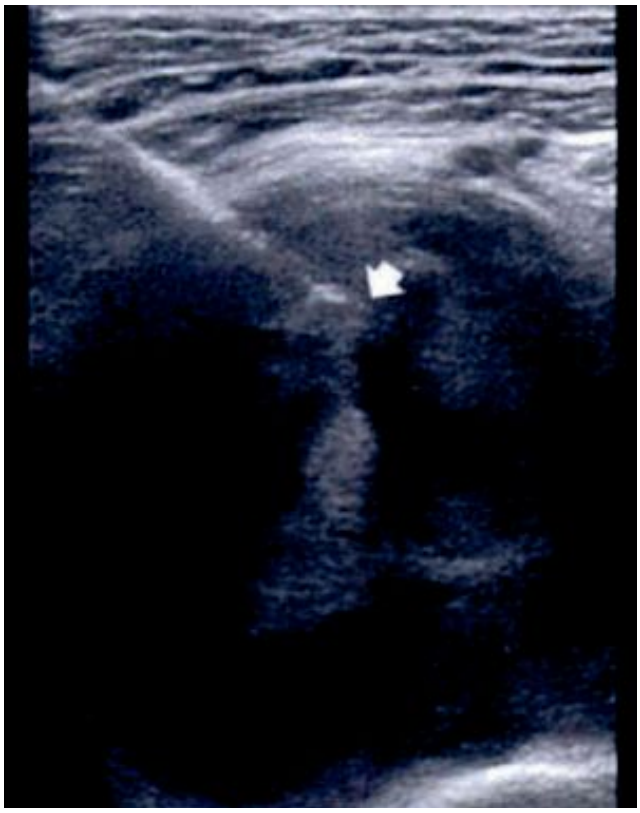


Figure 3
Ultrasound guided biopsy of a groin mass in a 56-year-old man. The tip of the core biopsy needle is seen (arrow) within the mass. Biopsy revealed schwannoma with central hemorrhage.
(Murphy MD. Imaging of Soft Tissue Tumors. 2014.)

traumatic hematoma as it tracks along fascial planes. When bleeding within a tumor occurs, blood is typically contained within the tumor capsule and rarely reaches the superficial tissues. A warm, red, swollen or fluctuant mass is typical of an abscess; however, sarcomas can be warm to the touch secondary to tumor neovascularization and increased blood flow. Large tumors that compress the neurovascular structures can cause edema due to the dilation of peripheral veins or decreased pulses distal to a site of arterial compression. A loss of sensibility or motor function can occur in the distribution of a compressed peripheral nerve.

Some specific findings can narrow the differential diagnosis even further. Synovial or ganglion cysts will trans-illuminate with a pen light. Vascular lesions such as a hemangioma or arteriovenous malformation may have bruits or a palpable thrill. Peripheral nerve sheath tumors may have a positive Tinel's sign or pain with compression. Ulceration of the overlying skin can be seen with epithelioid sarcoma. The clinician should carefully examine the skin and document the presence of any previous incision or scars. These findings can be critically important as they may represent the site of a prior biopsy or attempted surgical excision. Furthermore, the location of prior incisions becomes important for preoperative planning and may determine or alter the tumor surgeon's surgical approach if an excision is required.

Diagnosis

Laboratory Studies

Currently, no specific laboratory studies exist that are of significant benefit in the evaluation of soft-tissue masses. Routine studies like a white blood count, erythrocyte sedimentation rate, and c-reactive protein may be elevated in a variety of conditions. Calcium and phosphorus levels may be abnormal in the setting of tumoral calcinosis. An elevated lactate dehydrogenase level is seen in patients with lymphoma. Uric acid levels can be elevated in gout. These tests are nonspecific and are generally of limited use.[1]

Imaging Studies

The evaluation and management of soft-tissue tumors often relies heavily on information gathered through imaging and may involve plain radiography, computed tomography (CT), ultrasound (US), and magnetic resonance imaging (MRI). Plain radiography, though it has a limited role in the definitive diagnosis and staging of soft-tissue tumors, should be obtained first to determine the presence or lack of bony involvement. Plain radiography may only reveal a non-specific alteration of normal soft-tissue shadowing. Though rare, bony involvement either by a benign or a malignant soft-tissue mass can be appreciated on plain radiographs and may be seen in the form of cortical erosion, cortical hyperostosis or a periosteal reaction.

Ultrasound is another cost effective imaging modality with a high negative predictive value for soft tissue masses.[8] US can help to determine the consistency (solid or cystic), relationship to adjacent structures, vascularity, size, and shape of the mass. The use of US may obviate the need for more costly imaging such as MRI, avoid unnecessary biopsy, and guide the appropriate treatment plan. However, when the diagnosis remains uncertain or concerning features of the mass are identified, further imaging should be performed. Importantly, US can be used intraoperatively for biopsy or excision and is especially valuable if the mass is not palpable.[9] (Figure 3)[4]

MRI is the most sensitive and specific imaging modality available in the evaluation of soft-tissue masses. MRI is the study of choice for the localization and staging of soft-tissue tumors as is offers the best delineation of the soft-tissue structures and the relationship of the mass with respect to neurovascular structures.[1 10,11] T1-weighted MRI is best for defining anatomic relationships, while T2-weighted MRI identifies free extracellular water and tissue edema.

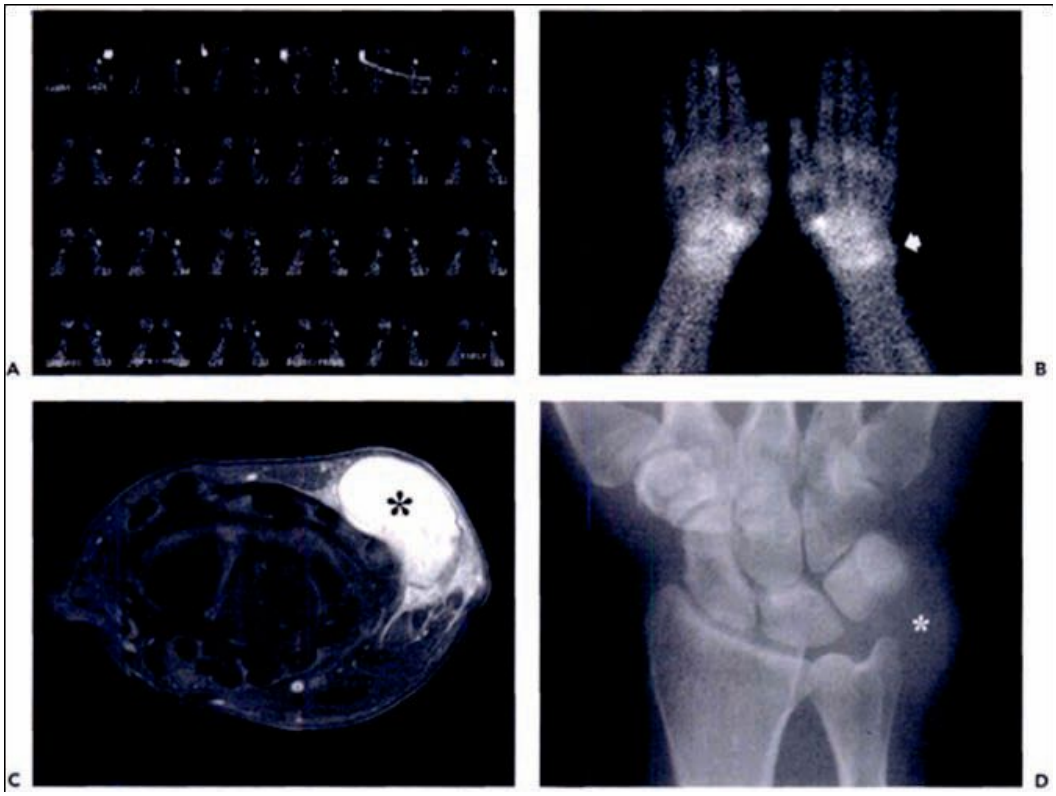


Figure 4
High-grade undifferentiated sarcoma in the wrist. (A) Dynamic and (B) static (B) bone scintigraphy shows increased flow and tracer accumulation in the tumor (arrow). The corresponding contrast enhanced, fat-suppressed, axial T1 weighted MR image shows intense enhancement of the mass. (D) Anteroposterior radiograph of the wrist shows the mass (asterisk) with no adjacent osseous abnormality.
(Murphy MD. Imaging of Soft Tissue Tumors. 2014.)

Fat suppression techniques subtract the signal produced by adipose tissue and can better highlight abnormal fluid collections and areas of tumor transition. Gadolinium-enhanced MRI has become an important part of the workup for soft-tissue masses because it allows the clinician to differentiate between cystic and solid lesions. Cystic lesions will have rim enhancement, which is not present in solid lesions. This is especially important for differentiating between myxomas, myxoid liposarcomas, and fluid-filled cysts. (Figure 4)[4]

The use of computed tomography (CT) for diagnosis of soft-tissue masses has declined as the role of MRI has evolved. CT is often the imaging modality of choice for patients who cannot undergo MRI, including those with pacemakers or indwelling cardiac stents. Unlike MRI, which is limited in the setting of mineralization secondary to the variable signal intensity of calcium, CT is better able to delineate any bony involvement and distinguish calcification from ossification. [12]

Positron emission tomography (PET) is commonly used in conjunction with CT (PET-CT) and provides precise anatomic correlation of tumors and information about metabolic activity within a soft-tissue tumor. PET-CT detects positron emission decay from an administered radioisotope and generates an image of the entire body. The amount of radiotracer activity within the cells reflects metabolic activity. Typically, high-grade malignant soft-tissue tumors have high rates of glucose metabolic activity. Although PET-CT is not used for initial evaluation of soft-tissue sarcoma, it has been found to be useful to assess treatment response after systemic therapy or to identify recurrence. [13]

Biopsy

Though it is a seemingly simple procedure, biopsy of soft-tissue masses is technically challenging and potentially fraught with complications. It is recommended that the biopsy of soft-tissue masses be deferred to a tumor-trained orthopaedic surgeon when possible and is preferably performed by the same surgeon who will perform the definitive surgery if indicated. [14] Careful planning is required to determine the exact location and approach to the mass. When possible, the surgeon should consult with both the radiologist and pathologist prior to proceeding to biopsy.

Two forms of soft-tissue biopsy exist: needle biopsy and open biopsy. Needle biopsies involve the passing of a needle into a mass for tissue sampling. When possible, the needle tract should pass through the muscle that is in contact with the tumor and away from major blood vessels or nerves. The tract must also be placed in a location that will allow for the tissue to be excised at the time of definitive surgery.

Needle biopsy is further divided into fine-needle aspiration (FNA) and core needle biopsy (CNB). FNA involves aspirating the mass with a 20-gauge needle or

smaller, whereas, CNB uses a larger bore needle and requires multiple needle passes to gather tissue. The advantages of FNA include that it is relatively inexpensive, can be done in the clinic with minimal local anesthetic, results in limited soft-tissue contamination, and can be processed in minutes if a pathologist is available. FNA has a wide range of reported accuracy, especially in diagnosing sarcoma with sensitivity of 86-100%, specificity of 36-100%, and diagnostic accuracy of 21.9 – 98%. However, FNA yields only tumor cells which can be used for cytology studies, as opposed to CNB which provides ample tissue for additional testing. CNB allows for the cell structure and cellular matrix to be examined by pathology, improving diagnostic accuracy. CNB has a reported sensitivity of 81.8-100%, specificity of 91-100%, and diagnostic accuracy of 72.7-100%.[15] While needle biopsies have the potential to be a cost-effective method for the diagnosis of soft-tissue tumors, the accuracy of tumor grade and histology subtype varies and is dependent on the pathologist's experience. [16–18]

In contrast to needle biopsies, open biopsy is an even more technically demanding procedure. Open biopsy can also be subdivided into two types: incisional and excisional biopsy. In an incisional biopsy, a portion of the tumor is removed to make a diagnosis. Excisional biopsy implies a planned marginal resection of the mass and is reserved for masses that are thought to be benign, such as a lipoma or peripheral nerve sheath tumor. Open biopsies yield a larger tissue sample which allows for molecular-diagnostic testing. The smallest incision possible (less than 5 cm) should be used to allow for an adequate sample with the least risk of complication. Incisions should be longitudinal and placed along the future limb salvage incision, or just parallel to it. Any tissue exposed during open biopsy must be removed during definitive surgery, including blood vessels and nerves. Poorly placed biopsy sites may adversely affect the surgeon's ability to resect the tumor, significantly increasing recurrence and need for further treatment that may include amputation. [15 16–18]

Management

Resection

There are 4 types of resection procedures that can be performed: intra-lesional, marginal, wide, and radical. Figure 5 illustrates the surgical resection types described by Enneking and Dunham. A key principle of tumor surgery is to attempt to avoid inter-nervous plans or the violation of multiple compartments. Approaches that traverse muscle bellies and limit contamination are selected. Intra-lesional resection involves incising the tumor capsule and removing only a part of the mass. This is preferred for benign masses such as a hematoma. Marginal excision refers to removal of the mass in its entirety while keeping the reactive zone or thin capsule intact. This is preferred for benign tumors such as lipomas, giant cell tumors of tendon sheath or neurofibromas. Wide excision involves removing the tumor as well as a cuff of normal tissue surrounding the mass. This is the preferred treatment for locally aggressive tumors and sarcomas. Finally, radical resection refers to removal of the entire compartment, which is rarely required.[19,20]

Adjuvant Therapies

Currently available adjuvant therapies fall into 3 categories: local treatment (cryotherapy, radiofrequency ablation (RFA) etc.), chemotherapy, and radiation therapy. Cryotherapy and RFA have been utilized effectively in the management of metastatic lesions or for tumor recurrence where surgical resection is not possible. Both have successfully been performed to manage soft tissue sarcomas, desmoid tumors, and metastatic diseases.[21]

External beam radiation is another modality that can be used for local tumor control. Radiation works by generating free radicals which then inhibit tumor cell DNA synthesis, ultimately leading to apoptosis. Thus, radiation primarily effects tumor cells with high turnover rate or mitotic index. However, rapidly dividing skin cells and hematopoietic cells are also affected. [23] Therefore, radiation is a useful adjunct in the treatment of those tumors known to have a high mitotic index such as Ewing's sarcoma, lymphoma, metastatic disease, and soft tissue sarcomas. Radiation therapy can be utilized pre-operatively to shrink the size of the tumor, postoperatively to treat unresected margins or unseen satellite lesions, or even as palliative therapy in lesions that are not amenable to complete resection. In one report, resection surgery alone led to a recurrence in 22 of 64 patients (34%) as compared to 11 of 69 (16%) when surgery was accompanied by either pre- or post-operative radiation therapy.[20]

Chemotherapy is an adjunct that acts systemically. While local adjuvants, radiation and surgery treat local disease, chemotherapies aim to eliminate distant or disseminated tumor cells. The goal of chemotherapy can be curative or palliative. Commonly used chemotherapeutic agents include doxorubicin which acts by binding tumor cell DNA and inhibits the S phase of the cell cycle, as well as cisplatin and cyclophosphamide which inhibit the tumor cell G2 phase DNA crosslinking and preventing cell division. Methotrexate is another commonly used agent which blocks folate synthesis leading to accumulation of a toxic inhibitory substrate. These and other agents may be used alone or in combination to treat systemic disease caused by a malignant soft tissue sarcoma. However, as it is with radiation therapy, the rapidly dividing cells of healthy tissues are also affected leading

to common side effects which may include easy bleeding, anemia, thrombocytopenia, hair loss, gastrointestinal discomfort, nausea and vomiting. [20,24,25]

Unplanned Oncologic Excision

A major concern of the orthopaedic and oncologic community is the incidence of unplanned resection. Reports have shown that 5-80% of patients with soft tissue sarcoma undergo unplanned resection, leading higher local recurrence and increased morbidity and mortality. [26] If the diagnosis is in question at the time of excision, a frozen section should be obtained to evaluate for malignancy. Additionally, the surgeon should take care to ensure that an adequate sample is obtained to establish a diagnosis. Conversely, overzealous dissection or exposure should be avoided as this could lead to further contamination.

Summary

The successful evaluation and management of soft tissues masses requires a systematic approach. A thorough history and physical examination in conjunction with appropriate imaging studies are essential for an accurate diagnosis. If the diagnosis remains unclear, biopsy should be performed by a musculoskeletal oncologist who will ultimately be responsible for the definitive surgery. The surgical resection of a soft-tissue tumor demands strict adherence to oncological surgical principles and techniques, mainly the avoidance of health tissue plane violation. Adjuvant therapies such as RFA, cryotherapy, radiation therapy, and systemic chemotherapy provided to the patient utilizing a multidisciplinary team approach will improve patient care. Adherence to these practices will reduce the incidence of unplanned tumor resection and lead more successful outcomes in the treatment of soft-tissue sarcomas.

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Disclosure

None reported.

MM

The Role of the Fracture Liaison Service in Osteoporosis Care

by Sean Bonanni, BA, Amelia A. Sorensen, MD, Jonathan Dubin, MD & Betty Drees, MD

The Fracture Liaison Service model has proven to improve diagnosis, improve long-term treatment and to decrease morbidity in these patients.





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Abstract

Osteoporosis is a disease classified by the alteration of bony microarchitecture predisposing a person to fragility fractures. This costs the US $19 billion per year and is expected to rise as our population ages. Only 20% of patients with fragility fractures receive treatment for osteoporosis. A Fracture Liaison Service is a cost-effective way to follow patients and improve appropriate work up and management from multiple medical disciplines.

Introduction

Osteoporosis is a disease classified by the alteration of bony microarchitecture and the loss of its structural integrity and predisposition to fracture.[1] The result is a weakened skeleton more susceptible to trauma. It can be thought of as a disease of fractures since this is the most common complication of the disorder. Worldwide, 1 in 3 women and 1 in 5 men are expected to be affected by osteoporosis.[2-4] In the United States, osteoporosis causes two million fractures and costs $19 billion per year. These numbers are expected to grow in the coming years as our country ages.[5-6] Common risk factors for this disease include advanced age, decreased activity level, race, smoking status and hormonal influences. As people age, they lose the ability to add bone mass and begin resorbing the calcium and phosphate stored in the bone to maintain their electrolyte homeostasis.[7] Weight-bearing activity creates forces acting on the skeleton and stimulates bones to retain their strength. A lack of activity decreases the demands on the skeleton and causes increased bone mass loss.

Deficiencies of sex hormones in both men and women have been tied to decreased bone mineral density. Estrogen plays an important role in maintaining bone mass. As estrogen production stops in women, there is an imbalance in the bony turnover causing the rate of bone resorption to outpace that of bone formation.[7] While men retain the ability to produce androgens this also decrease with age. The decrease in androgen production also decreases bone mass, although not to the same extent as the complete sex hormone deficiency seen in menopause.[8]

Given the global problems leading to and caused by osteoporosis, fracture liaison services came about to help diagnose and begin long-term management in these patients who sustain a fragility fracture as their initial presentation of osteoporosis. Fragility fractures result when a person falls from standing height or less, and are not attributed to high-energy traumas like motor vehicle accidents or high velocity mechanism of injuries.[9] In a healthy individual the result of such a fall may be bruised skin and a bruised ego. In patients with osteoporosis such a fall may result in hip, wrist or vertebral fractures.[10] The most common initial fracture in a younger population tends to be distal

radial fractures. Fracture liaison services seek to seamlessly transition these patients from surgical care of the fracture to long-term management of the disease in order to treat the disease process and prevent future injury.

Osteoporosis Screening, Diagnosis and Treatment

Per the USPSTF, osteoporosis screening is recommended in women over the age of 65 years old with a DEXA bone scan. Other tools are used such as the Fracture Risk Assessment Tool (FRAX tool) help to stratify a patient's risk of sustaining an osteoporotic fracture and to also guide management to reduce the chance of occurrence.[12] A FRAX score of greater-than-or-equal to 3% necessitates treatment.[5, 12] Historically, osteoporosis has been thought of a disease of women since 33% of women will sustain a fragility fracture in their lifetime as opposed to 20% of men. Currently both the National Osteoporosis Foundation and Endocrine Society recommend DEXA scans for all men aged 70 and older or over 50 with risk factors such as fragility fractures or a history of falls. Recent research has shown that there is little awareness among both physicians and men about their risk of developing osteoporosis. This has translated to only 11.4% of men being screened versus 88.6% of women. [13]

The gold standard in the diagnosis of osteoporosis is to assess a patient's bone mineral density (BMD) using a DEXA scan. A patient's BMD is compared to that of a healthy 30-year old in the form of a T-score. A T-score of -1 to +1 is considered normal. A T-score between -1 to -2.5 is considered to have low BMD while a T-score of greater-than or equal to -2.5 is sufficient to diagnose someone with osteoporosis and indicates the need for treatment. For children, younger persons and premenopausal women, a Z-score is used. Z-scores are age-adjusted so that it compares the patient's BMD to the average of their peers. A Z-score of -2.0 on a DEXA corresponds with a low BMD and increase risk of fragility fractures.[11] A clinical diagnosis of osteoporosis may be made in those patients who present with a fragility fracture. These patients typically warrant further investigation regardless of their age to assess their bony integrity as well as possible causes for their decreased BMD.

There are several treatment and management options available for osteoporosis and reduced bone mineral density (DMB) including lifestyle modifications as well as medical therapy. Treatment options are selected based on disease severity and clinical manifestation. It has been shown that it takes months of osteoporosis medical treatment before a "real-world" re-fracture reduction may be appreciated.[2] This delay between onset of treatment and result makes fall-risk management a high priority in the time following a fragility fracture. Physical therapy and diet and exercise help promote bone health and reduce fall risk.[2, 14] Dietary supplements, including vitamin D and calcium, provide a substrate on which bone can build. Current recommendations for Calcium intake for women ages 51-70 and over 71 are 1,200mg per day, while recommendations for men ages 51-70 and over 71 are 1,000mg and 1,200mg per day, respectively. The calcium may come from supplements or foods such as dairy products or vegetables. Though Vitamin D has been less rigorously studied, it is recommended that all adults 51-70 receive 600 IU per day while those over 71 receive 800 IU per day.[15] Other management options include exercise like walking or weight lifting to promote the formation of strong bones. Anti-resorptive medications, such as bisphosphonates, reduce the rate of bone loss. Monoclonal antibodies, such as denosumab, have also been used to combat bone loss by targeting and inhibiting osteoclast-activating pathways. Another option is hormonal therapies (i.e., PTH analogues), which stimulate bone mineralization and reverse the effects of osteoporosis.[7]

Shortcomings of Today's Management of Osteoporosis

There is a lapse in guidelines between the ages of 50-65 for those patients at risk of developing clinical signs of osteoporosis.[6] This population of patient remains too young to screen for the disease. Outside of fragility fractures and screening, osteoporosis is a largely silent disease and may go undiagnosed for years. Currently there is no progress in addressing this lapse in screening for decreased bone mineral density (BMD) in younger patients. Instead the current model relies on assessing these patients only after they have had a fracture. While the FRAX tool may be used in these patients, osteoporosis is seldom at the forefront of a provider's mind when seeing these patients.

Of the patients who present with fragility fractures, which means a patient has decreased bone mineral density (BMD); 9-20% eventually end up receiving osteoporosis treated.[1, 10, 17, 16] There is no clear explanation, but it is thought to be multi-factorial.[18, 19] Studies have shown that the persistence of a care gap in fragility fractures, the cost of diagnosing and treating osteoporosis, the risks and concerns of polypharmacy and the lack of clarity regarding which specialty manages these patients appear to be the biggest reasons.[20] Since these patients present their disease with a fracture, the first physician to see them is an orthopaedic surgeon. Traditionally, once the patient is discharged, they will follow-up with their surgeon as an

outpatient for 3-6months before being discharged from their care. Due to the finite nature of this relationship, there is some controversy regarding whether orthopaedic surgery should work up and manage these patients.[5, 18, 19] Recent studies have shown there is ambiguity in the medical field regarding who is responsible for these patients. Some feel that orthopaedic surgery should control the long-term management of osteoporosis while others feel that primary care, endocrinology or rheumtology should take over the medical management. [18, 19] Metaphorically known as the Bermuda Triangle of osteoporosis care of fractures, Dr. Harrington described this Triangle made up of orthopedists, primary care physicians and osteoporosis experts into which the fracture patient disappears.[21] The FLS model offers one solution for how to handle osteoporotic patients.

The Fracture Liaison Service

Fracture Liaison Services started in the United Kingdom in the late 1990s and sought to address not only the growing problem of osteoporosis and those at risk of fragility fractures, but to address the low rates of work up and management of these patients.[9] Since there is at least a two-fold risk in refracture following fragility fractures, the FLS model also sought to prevent subsequent fractures as a way to reduce morbidity and mortality due to osteoporosis.[2, 14] The goal of a fracture liaison service is to ensure that patients with clinical signs of osteoporosis receive appropriate evaluation and treatment. It is not the intension of a FLS to put every patient on a bisphosphonate but instead to assess the need for further interventions. Long-term studies show that approximately 75% of patients who sustain fragility fractures would benefit from medical interventions following surgery.[16] A fracture liaison service follows patients sustaining fragility fractures and/or osteoporotic fractures from the time of injury presentation until care is transitioned to the primary care provider. [18] It is an interdisciplinary service combining orthopaedic surgery, primary care, osteoporosis experts (e.g. endocrinology and rheumatology) and ancillary services like physical therapy and dieticians to ensure that patients are properly assessed and managed. [6, 16]

When a patient presents to a hospital following a low-energy fracture, orthopaedic surgery will treat the fracture and initiate the fracture liaison service in eligible patients. Criteria for enrollment into an FLS included being older than 50 years old and presenting with a fragility fracture of the wrist, humerus, hip and/or vertebrae. [3, 9, 22] During their stay, an FLS coordinator will meet with these patients and begin the process of coordinating osteoporosis education, evaluation and management. Physical therapy is consulted to assess fall risk and start a fall prevention program. Dieticians are consulted to assess for nutritional deficiencies that contributed to the patient's suspected decreased bone mineral density. During a patient's enrollment in an FLS, a patient may see specialties as an inpatient or outpatient. Other possible consultations include occupational therapy and endocrinology depending on the patient and institution. During the hospital stay, the patient is started on Calcium/Vitamin D supplementation. Once discharged, the FLS coordinator continues to stay involved in the patient's post-operative care by coordinating with orthopaedic surgery and primary care providers to obtain DEXA imaging and assess the need for further medical intervention. The coordinator individualizes the management of each patient including continuation of physical therapy or additional consultations. Once the patient is deemed fit enough to discharge from orthopaedic surgery care, the FLS coordinator then transitions care to the designated team (primary care or other osteoporosis expert) for long-term osteoporosis management before discontinuing care.

The Efficacy of the FLS and its Adoption

Since the first Fracture Liaison Services in the early 2000s, multiple studies have been conducted to investigate the utility of these fracture care models. Studies in the UK assessing the long-term efficacy of these services have shown that the FLS model not only reduces the frequency of subsequent fractures and improves adherence to treatment, it also provides cost savings.[1, 3, 9, 16, 18, 22] An 8-year audit in Scotland found that approximately 21,000 GBP is saved per 1,000 patients with a prevention of approximately 18 re-fractures in that same amount of time.[16] Utilization of a FLS increases the rate of diagnosis of osteoporosis and long-term adherence to medical management.[1, 10, 16, 23] The diagnosis rates of osteoporosis following fragility fractures are between 5-30% without a Fracture Liaison Service.[1, 18, 17, 23] Following enrollment into an FLS, this diagnosis rate improved to over 80%.[16] The FLS also provides a 30-40% reduction in risk of refracture, with a number needed to treat of 20 to prevent one re-fracture in 3 years.[22]

The International Osteoporosis Foundation began a movement known as Capture the Fracture to endorse, implement and standardize Fracture Liaison Services and fragility fracture management.[6] These global initiatives stemmed from the problems faced in addressing fragility fractures and the growing problem fragility fractures have on the world's aging population.[6] Given that close to a half a billion people will reach retirement age within the next 20 years, instituting an efficient and cost-effective method of reducing morbidity and mortality associated with

fragility fractures will become important to maintaining public health.[6] While this campaign is meant to provide a framework for the FLS model and improve public awareness of fragility fractures, it is not the only driving force in the adoption of the FLS.

In the United States there are several programs to address the fragility fracture problem in at risk groups using the FLS model. The Healthy Bones Program run by the Kaiser Southern California health-maintenance organization led to a decrease of 37.2% in hip fractures with savings of $30.8 million.[16] Project Healthy Bones is another California-based program to reduce the incidence of hip fractures. They conduct 6-month classes, which provide education on diet and exercise to improve bone strength and decrease the risk of osteoporosis.[24] In 2009, the American Orthopaedic Association started a program known as Own the Bone to provide a tool kit to set up an FLS. They provide a ten-step program as well as a reporting tool to track outcomes of these fragility fractures.[25] This program provides ways to manage patients who have fragility fractures, and ways to educate the public on the prevalence of osteoporosis and prevent fragility fractures from occurring.[25]

The Fracture Liaison Service model appears to address many of the historic shortcomings in traditional management of fragility fractures. It has proven to improve diagnosis, improve long-term treatment and to decrease morbidity in these patients. It also takes away ambiguity regarding which specialty manages the disease and allows for efficient communication between multiple specialties and reduces the chance a patient may get lost while navigating the current health care system. As the population continues to age, managing and preventing life-altering fractures will become an increasingly important issue. Given that the sentinel sign of osteoporosis is fracture, orthopaedic surgery and primary care physicians must work together to initiate and guide the initial management of these patients.

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Disclosure

None reported.

MM

Femoroacetabular Impingement Syndrome: A Cause of Hip Pain in Adolescents and Young Adults

by Christopher Shaw, MD

FAI is a common cause of hip pain in young adults and adolescents that often goes unrecognized and untreated. This syndrome can lead to early degenerative disease of the hip in otherwise young and healthy individuals.



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Abstract

The primary objective of this review is further education of the general practitioner, or family medicine physician, on an important, but often missed, cause of hip pain in the adolescent and young adult population, femoroacetabular impingement (FAI) syndrome. We hope that further understanding of the etiology, examination, diagnosis, and treatment of FAI, will lead to more accurate diagnosis and timely referral to the Orthopedic hip specialist for definitive treatment and management. Thus, preventing the complications, or late sequelae, associated with the condition.

Femoroacetabular Impingement (FAI) Syndrome

Femoroacetabular impingement, or FAI, syndrome refers to the constellation of signs and symptoms related to abnormal morphology of the acetabulum, proximal femur, or both. Abnormal anatomy at the hip leads to altered mechanics abnormal loading of the hip joint. As a result, labral injury, chondral delamination, and more diffuse, non-focal degeneration of the hip articular surface can occur.[1] The severity of these injuries correlates with time to diagnosis and definitive treatment.[2,3] According to Clohisy et al., the average delay to definitive diagnosis from the onset of symptoms in FAI patients is approximately 3 years. Also of concern, these patients see an average of 4.1 healthcare providers before definitive diagnosis and specialist referral for appropriate management.[4]

More recently, FAI syndrome has been recognized as one of the most common causes of early arthritis in the non-dysplastic hip.[5,6] As the primary physician is often the first to evaluate these patients, it is important that FAI syndrome is on their differential. This will hopefully result in decreased time to accurate diagnosis and facilitation of early referral to the orthopedic hip specialist.

Classification

CAM-type FAI

CAM-type FAI is characterized by abnormal anatomy of the proximal femur at the head-neck junction, in which there is typically an aspherical portion of the femoral head-neck junction that, with hip flexion and internal rotation, results in compression and shear forces to the labrum and acetabular rim, respectively. Over time, repetitive trauma resulting from a CAM-type FAI can lead to labral tears, chondral delamination and detachment.[7,8,9]

Pincer-type FAI

Pincer-type FAI is characterized by abnormal anatomy of the acetabular rim. This can cause either a focal,

or more global, over coverage of the acetabulum over the normal anatomic femoral head and neck. As a result, ROM is limited when the femoral neck comes into contact with the acetabular labrum, again with hip flexion. This force is subsequently transmitted to the acetabular cartilage and labrum. With repeated bouts of micro trauma in this fashion, there is focal degeneration of the labrum with eventual ossification in a well described and recognized pattern.[5,10] Another associated lesion with pincer type impingement is the contra-coup cartilage lesion of the femoral head.[5,11] Development of these lesions further compromises biomechanical forces across the hip, predisposing the hip to progressive, diffuse, degenerative changes over time.

Mixed FAI

This type of FAI presents with both CAM-type and pincer-type deformities with abnormal morphology of both the proximal femur and acetabulum, along with their associated characteristic lesions. Recent reports indicate that this may be the most common pattern of FAI.[1,5,12]

Diagnosis

History and Physical Examination

The diagnosis of FAI syndrome cannot reliably be made with only one modality. Rather the accurate diagnosis is made by combining the findings of a good history, physical exam including specific provocative tests, and appropriate imaging. According to the PROCESS survey performed by Ayeni et al., the majority of orthopedic surgeons made the diagnosis of FAI based on a history of groin pain (81.7%), and the physical exam finding of pain with rotation of the affected hip (78.7%).[13] Clohisy et al. looked at 51 patients in which the diagnosis of FAI was made. The average age of their patient population was 35 years old, and most participants were relatively active and high demand. The researchers noted that the majority of their patients reported pain of insidious onset. The pain was localized to the groin in 88%, however, many patients also reported discomfort in the lateral hip, thigh, low back and buttock. Clohisy et al. stressed the importance of recognizing the clinical presentation of FAI to facilitate timely and improved orthopedic care in efforts towards joint preservation and prevention of osteoarthritis.[4]

Tijssen et al., performed a systematic review to determine the accuracy and validity of physical tests reported in the literature that are utilized in making the diagnosis of FAI and labral pathology in the hip. They concluded that there were only three physical tests of good

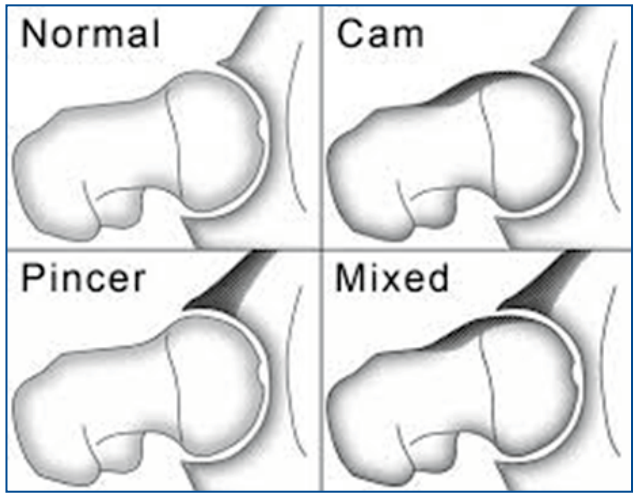


Figure 1
FAI can be subdivided into three categories based on morphology: CAM-type, Pincer-type, and Mixed.
Source: https://www.thornleighphysio.com.au/news/2015/12/4/is-it-hip-to-be-fai

quality, which include the anterior hip impingement test (FADIR test), the FABER test, and the resisted straight leg raise (RSLR) test.[14]

The anterior hip impingement test is performed with the patient in the supine position. The leg is passively flexed to 90 degrees, adducted, and internally rotated until end range of motion. Reproduction of the patient's pain with this test is considered a positive result.[14,15,16] Ayeni et al. reported that 70% of orthopedic surgeons that were surveyed utilized the FADIR test in making the clinical diagnosis of FAI.[13]

The FABER test is performed with the patient in the supine position. The leg is passively flexed at the hip and knee, abducted, and externally rotated until the lateral ankle rests just proximal to the knee on the contralateral extremity. The pelvis is then stabilized and a downward force is applied on the flexed knee, pushing it towards the exam table. A positive test is reported as either reproduction of pain or decreased ROM compared to the non-affected limb.[14,15,16]

The RSLR test is also performed with the patient in the supine position. The patient actively flexed the straight leg at the hip to 30-45 degrees of flexion. They are then asked to resist manual downward force on the leg applied just proximal to the knee. A positive test is reported as recognizable pain or weakness.[14,15,16] Although the aforementioned physical tests may be helpful tools, Tijssen et al. conclude that these tests are not able to reliably confirm or discard the diagnosis of FAI, when viewed in isolation. [14]



Figure 2
AP radiograph of the right hip demonstrating pincer-type femoroacetabular impingement.
Source: http://www.klinikum.uni-muenchen.de/Orthopaedische-Klinik-und-Poliklinik/de/Orthopaedisches-Behandlungsspektrum/hueft_ask/probleme_therapien/impingement/index.html

Diagnostic Imaging

Diagnostic imaging is utilized by most orthopedic surgeons in confirming the diagnosis of FAI. As described above, clinical history and physical exam alone, have not proven reliable in making a definitive diagnosis of FAI, therefore further studies are warranted.[17] The PROCESS survey reports that 66.3% and 70.8% of surgeons obtain plain radiographs and MRI, respectively, in confirming the diagnosis.[13]

At our institution, four plain film views are obtained in accordance with literature supported FAI radiographic assessment protocols. This protocol includes standing AP pelvis, standing false profile, supine modified Dunn lateral, and frog-leg lateral views. Each of these views provides specific information regarding the anatomy of both the acetabulum and proximal femur. Once familiar with the radiographic features of FAI, a reliable diagnosis should be able to be made by the practitioner.

In general, the standing AP pelvis and false profile views provides most useful information pertaining to the morphology of the acetabulum. From these views one can estimate the acetabular depth, inclination, and version, and measure the anterior and lateral center edge angles. These measurements are useful in estimating the amount of acetabular coverage of the femoral head.[18]

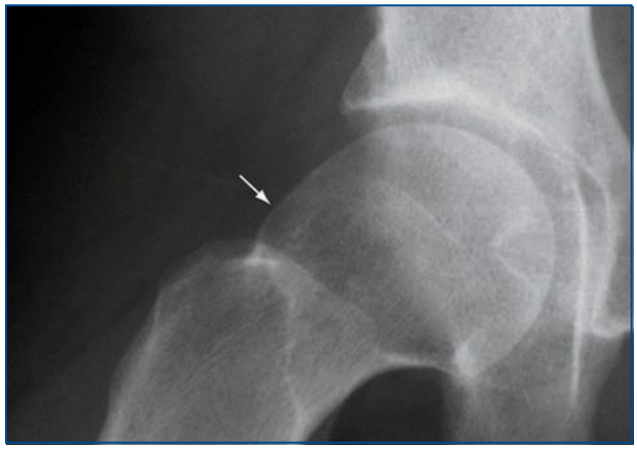


Figure 3
This is a frog leg lateral radiograph of the right hip demonstrating CAM-type FAI.
Source: http://clinicalgate.com/cam-type-femoroacetabular-impingement/

The supine modified Dunn lateral and frog-leg lateral views are most helpful when assessing morphology of the proximal femur. Head sphericity, as determined by gross inspection, or with the use of concentric circles, is determined using these radiographs. Femoral head-neck offset and head-neck junction deformities are often identified using these lateral views. The alpha angle is one useful quantitative measure used to evaluate these deformities.[18]

The alpha angle is determined by drawing a line through the center of the femoral neck and through the center of the femoral head. A circle is then drawn around the femoral head, using the spherical portion of the femoral head within the acetabulum as a guide to determine the radius of the sphere. A second line is drawn from the center of the femoral head to the anterolateral aspect of the head-neck junction where the radius exceeds that of the previously drawn sphere based off of the normal morphology. This is demonstrated in Figure 4 below. According to Clohisy et al, alpha angle greater than 42 degrees is indicative of femoral head-neck offset deformity, or CAM lesion. [18]

Treatment

Once the diagnosis of FAI is suspected or confirmed, early referral to the orthopedic hip specialist is recommended for timely evaluation and management. Conservative measures in the form of activity modification, physical therapy, non-steroidal anti-inflammatory medications, and pain medication may be trialed prior to more invasive techniques. However, as FAI

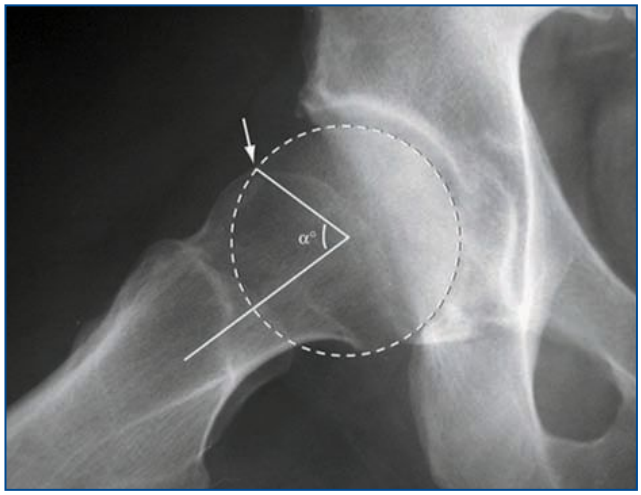


Figure 4
Demonstration of alpha angle calculation from the frog leg lateral view of the hip.
Source: http://clinicalgate.com/cam-type-femoroacetabular-impingement/

is a syndrome that is mechanical in nature, and tends to be diagnosed in young, active adults, many patients do not improve clinically with conservative measures.[19, 20] Failed conservative management has been generally accepted as an indication for surgical intervention in this patient population.

Orthopedic surgeons propose surgical treatment for the direct correction of anatomic deformities associated with FAI, as well as the associated lesions resulting from the abnormal morphology. Current surgical options include arthroscopy, open surgery with surgical hip dislocation, or a combination of the two. Surgical management is tailored to address the specific pathology and needs of each patient, and is also influenced by surgeon training and experience. Surgical intervention is also dictated by concomitant hip pathology. Especially when diagnosis is delayed, patients presenting with FAI and associated late sequelae, such as advanced osteoarthritis, are not ideal candidates for surgery aimed at correction of the FAI lesion. These patients are likely better served with joint arthroplasty.

Conclusion

FAI is a common cause of hip pain in young adults and adolescents that often goes unrecognized and untreated. This syndrome can lead to early degenerative disease of the hip in otherwise young and healthy individuals. Therefore, delays in diagnosis and treatment may have significant long-term consequences. Early diagnosis of FAI is vital to joint preservation, pain relief and restoration of function, and may improve quality of life in this patient population. As the primary physician is often the first practitioner to evaluate these patients, it is critical that they be familiar with the diagnosis and treatment of FAI, to expedite the appropriate management of these young patients to prevent the high morbidity associated with the disease process.

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Disclosure

None reported.

MM

Good Fats versus Bad Fats: A Comparison of Fatty Acids in the Promotion of Insulin Resistance, Inflammation, and Obesity

by James J. DiNicolantonio, PharmD & James H. O'Keefe, MD

A high-fat diet rich in certain fatty acids from natural foods such as olive oil, nuts, avocados, and oily fish can reduce obesity and improve long-term cardiovascular health.





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Abstract

Recently, debate has erupted in both the scientific community and throughout the lay public around whether a low-fat or low-carbohydrate diet is better for weight loss. In other words, is it better to cut fat or cut carbohydrate for weight loss. However, going beyond this debate (fat versus carbohydrate), are questions around whether certain fatty acids are worse for promoting insulin resistance, inflammation, and obesity. The overall evidence in the literature suggests that medium-chain saturated fats (such as lauric acid, found in coconut oil) and monounsaturated fat (oleic acid, found in olive oil) are less likely to promote insulin resistance, inflammation, and fat storage compared to long-chain saturated fatty acids (such as stearic acid found in large quantities in butter, but particularly palmitic acid found in palm oil) especially when consumed on top of a diet moderate in refined carbohydrates. Compared to long-chain saturated fats, lauric acid and oleic acid have an increased fatty acid oxidation rate, are more likely to be burned for energy and less likely to be stored in adipose tissue, and thus promote increased energy expenditure. Omega-6 polyunsaturated fatty acids (PUFAs), such as linoleic acid, as found in vegetable oils may contribute to obesity, whereas omega-3 PUFA may be protective. Importantly, both olive oil as part of a Mediterranean diet, and omega-3 from fish and fish oil have been proven to reduce risk of cardiovascular (CV) events.

Introduction

Obesity is characterized by an accumulation of adipose tissue either subcutaneously (underneath the skin) or ectopically (in and around organs). While many factors contribute to obesity, this paper will focus on the differences between fatty acids around insulin resistance, inflammation, and fat storage.

Upon their consumption, certain fatty acids are more likely to be stored in adipose tissue versus being burned for energy. This can be measured by the fatty acid oxidation rate after fatty acid ingestion. Medium-chain saturated fatty acids (C6-C12), alpha-linolenic acid (ALA), oleic acid, and linoleic acid have particularly high oxidation rates compared to certain long-chain saturated fats such as palmitate (16:0) and stearate (18:0).[1] In one study, the cumulative oxidation of different fats in humans over a nine-hour period from highest to lowest was laurate (41%), oleate

(18%), palmitate (16%) and stearate (13%).[2] In other words, long-chain saturated fats were less likely to be burned (lower oxidation rate) compared to laurate (found in coconut oil) and oleate (found in olive oil).

One study in eight normolipidemic subjects compared three isocaloric diets that were either high in saturated fatty acids (SFA), omega-6 polyunsaturated fatty acid (PUFA) or omega-3 PUFAs (30% of the fat came from fish oil) over 25 days. Each of the diets contained the same percentage of macronutrients (43% carbohydrate, 42% fat, and 15% protein). A fatty meal was then used for a fat loading test, consisting of 20% carbohydrate, 65% fat and 15% protein. Two fat loading tests were performed on each diet. Fasting insulin and the incremental two-hour post-prandial insulin over the fasting insulin from lowest (best) to highest (worst) were as follows, SFA diet (8 uU/ml and 10 uU/ml), omega-3 diet (12uU/ml and 14 uU/ml), and omega-6 PUFA diet (14 uU/ml and 25 uU/ml). Although the differences were not statistically significant, the particularly high insulin levels promoted by dietary omega-6 PUFAs suggests that these fatty acids in particular may promote greater fat storage compared to long-chain omega-3s or SFAs when consumed on top of a diet moderately high in carbohydrate.[3] Mechanisms whereby omega-6 PUFAs may promote fat mass accumulation include inhibition of omega-3s anti-obesogenic effects (such as increased fatty acid oxidation, increased basal metabolic rate, increased protein and muscle synthesis) and promotion of fat-storing prostaglandins, endocannabinoids and increased hunger.[4] Observational studies support this notion, whereby central obesity is positively associated with omega-6 PUFAs in adipose tissue but inversely with MUFAs and omega-3 PUFAs.[5]

The Kanwu study compared a diet high in SFAs to a diet high in MUFA in 162 healthy individuals on top of a diet moderately high in carbohydrate (~ 45% of total calories).[6] Those consuming the SFA diet used butter and table margarine high in SFA, whereas the MUFA diet used spreads and margarine with high proportions of oleic acid from high-oleic sunflower oil. Patients were instructed to eat isocaloric diets containing 37% energy from fat, the SFA-enriched diet containing 17% SFA, 14% MUFA and 6% PUFA and the MUFA-enriched diet containing 8% SFA, 23% MUFA and 6% PUFA. Insulin sensitivity was impaired (-10%, $p = 0.05$ borderline significance) in the diet higher in SFAs, whereas no change occurred in the MUFA diet. Moreover, in those eating less than 37% total energy as fat the difference between the groups was statistically significant (20.3% difference, $p < 0.03$). Insulin sensitivity was 12.5% lower in the diet higher in SFAs and 8.8% higher on the diet high in MUFA. Thus, a diet higher in MUFA may improve insulin sensitivity compared to a diet higher in SFAs when consumed on top of a diet moderately high in carbohydrates. These results may have been in part due to differences in the foods eaten in the diets, rather than the exchange of MUFA versus SFAs per se.[6] (See Table 1).

Table 1
Benefits of MUFA (oleic acid) versus SFA (palmitic acid) [12, 30]

- Increased fasting and postprandial fatty acid oxidation
- Increased daily energy expenditure
- Decreased visceral fat accumulation
- Decreased DAG and ceramide formation

A randomized parallel controlled-feeding trial was performed in 60 non-diabetics (40-65 years old) with mild abdominal obesity.[7] After consuming a two-week run-in diet high in saturated fat (19% energy), patients were placed on a high MUFA diet (20% energy), a Mediterranean diet (MUFA 21% energy) or high SFA diet for 8 weeks (carbohydrate intake was 47.3% energy in SFA, 46.4% in MUFA and 41.1% in Mediterranean diet). The high MUFA diet reduced TC, LDL-C and the TC/HDL compared to the SFA-diet. There was no significant difference in insulin levels or insulin sensitivity between the diets (no difference in C-peptide, HOMA-IR and glucose). The authors concluded, "…in our controlled-feeding trial, a high MUFA-diet and a Mediterranean diet did not affect insulin sensitivity compared to a high SFA-diet."

This result was similar to a paper published by Lovejoy and colleagues comparing diets high in SFA (9%), MUFA (9%) or trans-fat (9%) that found no difference in insulin sensitivity on top of a high carbohydrate intake (57% energy).[8] However, insulin sensitivity did worsen by 24% in the SFA versus the MUFA diet in overweight subjects. Thus, the evidence appears to indicate that a diet higher in MUFA is slightly better for improving insulin sensitivity compared to a diet high in SFAs in certain individuals (those eating less than 37% energy as fat or in those who are overweight who are eating a diet moderately high in carbohydrate).

Due and colleagues randomized 46 non-diabetic obese men and women to one to three diets: 1) a MUFA diet moderately high in fat (35-45% of total calories from fat, of which MUFA was > 20% energy); 2) a low-fat diet (20-30% of total calories energy from fat); and, 3) a control diet (35% of total calories from fat, of which saturated fat was > 15% energy).[9] Compared to the MUFA diet, the diet high in SFAs (the control diet) significantly increased fasting glucose, fasting insulin and HOMA-IR (a measurement

homeostasis model assessment of insulin resistance). However, the MUFA diet was also a low-glycemic diet, whereas the low-fat and control diets were medium and high-glycemic, respectively. Thus, the findings could be the result of the differences in the glycemic index of the diets rather than the differences in fatty acid composition.

Another study in 14 male volunteers showed that the five-hour postprandial fat oxidation rate was higher with a breakfast meal (42% carbohydrate, 43% fat, 15% protein) containing MUFA (extra virgin olive oil) versus cream.[10] In patients with a high waist circumference, there was also a significant increase in the thermic effect with the MUFA-rich versus the SFA-rich meal. The thermic effect of food is the amount of energy expenditure above the basal metabolic rate due to the processing of food. Thus, the amount of energy required to process MUFA was higher than that of SFA when moderate amounts of carbohydrate are consumed. This may partially explain why studies have shown increased fat and weight loss with MUFA versus SFA diets. For example, protein has a higher thermic effect (requires more energy to process) compared to carbohydrate and thus more calories are burned when consuming equal amounts of calories from protein versus carbohydrates.[11]

In humans, increasing the palmitic acid/oleic acid ratio reduces daily energy expenditure in men and decreases fat oxidation in the fed and fasted state in women.[12] In postmenopausal women, postprandial fat oxidation rate is higher after an isocaloric meal that includes extra virgin olive oil (EVOO) versus cream.[13] In this trial, in those who were obese, diet-induced thermogenesis was significantly higher in the isocaloric meal containing EVOO vs. cream (5.1% vs. 2.5%, $p = 0.01$, respectively). The authors concluded, "The present study showed that olive oil significantly promoted postprandial fat oxidation and stimulated diet-induced thermogenesis in abdominally obese postmenopausal women."[13] Meals enriched with MUFA vs. SFA have provided increased fat oxidation rates.[10] And the high oxidation rate of laurate may explain the lower weight gain that occurs with medium-chain saturated fats versus longer chain saturated chain fats.[2, 14] Medium chain saturated fats (8-14 carbons) are also oxidized slightly faster than even ALA and oleic acid.[15] This is partially why medium chain triglycerides are suggested for weight loss.

While it is well known that fatty acids enter muscle tissue in order to be oxidized for ATP production used for muscle contraction, it is less commonly known that MUFA may be directed more towards oxidation than long-chain SFA. Thus, long-chain SFAs are more likely to be stored in muscle versus MUFA, especially on top of a diet high in refined carbohydrates. This is why SFAs may cause greater muscle insulin resistance via increased intramyocellular lipid accumulation. Moreover, long-chain SFAs, as compared to unsaturated fats, are more readily incorporated into diacylglycerol (DAG) versus triacylglycerol (TAG), which may also increase inflammation and insulin resistance.

Palmitate can increase the cellular content of DAG and ceramide, which are pro-inflammatory molecules, whereas oleate mainly increases TAG, which is less inflammatory.[16, 17] SFAs have a lower affinity for DGAT2, the enzyme that converts DAG to TAG. This is why long-chain SFAs are more likely to be stored as DAG compared to TAG. And long-chain SFAs are also the rate limiting substrate of serine palmitoyl-transferase, which is the enzyme that forms ceramide, which is why ceramide formation is greater with long-chain SFAs compared to unsaturated fatty acids.[1]

Different fats have varying effects on insulin signaling and cell health. Incubating human myotubes with palmitate causes insulin resistance, whereas no such effect was found with oleate.[16, 18] Palmitate also increases ceramide synthesis, caspase 3 activation and apoptosis in skeletal muscle myotubes.[19] These results are likely only relevant in those with hyperinsulinemia or who are eating a moderate to high amount of refined carbohydrate, as dietary SFA per is not the main factor determining increases in palmitate in the body but rather refined carbohydrate intake.[20] Thus, the combined intake of refined carbohydrates with long-chain SFAs, which is typical for the standard American diet, creates the perfect storm for precipitating insulin resistance, inflammation, and obesity.

The Mediterranean diet is well known for its ability to improve the metabolic syndrome. Indeed, one study concluded, "Adherence to a Mediterranean diet is modestly associated with a better insulin sensitivity, lower levels of total cholesterol and lower levels of systolic blood pressure (BP) in overweight and obese subjects."[21] A meta-analysis of 50 studies (prospective studies and clinical trials) in over 500,000 individuals has found that the Mediterranean does indeed reduce the risk of the metabolic syndrome.[22] Olive oil may partially explain the benefits of a Mediterranean diet. Indeed, olive oil has been found to "rescue" palmitate-induced cell death by decreasing its incorporation into DAG and ceramides through multiple mechanisms including enhanced beta-oxidation and increasing its synthesis into TAG.[1, 23] Thus, by shunting palmitate into the TAG pool and increasing its beta-oxidation, oleic acid may be able to reduce the harms of a diet high in refined carbohydrates plus long-chain SFAs.[20]

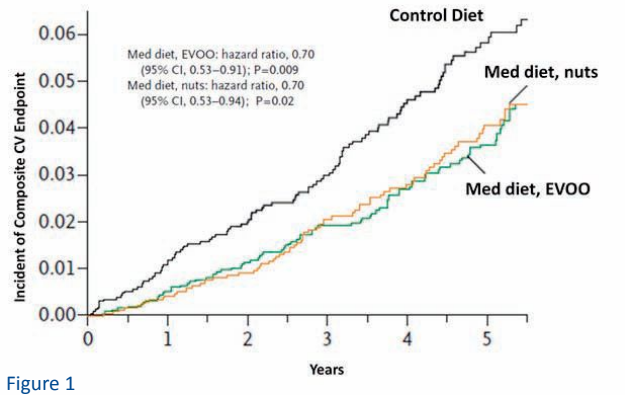


Figure 1
Kaplan-Meier Estimates of the Incidence of Outcome Events in the Total Study Population: The incidence of the primary end-point (a composite of acute myocardial infarction, stroke, and death from CV causes). Hazard radios were stratified according to center (Cox model with robust variance estimators). CI denotes confidence interval, EVOO extra-virgin olive oil, and Med Mediterranean.[31]

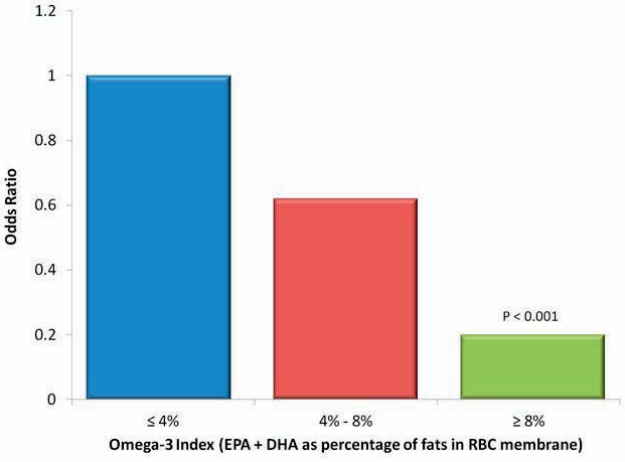


Figure 2
Omega-3 index as a risk factor for coronary heart disease.[32]

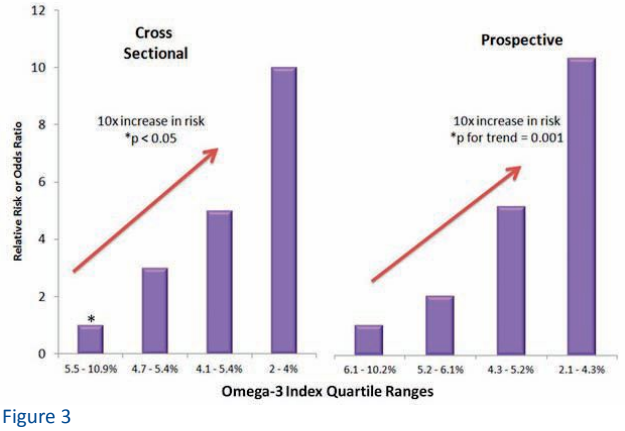


Figure 3
Risk of primary cardiac arrest as a function of quartiles of red blood cell EPA plus DHA levels. [32]

Most foods that are high in saturated fat are also high in oleic acid. Thus, demonizing saturated fats per se is inappropriate, especially when the concomitant intake and type of dietary carbohydrate is not considered. However, on top of a diet that is moderate to high in refined carbohydrates, a diet higher in oleic acid, as compared to long-chain saturated fats (particularly palmitic acid found in full-fat dairy and palm oil) will likely improve insulin resistance and promote fat loss. In other words, reaching for olive oil compared to heavy cream or butter will likely lead to less fat gain when consumed on top of a diet moderately high in refined carbohydrates. And this has been shown in a randomized cross-over study.[24] Indeed, in overweight or obese men replacing a diet high in SFA with MUFA for four weeks significantly reduced body weight (-2.1 kg) and fat mass (-2.6 kg) despite the same number of calories and fat being consumed.

Long-chain saturated fats are also more likely to be retained in the liver, whereas MUFA is more likely to enter muscle cells.[1] Cell line studies using endothelial and vascular smooth muscle cells have found that palmitate induces cardiovascular (CV) insulin resistance, whereas oleate had a protective effect against palmitate induced insulin resistance.[25] The authors concluded, "…oleate protects against CV insulin resistance, improves endothelial dysfunction in response to proinflammatory signals and finally, reduces proliferation and apoptosis in vascular smooth muscle cells that may contribute to an ameliorated atherosclerotic process and plaque stability." Elevated levels of palmitate may also induce inflammation and insulin resistance in skeletal muscles via diacylglycerol-mediated activation of protein kinase C and activation of toll-like receptors.[25] However, oleic acid has even been found to prevent mitochondrial dysfunction, inflammation and insulin resistance in neuronal cells[25, 26] and skeletal muscle[27, 28] induced by palmitate.

Long-chain saturated fats (such as palmitic acid 16:0 and stearic acid 18:0) are more likely to be retained in the liver and skeletal muscle compared to oleic acid, which is reflected by the lower postprandial oxidation rate of long-chain SFAs compared to oleic acid.[1] This may also reflect MUFA being more readily packaged into VLDL triglycerides and exported out of the liver rather than being stored in adipose tissue. Additionally, compared to SFA, MUFA is more readily taken up by peripheral tissues, which may also lead to lower non-esterified fatty acid levels and less insulin resistance.[1] Palmitate may particularly increase visceral fat storage, whereas oleate seems to store fat in subcutaneous adipocytes.[29] Fat storage versus burning is ultimately determined by the background intake of refined carbohydrates and the type of

fat (palmitic acid being stored in the visceral fat, whereas oleic acid is generally stored subcutaneously). This has been confirmed in obese patients, whereby greater amounts of saturated fats are stored ectopically (perivascularly), whereas monounsaturated fats are stored subcutaneously.[5]

Conclusion

In summary, a diet high in MUFA (for example, olive oil, avocados, almonds, peanuts, macadamia nuts or hazelnuts) will likely lead to improvements in insulin resistance as well as fat and weight loss compared to diets higher in long-chain SFAs (for example, cream or butter). A diet higher in omega-6 PUFA as compared to long-chain omega-3 PUFA may also promote insulin resistance, inflammation, and obesity. Importantly, olive oil and nuts as part of a Mediterranean diet (See Figure 1),[31] and omega-3 from fish and fish oil (See Figures 2 and 3)[32] have all been proven to reduce risk of CV events. Thus, a high-fat diet rich in certain fatty acids from natural foods such as olive oil, nuts, avocados, and oily fish can reduce obesity and improve long-term CV health.

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Disclosure

JO is Chief Medical Officer and Founder of CardioTabs, a nutraceutical company. He has a major ownership interest in the company. CardioTabs does sell products that contain Omega-3. JD is the author of The Salt Fix and operates the website thesaltfix.com. **MM**

Penetrating Ocular Trauma from a Bean Bag Gun: A Case Report and Review of Less-Lethal Force and Their Consequences

by Daniel Wehrmann, MD, Jastin Antisdel, MD, Scott Walen, MD & Joseph Brunworth, MD

Even non-lethal munition can have severe morbidity associated with their use.



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Abstract

Although bean bag guns are considered a "less-lethal" form of law enforcement, these blunt projectiles have risk. The purpose of this study was to perform a literature review of morbidity and mortality associated with less-lethal munitions and present a case report of a bean bag injury leading to a traumatic globe evisceration and skull base fracture. Patients presenting with bean bag gun associated injuries warrant a high clinical suspicion for injury to deeper structures.

Introduction

The bean bag gun is considered a "less-lethal" weapon used primarily by law enforcement agents (often in riot situations) as an alternative to lethal methods of protection. (See Figure 1.) Although many manufacturers produce different versions of this blunt projectile, the basic composition includes a sturdy fabric encasement filled with small diameter lead shot that is loaded into a shotgun cartridge and fired from a 12-gauge shotgun[1]. The intended usage of the bean bag gun is to render the offending party into a controllable state without causing life threatening or permanent sequalae.

Case Report

In our case, the patient presented to the emergency room after being shot in the eye by the blunt projectile. The patient described instant vision loss and severe right-sided facial pain. He was evaluated in the emergency room with computed tomography of the head and facial bones. This revealed a 3cm hyperintense mass that had traversed through the right orbit, fractured the superior, medial, and inferior orbital walls, the ethmoid air cells, the greater wing of the sphenoid, both anterior and posterior tables of the frontal bone as well as cribiform plate as seen in Figure 2. Beyond these injuries, it was difficult to assess further osseous injury given the significant artifact created by the lead shot. Considering the proximity of the retained foreign body to the cavernous carotid artery, the decision was made to perform a formal angiography to better assess the risk of arterial rupture during surgery. The angiogram did not show obvious damage to the internal carotid system and at that time, given

risk of prolonged lead exposure and infection, the decision was made to proceed to the operating room for wound exploration and extraction of foreign body. Options for extraction of the foreign body within the sphenoid sinus region included a transnasal endoscopic approach, transorbital, lateral rhinotomy, or midface degloving.



Figure 1
Less-Lethal Close Quarters Combat Shot Gun by WilsonCombat.com

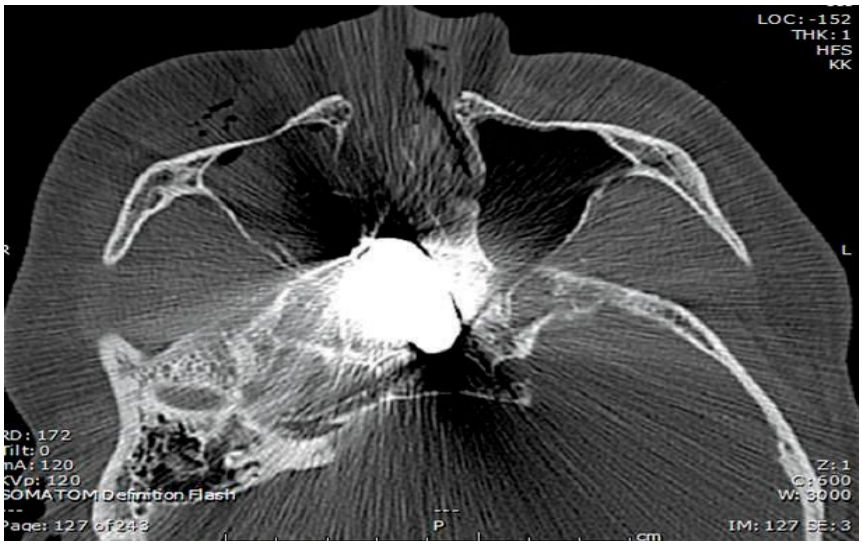


Figure 2
An axial CT scan at the level of the sphenoid sinus showing the projectile lodged against the anterior skull base in the nasopharynx.



Figure 3
The bean bag after removal from nasopharynx via an endoscopic approach.

Surgical Technique

Under general anesthesia, the patient was prepared for standard endoscopic sinus surgery setup with an additional field created over the right lateral thigh for emergent muscle patch should carotid bleeding have been encountered. During nasal endoscopy, significant narrowing of the nasal passage was seen due to swelling, septal deviation (towards the side of the foreign body), and significantly comminuted fractures of the lateral nasal wall/ medial wall of the orbit. The decision was made to perform an endoscopic septoplasty, right middle turbinectomy, and inferior turbinoplasty in order to create a passageway for the projectile to be removed. Using slow and steady traction, the foreign body was able to be removed through the ipsilateral nostril as seen in Figure 3. After removal of the foreign body, orbital contents were identified within the nasal cavity, including avulsed eyelid skin with eyelashes still attached. After the extraction, the patient also underwent an attempted enucleation of the remainder of the right globe with closure of complex right lower eyelid. The tattered eyelid found in the nasal cavity was non-viable and thus unable to be incorporated into the closure.

Discussion

Less lethal ballistics have become an alternative to traditional bullets amongst law enforcement for crowd

Table 1: Literature reporting injury* from less-lethal munitions

	Total No. of injuries	No. of fatalities	No. of retained projectiles	No. of head/neck injuries	No. of orbital injuries
Sehgal and Challoner 1997	3	0	1	0	0
de Brito et al 2001	69	1	7	5 (7%)	1
Grange et al 2002	4	0	3	0	0
National Institute of Justice 2004***	373	8	NA	2%	0
Dojcinovic et al 2007**	1	0	1	1	0
Current case 2014	1	0	1	1	1

*injury=additional injury outside of contusions, hematomas, or abrasions
** Dojcinovic case was a FN303 paintball ballistic rather than a bean bag (1-4)
*** NIJ reports all non-lethal ammunition 65% reported is bean bag, 1 of the deaths from injury to the head and neck

control and rioting. These have ranged from batons, to stun guns, to blunt projectiles including rubber bullets, paint balls,and bean bags. Blunt projectiles have continued to blossom over the past several decades. However, little research has been done on the sequelae from this less lethal munition.

Less lethal law enforcement has become an acceptable alternative to subdue suspects. Throughout the literature there have been case reports and case series looking at sequelae of this form of crowd control[1-4]. In 2004, the National Institute of Justice published the impact of less lethal munitions. There publication is the most inclusive to date, reviewing 373 injuries, caused by all less lethal munitions. They note that bean bag munitions comprised 65% of all injuries. In their study, they note eight deaths, one linked to a penetrating neck wound. The remainder of the deaths were from thoracic injuries.[5] Prior to our case, there was only one previously published case of orbital trauma from a bean bag injury, however in this case the bean bag and the casing did not separate and both were removed from the orbit. However, to our knowledge, to date there is no reported penetrating ocular trauma involving only the bean bag munition. The injuries described in the past include contusions, hematomas, abrasions and penetrating injuries. The most common location of injury is the thorax. The overall rate of injury to the head and neck from all previously published research is 2-3%, as detailed in Table 1.

In this case, during a period of civil unrest, the patient suffered a penetrating shot through the globe leading to enucleation of the eye, fractures of the globe, and skull base. The patient went urgently to the operating room with ophthalmology for formal enucleation of the globe. Further discussions were had with law enforcement, the material within the bean bag was lead and the decision was made to go for formal extraction of the bean bag with closure of cerebrospinal fluid leak.

This case shows that even non-lethal munition can have severe morbidity associated with their use. As a clinician, one must have a heightened awareness of the significant injuries that can be associated with this type of munition and complete an extensive physical exam to rule out any other associated injuries that are not uncommonly seen with this type of non-fatal law enforcement.

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Disclosure

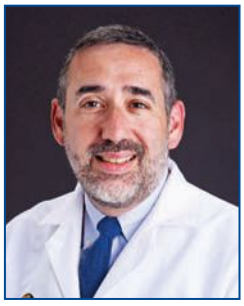
None reported.

MM

Sleep and Dementia

by Joel I. Shenker, MD, PhD & Gurtej Singh, MD

The relationship between problems with sleep and impaired neurocognition is likely complex and bidirectional.



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Abstract

Neurocognitive and sleep problems are common, underdiagnosed, and frequently co-morbid. Sleep disruption, and fatigue, predict cognitive impairment. Cognitive impairment, in turn, can worsen sleep hygiene. In dementia patients, sleep disorders are common, and dementia medications affect sleep. Emerging insights on the brain's glymphatic system suggests that sleep may drive clearance of Aβ peptide to affect Alzheimer pathophysiology. Parkinsonian dementias are linked with REM behavior disorder, a highly treatable problem that predicts future conversion into dementia.

Introduction

Sleep problems and neurocognitive impairment have a lot in common. Both frequently occur, yet in clinical practice, are frequently missed. Sleep disorders exist in as many as 70 million people in the United States, based on epidemiological data, but a retrospective review of over 100,000 contacts with over 20,000 patients in a large primary care network found that a sleep disorder was diagnosed in under 3.5% of patients[1]. Similarly, neurocognitive disorders are common, and under-diagnosed. In one study, nearly 4000 primary care patients 60 years or older underwent prospective cognitive testing. Whereas 15.7% had demonstrable cognitive impairment, it was seldom noted in a retrospective review of individual medical charts. Even for those with moderate to severe impairment, under 25% of the time had clinicians noted the problem[2]. Perhaps unsurprisingly, in addition to being prevalent and under-recognized, sleep and neurocognitive concerns often occur together. Amongst cognitively normal elderly, daytime sleepiness is an independent risk for neurocognitive decline[3]. Similarly, when cognitive concerns are the index clinical marker, sleep is often impaired. In one study that queried 431 consecutive patients seen for mild cognitive impairment or dementia across 10 centers, more than 60% also met criteria for a sleep disorder[4]. Thus, there is wide overlap between the constructs of sleep disorders and neurocognitive disorders.

The purposes of this review are (1) to provide information a busy clinician may use in patients with problems relating to sleep or cognition, and (2) to highlight prominent research themes likely to dominate future work in this area.

Sleep Problems and Neurocognition

Sleep problems can cause

cognitive difficulty. Thus, in a clinical setting, a sleep complaint should prompt investigation for a neurocognitive consequence, and a neurocognitive complaint should prompt concern for a possible causative sleep problem. Sleep problems can worsen cognition for nonspecific as well as more specific reasons. Nonspecific issues begin with the fatigue that a sleep problem can create. Fatigue may worsen neurocognitive performance, for example, when reduced alertness makes it harder to use one's neurocognitive capacity. From this point of view, fatigue, whatever its cause, simply creates an additional burden for a specific neurocognitive task to overcome, in addition to the need to address the neurocognitive challenge itself. In this way fatigue from a sleep disorder might not alter one's true neurocognitive capacity in a primary sense, but may merely make it harder to use that capacity. One way in which fatigue may have such effects is by hampering the brain's fundamental computational functions. This idea is seen in a study that found an association between fatigue and decreased functional connectivity in the so-called "default mode network" (DMN). The concept of a DMN is that it is a widely distributed neurocognitive network of anatomically connected brain regions that tend to become active or quiescent together, by default, when a person is awake but disengaged, as when one lets one's mind wander. The DMN is commonly assessed using such technologies as functional magnetic resonance imaging (fMRI). One study[5] found that the more that subjects reported fatigue, the more they had reduced DMN functional connectivity on fMRI. The association of increased fatigue with worse DMN fMRI connectivity was the same in young and older individuals, suggesting that the relationship was not due to age per se. Though correlational, these data are intriguing because they suggest that fatigue affects neurocognitive performance by altering the baseline DMN, a basic neurocognitive substrate from which more specific neurocognitive modalities might draw.

In addition to nonspecific matters, some sleep disorders may disrupt neurocognition in a more specific, or at least nonrandom, manner. One example of such a relationship was shown in a systematic literature review of 65 published studies of obstructive sleep apnea[6]. The review concluded that across the published reports identified, though some "controversies" existed, neurocognitive function was commonly impaired. Certain neuropsychological domains were likely to be affected (e.g. attention, memory), some were unlikely to be affected (e.g. language, psychomotor speed), and some were inconsistently affected (e.g. executive function). Thus, a sleep disorder may not affect all neurocognitive domains to the same degree.

Sleep problems may harm waking neurocognition in a manner separate from the degree to which fatigue is simply imposed on neurocognitive performance. Disrupted sleep itself may directly hamper neurocognition. One reason is that the components of the normal "architecture" of sleep, with repeated cycling through rapid eye movement (REM) and non-REM sleep, may make specific contributions to waking cognition. In an animal model of this relationship, when experimenters forced fragmented sleep architecture onto animals, doing so caused disrupted hippocampal long-term potentiation and worsened a behavioral learning task, outcomes apparently not attributable to fatigue alone since animals did not sleep more when allowed to do so[7]. Such findings raise the suggestion that human sleep disorders could disrupt waking cognition via primary effects on sleep architecture itself. Indeed, such appears to be the case in sleep disordered breathing, for example, where cognitive impairment may be associated with more time in non-REM stage 1 sleep and less time in REM sleep[8].

Given these considerations, it is unsurprising that in a large sample of elderly patients, when people reported more fatigue or worse sleep quality, and when they were observed to have inefficient or reduced sleep, these variables predicted observed cognitive decline[9]. Thus, when a patient has neurocognitive trouble, sleep is a good place to look for a possible cause.

Sleep Problems in Neurocognitive Disorders

People with dementias of all types are more likely to have a protean variety of sleep problems[10]. This linkage may be independent of the specific brain neurocognitive disease. The idea that a neurocognitive disorder could impair sleep makes sense. Since a person with dementia would be expected to make less good decisions about behavior and self-care, such a person may also make worse decisions regarding sleep hygiene, too (e.g. planning and sticking to regular times to go to bed or wake up; avoiding fluids, caffeine or alcohol before bed; remembering to turn off lights and eliminating sources of noise). Another reason to expect sleep problems in dementia patients is because misinterpretations

about the meaning of night time experiences may make for a tormenting exercise – fatigue related cognitive decompensation, dreams being mistaken for reality, failure to recognize a sleeping partner, increased risk of visual agnosia or visual hallucinations in low lighting conditions, for example, could collectively conspire to make a night's sleep a challenging experience.

Commonly, people with dementia have impairments in diurnal sleep-wake variations. Because the neurological diseases that cause dementia may also affect brain structures such as the suprachaismatic nucleus, a region that helps maintain circadian rhythmicity, chronobiological difficulties occur in many individuals with a neurodegenerative dementia[11]. Such a finding may explain why even subtle changes in circadian behavioral activity may more than double the conversion rate into a clinical state of mild cognitive impairment (MCI) or dementia[12]. One type of chronobiological problem may be particularly vexing in those who suffer from dementia. When advanced sleep phase problems ensue, sleep onset tends to occur earlier than may be usual based on environmental cues. Such problems could contribute to the "sundown" phenomenon, wherein a dementia patient becomes more agitated or worsens neurocognitively in the late afternoon or early evening. Advanced phase problems might also result in a patient waking up early, feeling a need to dress and take on the day while others are still asleep, thus resulting in the common caregiver's report that a patient is "mixing up day and night." An otherwise well-intended clinical response to prescribe sedative-hypnotics at bedtime does not address the underlying causal chronobiological problem per se, and may risk causing more unwanted side effects than may be worth the effort. By contrast, judicious use of such modalities as melatonin, light therapy, encouraging daytime activity to delay sleep, and other caregiver-assisted sleep hygiene maintenance may be better choices with more efficacy, tolerability, and less cost[13].

Another matter is that many dementia patients are prescribed cholinesterase inhibitors – donepezil, galantamine, or rivastigmine[14]. Though all three agents are FDA approved for Alzheimer disease, and one (rivastigmine) is FDA approved for Parkinson disease dementia, off-label use is common. Though these agents provide clinical benefit to the degree that future decline in cognition, behavior, and function may be less for individuals on medications as compared to those not on medications, their cholinomimetic effects are not without possible additional effects. Cholinesterase inhibitors may have a multitude of sleep consequences. Double-blind placebo-controlled trials show that a cholinesterase inhibitor reduces sleep apnea and increases night time oxygen saturation, and as would be expected for a pro-cholinergic medication, there is a marked stimulatory effect on REM sleep[15]. The latter consequence may explain why some patients report "wild" or "vivid" dreams on cholinesterase inhibitors. While we have anecdotally noted that restricting oral administration of such medications to a morning dose may minimize the complaint of overly vivid dreams, in some people the complaint persists and remains disruptive to sleep quality, if not quantity. Thus, the clinician may have to make a patient based judgment about how best to balance the functional costs of cholinesterase inhibitor use versus their theoretic clinical drug benefits.

Sleep and Alzheimer Disease

An intriguing emerging notion posits that sleep issues may play a direct role in causing Alzheimer disease, the most common disease leading to dementia. This argument rests on three main conclusions. First, the argument linking sleep to Alzheimer disease begins with accepting the "amyloid cascade" model of Alzheimer etiology[16]. First proposed in the early 1990s, and revised substantially since, the current instantiation of the amyloid cascade hypothesis posits that Alzheimer disease is caused by a series of molecular and cellular events that ultimately result in the formation of extracellular amyloid plaques. Key to this model is the notion that pathological splicing of trans-membranous and extracellular portions of the amyloid precursor protein (APP) yields a potentially toxic soluble extracellular peptide, Aβ, the primary molecular species that accumulates in amyloid plaques. Considerable evidence has established that such an amyloid cascade does occur in people with Alzheimer disease. It has been hypothesized that events which tend to oppose soluble Aβ peptide should tend to prevent or delay the symptomatic brain damage of Alzheimer disease, whereas events that tend to promote soluble Aβ peptide may accelerate Alzheimer related brain dysfunction, though it remains unclear which step between generating soluble Aβ peptide and amyloid plaque formation is most critical for brain dysfunction itself. While there is some debate

about the extent to which the amyloid series of events is a cause of Alzheimer disease, or simply a marker of it[17], the model remains influential and widely accepted as involved in Alzheimer etiology.

The second pillar to the argument linking sleep to a cause of Alzheimer disease rests on the functioning of the recently proposed "glymphatic" system, a system thought to be the brain's analog to the body's lymphatic system[18]. The notion of glymphatic flow is that brain astrocytes create movement of extracellular fluid, a process that may help clearance of waste substances and other materials out of the central nervous system. It stands to reason, then, that an extension of the amyloid cascade hypothesis and the concept of a glymphatic system is the speculation that glymphatic flow may help remove soluble extracellular Aβ peptide from the brain.

The third key point in the argument linking sleep to Alzheimer etiology is that sleep modulates the glymphatic system, and that this modulation helps control Aβ clearance from the brain. Supporting such a view are several findings of interest: (1) Aβ concentrations in the brain's extracellular milieu fall during sleep and rise during wakefulness[19]; (2) mice that are genetically programmed to create Aβ show more Aβ deposition when sleep deprived as compared to when the mice are not sleep deprived[19]; (3) exogenously infused Aβ peptide is largely cleared during slow wave sleep (SWS) in a mouse model[20]; and (4) in humans, non-REM SWS impairment is correlated with increased amyloid[21].

By implication, then, an emerging hypothesis is that sleep, perhaps SWS in particular, may help clear Aβ peptide out of the brain via glymphatic flow, and thus impaired SWS could contribute to the processes that directly cause Alzheimer disease, or at least it may be that impaired SWS could influence ongoing Alzheimer pathophysiology. This line of inquiry promises to be a topic of future research as it carries potential for therapeutic intervention if a way can be found to promote more adaptive sleep patterns to help slow Alzheimer pathology. Also, sleep related modulation of glympahtic clearance of Aβ may serve as a template for understanding underlying etiology of other neurodegenerative diseases where a pathologic accumulation of a toxic molecular species may be hypothesized to occur.

Sleep and Parkinsonsonian Dementias

One of the most robust connections between a sleep disorder and a dementia-causing disease is seen in the association between REM behavior disorder (RBD) and neurodegenerative Parkinsonism, a topic substantially reviewed in its own right[22]. In normal REM sleep, a stage of sleep in which most dreams occur, normally most of the body's skeletal muscles are paralyzed (sparing muscles that move the eyes, and muscles of respiration). By contrast, in RBD, the expected skeletal muscle atonia that should have occurred throughout the body in REM sleep does not occur. As a result, when the sleeper experiences a dream, movements may occur, such that it may appear that the person is acting out the dream. A caregiver may report that the patient makes subtle movements or dramatic and violent ones, and the matter can thus pose a safety risk for both sleeper and sleep partner, as well as create greater sleep fragmentation. The condition is often quite treatable with melatonin or low dose clonazepam. But, a diagnosis based on history alone can be difficult, since motor activity during non-REM sleep is not pathological, and some dreams and other mental activity can occur in non-REM sleep. Thus, even a caregiver report of observing possible dream enactment movements during sleep may be non-definitive. An RBD diagnosis can only be made when it is known that a sleeper is moving during REM sleep. Thus a polysomnogram is often needed for a definitive diagnosis.

Interestingly, longitudinal studies of people with RBD show that in those who have this diagnosis, virtually all go on to develop a neurodegenerative Parkinsonian disease, though in some cases, such may emerge only after many years' delay. Approximately 50% of people with RBD show neurological signs of a Parkinsonian disorder (e.g. Dementia with Lewy Bodies, or Parkinson Disease) within a decade, and as much as 90% do so at some future point thereafter[22]. In a review of over 5000 studies that evaluated risk factors for Parkinson disease dementia (PDD), of the studies that met criteria for further analysis, the average relative risk for PDD was estimated to be 8.38 in individuals with RBD, higher by far than for any other factor[23]. Thus, the finding of RBD in a patient should particularly prompt close clinical attention for the potential future emergence of a Parkinsonian condition, a complication of which is highly likely to include dementia at some point. Similarly, in a patient with a dementia, careful attention to clinical history or a formal sleep study to rule in RBD should prompt high suspicion for concluding that the

cause of the dementia might be a Parkinsonian spectrum condition, even if not otherwise clinically apparent at that moment.

Conclusion

Sleep disorders and neurocognitive disorders are both frequent categories of disease, but they often are missed in regular clinical practice. In this brief review we have shown that sleep and neurocognitive disorders often occur together. The relationship between problems with sleep and impaired neurocognition is likely complex and bidirectional. In some instances the co-occurrence of sleep and neurocognitive difficulty may be because sleep problems cause cognitive difficulty, in both nonspecific ways and specific ones. In other cases a disease causing a neurocognitive disorder, or some of its symptomatic or iatrogenic sequlae, may lead to impaired sleep. Alterations in sleep may be a fundamental substrate or major relative risk for some neurodegenerative causes of dementia. As some of the involved conditions are treatable, and most can be highly symptomatic with risks that patients and support systems alike are well advised to be aware of, it behooves the clinician to be proactive and aggressive in diagnosing both sleep disorders and neurocognitive ones. As we have argued in this review, then, the finding of a sleep disorder should prompt careful clinical attention to the possibility for an occult neurocognitive impairment, and vice versa.

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Disclosure

None reported. **MM**

Embedding a Medical Search Engine Within an Electronic Health Record

by Patricia Alafaireet, PhD, Jeff Belden, MD, Matt Botkin, Karl Kochendorfer, MD, Robin Kruse, PhD, Dylan Strecker, BS & Jayne Williams, MA

Studies show that 64-70% of clinical questions go unanswered, despite the existence of an answer, because physicians did not expect to find an answer or lacked time to pursue one.



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Abstract

This study investigates an information retrieval tool embedded in an electronic health record (EHR). 1-Search provides a single search for retrieving information from a variety of content sources. 1-Search's usefulness and impact were determined by measuring the extent of physicians' information needs, pre- and post-implementation user satisfaction, and the impact of 1-Search on clinical decision-making. Results support incorporation of 1-Search into the EHR, the continued use of 1-Search, and further development.

Introduction to the Problem

Studies show that 64-70% of clinical questions go unanswered, despite the existence of an answer, because physicians did not expect to find an answer or lacked time to pursue one.[1-4] On average, physicians generate about two questions per every third patient encounter, and often need answers to medical questions while they are seeing patients.[1,4-11] In 2009, patients made 1.3 billion visits to physicians' offices, hospital outpatient departments, and hospital emergency departments.[12] These visits generated an estimated 867 million clinical questions, of which, by basic calculation, about 607 million (70%) went unanswered, potentially affecting the quality of care for 405 million patient visits.[12]

Physician's information needs are often complex and require access to high-quality, specialized information from multiple, dispersed sources, including electronic resources produced by publishers and content aggregators, each of which varies in breadth of content, depth of information, and quality of evidence.[2,13] These sources may be difficult to navigate and time-consuming to access at the point of care.[3,13,14] Searching multiple information sources during the typical 15-minute patient consultation may be too time-consuming and detract from patient-physician communication. The time-consuming nature of searching for information results from a number of barriers, including the inability to link directly from the EHR to algorithms and patient education materials; the burden of accessing multiple websites, each with its own internal search engine; and the inherent difficulties of navigating websites and other sources across levels of information ranging from guidelines to primary research.[15] Additionally, most search results are not easily exported to a personal digital library of preferred content.[15]

Insufficient time to search is one of the two major reasons physicians do not pursue answers to clinical questions.[1-3] Another common reason that physicians' questions go unanswered is their uncertainty that an answer exists, in spite of an enormous output of published clinical evidence.[2,16] In the last ten years, more

than 9 million citations have been added to the MEDLINE database alone.[17] Muir Gray, the former director of Britain's National Library for Health, referred to this as an information paradox; a situation where physicians are overwhelmed by new information yet have many unanswered questions.[16] Recent studies comparing several evidence-based electronic resources for their ability to answer clinical questions demonstrate that no single resource answers all questions.[1,13,14] One study found that the success rate for finding an answer improves as the number of databases searched increases.[13] In short, no single source can answer all questions, and a variety must be available to comprehensively meet physicians' information needs.[18]

Un-embedded information retrieval systems can increase the evidence that physicians use in decision-making, but the obstacles to their use in the clinical environment are substantial.[19-23] These barriers include unintuitive and time-consuming navigation issues as well as the scope of retrieval and quality of the retrieved information. Pub Med, perhaps the best-recognized biomedical search engine, requires its users to navigate to external websites to access information. Other existing general web search engines often fail by retrieving information that, for physicians, lacks depth and relevance. Many commonly accessible web search engines are horizontal, meaning they provide a wide scope of search results from a variety of different sources. These search engines frequently only locate web pages by key words, titles and other more easily identified data; their ability to search proprietary database content is superficial at best.[24] Horizontal search engines (e.g., Google) are more likely to guide users to popular sites, and may offer little information about the quality of that resource. Although "popularity ranking" may serve the non-clinicians well, it may not work at all for a biomedical textbook or a healthcare organization's intranet resources.[18]

Another less researched barrier is the lack of web and enterprise architecture that leads to the storage of valuable information in silos.[15] This separateness, along with the varied construction of databases, websites, and intranets, adds another level to the already time-consuming and difficult process physicians must carry out to access or share information. This increases the probability that a clinical question will go unanswered.

Solution Development

MedSocket of Missouri Inc., formerly MedSocket LLC, is a health IT company dedicated to delivering needed information to healthcare providers at the point of care. MedSocket's patented, medical search engine, 1-Search, was invented by Dr. Karl Kochendorfer. 1-Search was designed from the healthcare provider's perspective, with specific attention to clinical information needs at the point of care. Using a single interface, 1-Search's innovative design features customized aggregation of pre-appraised content sources (e.g., UpToDate, OVID MEDLINE, DynaMed), organizational data (e.g., secure intranet) and personal notes (e.g., uploaded and shared documents). Search filters allow users to narrow their search by information type (e.g., guidelines, patient handouts, drug information, etc.). It also allows individual institutions to customize aggregation of content sources according to their electronic resource licenses and subscriptions. Additional features offer customized (user-specific) profiles that automatically retrieve information from the clinician's area of expertise when performing a search. These profiles enable information gathering from the most highly utilized textbooks and resources covering the breadth of a given subject. The ability of profiles to act as custom filters has enormous potential for increasing the relevancy of search results while maintaining user autonomy.

A 1-Search family medicine profile was established and first deployed at the University of Missouri's Department of Family and Community Medicine in August 2011. The Department supported this technology financially with an annual license and commissioned an evaluation of the technology. Preliminary data showed that more than 80 users performed over 4,400 searches with the un-embedded version, and demonstrated extensive heterogeneity of information needs. A key finding of this evaluation was that users frequently said that they would prefer to access 1-Search from the EHR. A second key finding was that although the Department mandates the use of the EHR, significant variation exists in how clinicians use it. This variability appears to provide sufficient sample stratification to allow identification of potential differences in frequency of information access during patient consultations. These characteristics (of this test site and population) supported the subsequent evaluation with grant funding from the National Institutes

of Health. The team sought and received Small Business Innovation Research grant funding to research the feasibility of integrating its medical search engine within an EHR and measure its effect on information seeking by clinicians.

In 2013, 1-Search was embedded in Cerner's EHR system as part of the funded study (R43LM011590). Clinicians in the Department of Family and Community Medicine at the University of Missouri were able to access patient records through the EHR and use the embedded search box to seamlessly search across multiple clinical evidence resources and the healthcare organization's intranet without switching or logging into another system.

Evaluation Strategy

This project focused on enhancing physicians' and other clinical providers' access to information from high quality resources at the point of care by integrating 1-Search with Chart Search in Cerner's EHR system. To measure the impact of this integration, the researchers gathered and evaluated qualitative and quantitative data by measuring time spent searching, level of information quality, and physicians' ability to make decisions as well as other factors. This approach allowed for a thorough evaluation in a limited timeframe and laid the groundwork for longitudinal patient-outcome studies assessing the value of information retrieved using 1-Search. We used two strategies to measure the impact of the use of 1-Search on physicians – surveys and analysis of computer log file. This combination provided maximum information with minimum demands upon physician time. The physician experience surveys were based on the DeLone and McLean model for information system success.[25]

Evaluation began with an invitation to all family physicians at the University to participate in the research with the option to opt out at any time without penalty. Participants were informed that survey completion constituted informed consent. The Health Sciences Institutional Review Board at the University of Missouri approved the study.

Recruitment of physicians, including residents, into the study began with presentations during the Department's weekly faculty and resident meetings one month prior to 1-Search's launch in the EHR. Training was accomplished with two 30-minute sessions (one for faculty physicians and another for residents) as well as training that was incorporated into weekly faculty and resident meetings. An e-mail invitation was sent to all faculty and resident physicians. The invitation included general study information, the pre-implementation survey, and notification of the introductory training sessions. A basic user manual for 1-Search was accessible to participants during the study period.

To protect confidentiality, each participant was assigned a unique, arbitrary identifier. The identifier was also embedded in survey links so that an individual's pre- and post-surveys could be linked. Because both attending physicians and resident physicians participated, and because physicians rotated within our academic training programs and sites, not all participants completed both pre- and post-surveys.

Table 1
Barriers to Answering Clinical Questions Reported by Respondents to the Pre-Survey (N=61).*

Issue or Barrier	Number (Percent) responding "Yes"	
Finding time	43	(70.5)
Must check multiple places	29	(47.5)
Knowing where to look	24	(39.3)
No answer seems to exist	19	(31.1)
Lack of searching skills	17	(27.9)
Lack of remote access	11	(18.0)
Searching too slow	9	(14.8)
Material in difficult format	5	(8.2)
Lack of computer access	3	(4.9)
Lack of computer skills	2	(3.3)

*Respondents who chose at least one barrier

Results from Pre- and Post-Surveys

The pre-survey was sent to 98 physicians and the post-survey, to 99. The pre-survey was administered before training in how to use 1-Search. The post-survey was administered after training and a minimum trial period of 90 days of 1-Search use. Both surveys were conducted using Survey Monkey. Participation was voluntary and no incentives were provided. For the pre-survey, 69 of 98 responded, and for the post-survey, 58 of 99 responded. Forty-one people answered both surveys. In the pre-survey, 29 respondents (42%) reported prior 1-Search use. In the post-survey, 30 respondents (52%) reported using 1-Search. The proportion of 1-Search users between surveys did not differ ($p=0.23$). Of the 41

Figure 1
Potential barriers identified by respondents regarding 1-Search use (Pre-deployment)

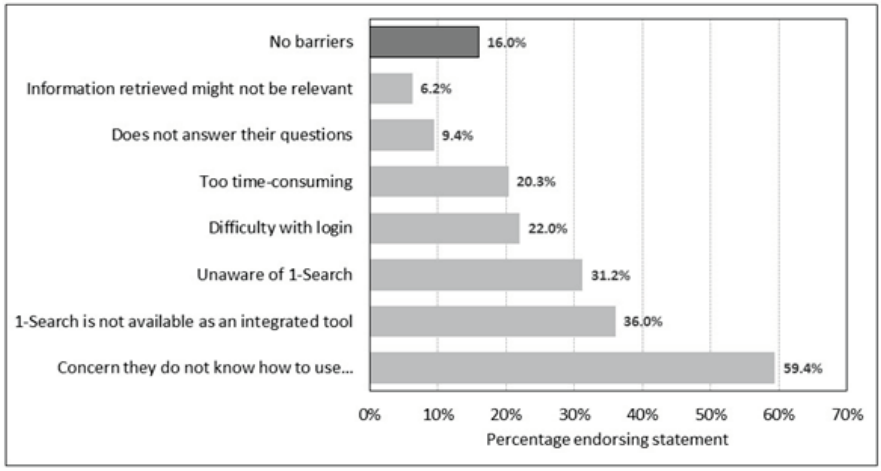
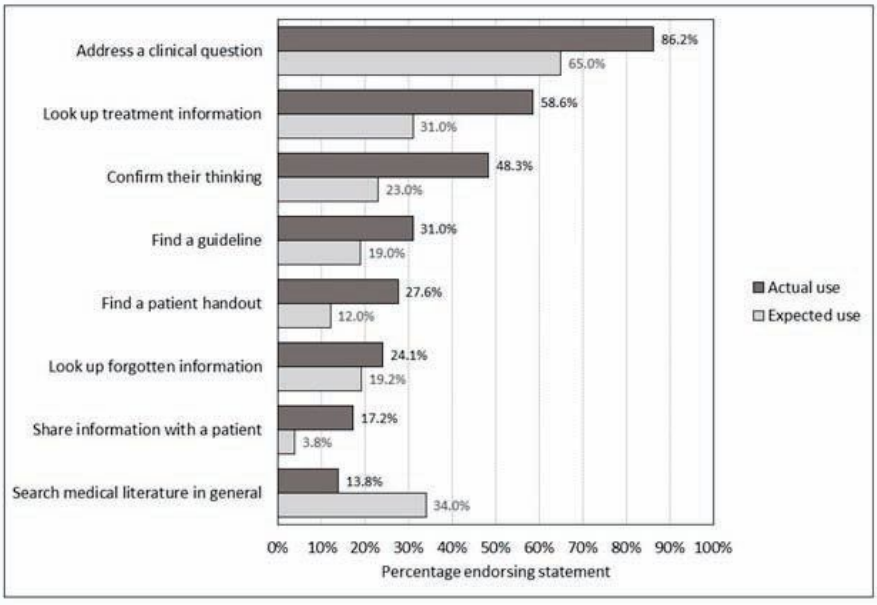


Figure 2
Expected and actual use of 1-Search



who answered both, 17 reported they had used 1-Search on both surveys, 13 reported they had not on both, and the remaining 11 reported different use between surveys.

Of those who responded to both surveys, 36 reported how upset they would be if 1-Search were no longer available. On the pre-survey, only 6% indicated they would be moderately to very upset, compared with 22% on the post-survey ($p=0.02$). Among those who reported 1-Search use, 52% reported being satisfied or extremely satisfied with 1-Search on the pre-survey compared with 66% on the post-survey ($p=0.31$). In the pre-survey, respondents reported using multiple search engines (Google – 85%, Pub Med/Medline – 49.2%, Google Scholar – 31%, Wikipedia – 31%, an internal SharePoint site – 28%, Web MD – 15%, 1-Search – 12%, and Bing – 1.5%). The use of 1-Search did not seem to positively affect the likelihood that clinicians had their clinical questions answered using electronic resources, but 87 % did feel they could find clinical answers using electronic sources. In fact, 86% were confident that they could find clinical information online and 66.67% thought electronic resources were quick and easy to use, but 49% frequently failed to find the needed information when searching. Multiple barriers to the use of electronic resources for answer clinical questions exist (See Table 1).

In the pre-survey, respondents identified multiple pre-deployment barriers to the use of 1-Search (See Figure 1). Barriers identified are not mutually exclusive. The most common barriers include lack of time (70.5%), the need to check multiple sources (47.5%), and knowing where to look (39.3%).

Clinicians expected to use 1-Search in a number of ways. Figure 2 illustrates expected uses reported on the pre-survey and the ways 1-Search was actually used as reported in the post-survey. Respondents could endorse more than one response. The results suggest that the use of 1-Search helped clinicians gain access to treatment information and to locate guidelines and other information to support improved interaction with patients.

In the post-survey, more than 65% of physicians reported being satisfied with 1-Search and almost 38% felt that using 1-Search saved them time. However, more than 13% of users felt 1-Search was too slow. Nearly 80% of users agree that 1-Search results were useful in their

clinical practice, while only 28% felt that that 1-Search often failed to retrieve useful information. Results were mixed regarding reliability of the evidence retrieved by 1-Search and its ease of use. However, 58.6% of users believed that 1-Search helped them diagnose and treat patients, and 31% believed they had learned something new from the use of 1-Search. No users felt that using 1-Search was potentially harmful to a patient.

Results from log file analysis

We analyzed computer log files to investigate the frequency of 1-Search use as well as other search characteristics. The data were collected over a period of 62 days. The day of the week that saw the highest 1-Search use was Wednesday (35%), likely reflecting the higher level of clinic visits experienced that day. The type of source for accessed material varied widely. Seeking clinic information was the most frequent activity (33.5%); accessing patient handouts occurred in about 14% of uses. The actual duration of the search (not inclusive of reading or printing time) ranged from less than 1 second to 5+ seconds, with the largest percentage of searches taking 3 to 4.9 seconds to complete. Generally, only one click was needed for physicians to access the needed information. Attending physicians were, by far, the most common users, and the percentage of uses of 1-Search were relatively equally distributed over the different clinic sites.

Conclusion

The results of this research suggests that the 1-Search, as an embedded information retrieval tool, holds promise to improve care though reduced cognitive workload, more compressed reference information delivery, and timely access to information within a typical clinical workflow. Physicians supported incorporation of 1-Search into the EHR and provided evidence to support the continued use of 1-Search as well as its further development.

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Disclosure

KK, JW, and MB are employed by Medsocket of Missouri, Inc. They did not take part in any data analysis. **MM**


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