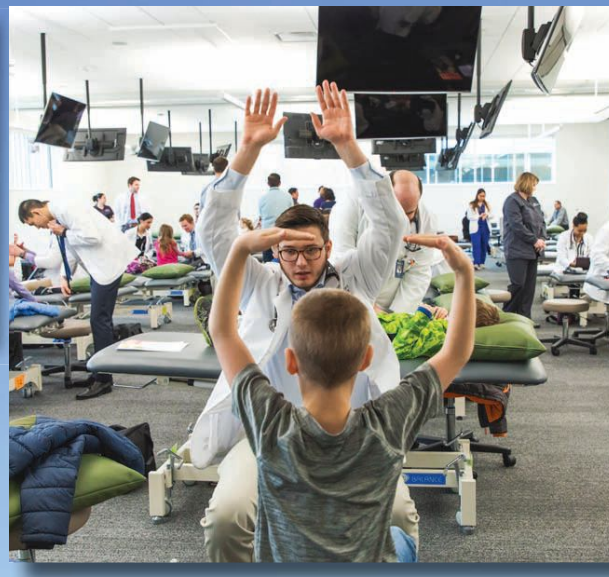
Missouri Medicine

The Journal of the Missouri State Medical Association www.msma.org/missouri-medicine September/October 2019

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Advertising Increases Health Care Costs and Undermines Medical Ethics

by Arthur Gale, MD

In its suit against the AMA, the FTC demanded the removal of Section Nine in the AMA Code of Ethics which prohibited advertising.

Advertising was generally prohibited in medical practice until a little known unanimous U.S Supreme Court decision in 1975 known as Goldfarb.[1] This decision fundamentally changed the practice of medicine. It declared that medicine (and law) were no longer learned professions but were in the words of the court "ordinary purveyors of commerce." The putative purpose of the Goldfarb decision was to lower health care costs through free market competition.

The Goldfarb decision placed the medical profession under the control of the Federal Trade Commission (FTC). Medical ethics henceforth were to be subordinated to free market competition. The cornerstone of free market competition is advertising which is intended to be the means by which prices are lowered.

The ink was barely dry on the Goldfarb decision when the FTC sued the American Medical Association (AMA) over its Code and Principles of Medical Ethics.[2] The FTC contended that the AMA engaged in monopolistic anticompetitive practices specifically where its code of ethics prohibited advertising.

AMA president Max Parrott, MD, and AMA Board Chairman Raymond Holden, MD, responded quickly to the lawsuit:

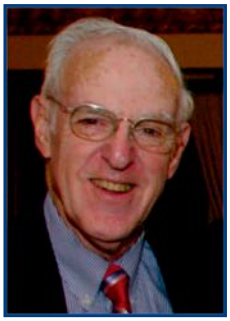
"We are somewhat hampered in responding to the FTC complaint since we received a copy of it–unofficially –only after it had been made public through the media. The complaint is directed at the AMA Code of Medical Ethics more than 100 years old. It is ironic that the FTC should attack a code devised and operated as a standard of conduct in the best interests of professionalism. **Advertising by a professional is the very antithesis of professionalism** (emphasis added). Physicians should not solicit patients. A patient should go to a doctor on the basis of need, not on the basis of advertising. Do patients want to be treated in accordance with the best professional's judgment concerning their health and safety? Or do they want medical services that are sold and promoted? We think that there is enough hucksterism in medicine. And we're going to fight it."[3]

The AMA did fight the Goldfarb decision all the way up to the U.S. Supreme Court. The AMA lost in a tie vote. A tie vote means the plaintiff loses.

At the time that the Goldfarb decision became law health care costs in the U.S. were no higher than in other industrialized democracies. These countries are collectively known as the Organization for Economic Cooperation and Development (OECD). After the Goldfarb decision the U.S. shifted to managed care which was supposedly based on free market competition. Under managed care advertising was to play a crucial role in keeping prices under control. However, since the Goldfarb decision became the law of the land forty-five years ago health care costs have not declined. They have risen at far higher rate than in the other OECD countries without any measurable difference in quality of care. Per capita health care costs in the U.S. today are by far the highest in the world.[4]

The Removal of Ethical Guidelines

In its suit against the AMA the FTC demanded the removal of Section Nine in the AMA Code of Ethics which prohibited advertising. The FTC also demanded the removal of Section eight of the AMA's Principles of Medical Ethics. Section eight was virtually a restatement of the Hippocratic Oath which declares that a physician should always act in the best interests of the patient.[5]



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Thus the cornerstone of medical ethics–the Hippocratic Oath was removed–in the interests of resolving a fictitious health care cost crisis. Physicians were now free to act on behalf of commercial interests which were not necessarily in the best interests of patients.

Today the majority of physicians are owned by hospitals.[6] And hospitals aggressively market their practices especially the most lucrative practices such as cardiology and the surgical specialties. But physicians are also personally engaged in marketing primarily for the pharmaceutical industry.

Former editor of the *New England Journal of Medicine* Marcia Angell, MD, was one of the first to chronicle this change in physician practices in her book "The Truth About Drug Companies."[7] She pointed out that authors of scientific papers published in leading medical journals were receiving compensation from drug companies. She believed this compromised their research and stated that many so called independent researchers had become nothing more than "hired hands" of the pharmaceutical industry.

Angell pointed out that even members of the Federal Drug Administration (FDA), which approves new drugs and devices, as well as members of the Advisory Committee to the FDA have received payments from drug and device companies. The researchers rationalize these payments by including conflict of interest disclosures. Disclosures of conflicts of interest do not remove bias in clinical or scientific research.

The most egregious example of the harm done by physicians being paid by drug companies is that of Russell Portenoy, MD. Portenoy was Chairman of Pain Medicine and Palliative Care at a leading hospital in New York and was a professor of medicine at the Albert Einstein College of Medicine. Drug companies especially Purdue pharmaceuticals which manufactures the opioid oxycontin paid Portenoy and his department large sums of money.[8]

Portenoy was considered a "thought leader" in medicine and was known as the "king of pain." He and other "thought leaders" wrote many articles in leading journals stating that the risks of opioid addiction were minimal. They were so influential that regulatory agencies such as the Joint Commission for Accreditation of Hospitals[9] and the Federation of State Medical Boards wrote guidelines for the treatment of pain which was to be considered the fifth vital sign. In many cases hospital lawyers warned physicians that they could be sued they not treat pain "properly."[10] Nurses were required to ask patients on rounds to grade their pain on a scale of one to ten and then give a narcotic accordingly. This practice still occurs today in many hospitals.

Now the U.S. has a serious opioid epidemic. Opioids are the leading cause of preventable death in the U.S. It is estimated that between one-third and one-half of patients with opioid addiction started using opioids as a result of doctors' prescriptions. The opioid epidemic has caused tens of thousands of deaths. It is responsible for an even larger number of devastated and broken families. It affects all socioeconomic classes.

States and other plaintiffs have sued Purdue and other pharmaceutical manufacturers of opioids for hundreds of millions of dollars. And recently they sued Russell Portenoy personally. Portenoy has now turned on his erstwhile financial benefactors and has agreed to testify against the drug companies. He now claims that he too was a victim of drug advertising.[11]

One of the class action attorneys succinctly summarizes Portenoy's change of heart:

"Although it's nice that Dr. Portenoy has changed his view on the use of opioids it doesn't help the millions who have died and become addicted over the years while he was a shill for Purdue and the rest of the opioid industry."[12]

In a recent article in the *Journal of the American Medical Association (JAMA)* authors Lisa M. Schwartz, MD, and Steve Woloshin, MD, found that spending on health care marketing in the U.S. from 1997-2016 increased from $17.9 billion to $29.9 billion.[13]

The authors report that "in 1996 without supporting evidence, the American Academy of Pain Medicine and the American Pain Society, both substantially funded by opioid manufacturers, issued a consensus statement endorsing opioids for chronic non cancer pain, describing addiction risk as low."

The opioid debacle is the highest profile scandal to hit physicians and medical professional organizations but it is just the tip of the iceberg. Many medical professional organizations and societies accept money from drug and device companies. Authors Schwartz and Woloshin state "Physician consultants [serve] on advisory board that design disease awareness campaigns, develop disease management programs or participate in company-funded workshops defining diagnostic criteria and treatment thresholds." Schwartz and Woloshin conclude their detailed study with the warning: "Despite the increase

in marketing over 20 years, regulatory oversight remains limited."

It is quite tempting for physicians who accept money from drug companies to become "shills" or in the words of Marcia Angell nothing more than "hired hands." The monetary gain for physicians can be huge.

One hears supporters of managed care, often hospital administrators, condescendingly refer to pre-managed care medicine as a "cottage industry." That era of medical practice had its flaws, but it did not play a major role in producing a massive opioid epidemic like the one we have today because most doctors tried to adhere to accepted ethical guidelines. In our current commercialized managed care environment everything is for sale including doctors (or as they are now called providers).

The warnings of Doctors Parott and Holden of the AMA in 1975 were prophetic. They predicted advertising would increase costs and decrease professionalism. [14]

And that's exactly what has happened over the ensuing years.

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Dentists' Current and Optimal Opioid Prescribing Practices: A Proactive Review

by William R. Reynolds, DDS, MD & Evan S. Schwarz, MD

The proportion of dental prescriptions written for opioids in the U.S. was 37 times higher than that in England (22.3% vs 0.6%). These discrepancies held when corrected for population and number of dentists.

Introduction

The large amount of opioid prescriptions currently written contribute to an unprecedented epidemic in the United States. In 2015, Health and Human Services (HHS) estimates that 12.5 million individuals misused prescription opioids and 33,091 individuals died following an opioid overdose.[1–3] Practitioners of medicine, surgery, and dentistry have noticed the increased number of opioid prescriptions in their practices. Patients for years have requested, expected and, received opioids for many of the common procedures and conditions in the practice of surgery and dentistry. These expectations and demands, and physician/dentist compliance must change to abate the morbidity and mortality of opioid abuse.

Scope of the Opioid Problem

It is interesting, and disturbing, that dentistry represents a minority of health care providers but accounts for a large number of prescribed opioids. This was clearly demonstrated in papers published in major society journals.[4,5] When compared to dentists in England, dentists in the United States prescribe vastly more opioids.[6] This was demonstrated in a population-level analysis of national databases in the United States and England. U.S. data was obtained from IQVIA LRx which captures 85% of all outpatient prescriptions. Data from England came from the NHS Digital Prescription Cost Analysis, which covers 84.2% of the UK population. In 2016, U.S. dentists wrote more than 11.4 million opioid prescriptions while dentists in England only wrote 28,082. The proportion of dental prescriptions written for opioids in the U.S. was 37 times higher than that in England (22.3% vs 0.6%). These discrepancies held when corrected for population and number of dentists. Tompach reported in the *Journal of Oral and Maxillofacial Surgery* that dentists have actually decreased the volume of opioid prescriptions from a high of 15.5% in 1998 to 6.4 % in 2012. However, the number of opioid prescriptions per 1,000 dental patients increased in patients 11-18 years of age.[7] Importantly adolescents that received prescription drugs are at an increased risk of future misuse of opioids.

A Safer Alternative to Opioids

It is a goal of practicing dentists to control pain after dental procedures. The large number of opioids prescribed for dental pain are usually for the acute pain occuring with an infection, surgical removal of teeth, periodontal surgery and dental implants. Long term dental pain associated with Temporomandibular Joint (TMJ) Syndrome, for example, does not represent a large number of opioid prescriptions.[8]

As the physiological and biochemical understanding of pain is better elucidated, medicines more suitably directed at the source of pain were prescribed. For example, in a routine tooth extraction or rotation flaps in periodontal surgery, the acute phase of healing releases prostaglandins





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Table 1. Pharmacologic Recommendations for Post-Operative Dental Pain

Pain Severity	Therapeutic Intervention
Mild	Ibuprofen 200-400 mg q 4-6 hours
Mild to Moderate	Ibuprofen 400-600 mg q 6 hours for 24 hours Ibuprofen 400 mg q 4-6 prn pain on POD #1 (after first 24 hours)
Moderate to Severe	Ibuprofen 400-600 mg with APAP 500 mg q 6 hours for 24 hours. Ibuprofen 400 mg with APAP 500 mg q 6 hours on POD #1 (after first 24 hours)
Severe	Ibuprofen 400-600 mg with APAP 650 mg and Hydrocodone 5 mg q 6 hours for 3 days; then Ibuprofen 400-600 mg with APAP 500 mg q 6 hours on POD #4 (after first 72 hours).
If NSAIDs are contraindicated	
Mild	APAP 650-1000 mg q 6 hours for pain
Moderate	APAP 650-1000 mg with hydrocodone 5 mg q 6 hours for 3 days; then APAP 650-1000 mg q 4-6 hours (after first 72 hours)
Severe	APAP 650 mg with hydrocodone 5 mg q 6 hours for 3 days, then APAP 650-1000 mg q 6 hours (after first 72 hours)

APAP acetaminophen (Tylenol)
Ibuprofen maximum daily dose is 2400 mg
APAP maximum daily dose is 3000 mg
Adapted from References: [4,7,11,13,14]

from the injured tissue. This contributes to acute post procedural inflammatory mediated pain at the site of injury. Non-Steroidal Anti-inflammatory Drugs (NSAID) are inhibitors of prostaglandin formation and are used to help control pain locally. It is better to prescribe NSAIDs for such cases as it targets the source of pain. NSAIDs do not affect cognition or motor skills so that the patient can return to their normal activities.[9,10] Opioids act centrally and can affect cognition and secondarily motor skills.

This NSAID therapeutic strategy augments long held surgical axioms like "Control the infection and control the pain" or "Control the inflammation and control the pain." These axioms represented the clinical thinking of common-sense surgical practice before the biochemical and physiological understanding that exists now. Optimally, if an infection is present prescribe the appropriate antibiotic and an NSAID instead of adding an opioid such as codeine, hydrocodone, or oxycodone.

Controlled studies and best practices are being developed which incorporate this newer paradigm that uses non-opioid drugs which are more effective in eliminating pain after dental procedures. An extensive review of the dental literature, concluded "the use of NSAIDS, with and without acetaminophen, is equal or superior to that provided by opioid-containing medications."[11,12]

Table 1 is a summary of recommendations from published papers for control of post-operative dental pain. The therapeutic recommendations are based upon the patient's perceived degree of pain or the clinical experience of the practitioner. For example, what type of pain the clinician would expect for a particular procedure e.g. a simple tooth extraction (mild pain) vs an impacted 3rd molar extraction (severe pain). The generally accepted best practices recommend that opioids should be reserved for a minority of clinical situations in which NSAIDs provide inadequate pain control.[4,7,13] If opioids are prescribed, risks should be discussed with the patient and should be prescribed at the lowest effective dose.[13]

One Opioid Prescription Can Create a Lifetime of Addiction

In susceptible individuals a single opioid prescription can lead to a lifetime of addiction. It is extremely important to limit opioid exposure especially if other alternatives may provide adequate pain relief . While only a small number of patients will develop an opioid use disorder, we unfortunately have limited means to determine who they are.[15] There is plentiful literature demonstrating sustained opioid use of approximately 5-7% following an initial prescription in opioid naïve patients.[16,17] Dentistry and dental complaints are no different. A retrospective cohort of opioid naïve patients from a research database of claims data aged 18-25 was reviewed.[18] Any patient with an opioid use disorder or with certain complex

chronic conditions were excluded. All patients received the initial opioid prescription following a dental complaint or procedure. All patients received a prescription for an opioid from a dental clinician and had not received a prescription for an opioid in the 12 months preceding the prescription. They were maintained in the insurance database for 12 months following the initial prescription. Nearly 30,000 of the 754,002 patients in the database received a prescription from a dental provider in 2015, with 14,888 receiving opioids. Of those, 1,021 patients (6.9%) received another opioid prescription 90-365 days later. In this same database, a randomly-selected cohort of age and sex matched controls that did not receive an opioid were also studied. Of these 29,776 patients, only 30 patients (0.1%) received an opioid within the next 365 days (adjusted absolute risk difference of 5.3%; 95% CI 5.0%-5.7%). Most of the repeat prescriptions were not provided by a dental provider (73%) with a median number of 20 pills (interquartile range of 16-28) being dispensed in the second prescription. This does not imply that all patients that received a second prescription developed an opioid use disorder; 866 of the 14,888 (5.8%) that received an opioid did later receive an opioid-abuse related diagnosis. A second study reviewed patients aged 13-30 years in the Truven Health MarketScan Commercial and Dental database with persistent opioid use following wisdom tooth extraction.[19] Patients could not have filled an opioid prescription within 6 months of the index prescription or have had additional anesthetic or dental procedures for a year following the dental extraction. The primary outcome was opioid prescriptions filled either 4-90 days or 91-365 days after the procedure. Nearly 57,000 patients (80%) filled a prescription for an opioid following wisdom tooth extraction. Persistent opioid use occurred at an adjusted rate of 13 per 1000 patients (95% CI 9-19) in the group that filled an opioid prescription compared to 5 per 1000 patients (95% CI 3-7) that did not initially fill a prescription.

What Dental Schools are Doing to Optimize Opioid Prescribing

Curriculums in medical and dental schools are now being taught that incorporate a better understanding of opioid and NSAIDs as therapeutics. As such, this new generation of dental practitioners will hopefully help abate the current opioid crisis. The Committee on Dental Accreditation implemented standards that require schools to address opioid prescribing and misuse. Through an NIH grant, Massachusetts dental schools (Harvard, Boston University and Tufts Dental Schools) have addressed core competencies in prescribing opioids using training modules. Dental, medical, nursing and pharmacy students are taught pain management in such a way to address the opioid crisis.[20] Dental schools in Missouri are also incorporating this into their curricula. At the University of Missouri-Kansas City (UMKC), students receive specific didactic instructions in their second year which is continued during their third and fourth year rotations. Students learn about illicit and prescription drugs, opioids, substance abuse, and ethanol abuse and their effects on patients. SBIRT (screening, brief intervention, and referral to treatment) is also part of their third year curriculum. Online courses as well as role play scenarios and standardized patient scenarios are mandatory parts of their education. A.T. Still University Missouri School of Dentistry & Oral Health is also being proactive about addressing opioid use and substance use in their curriculum. Hopefully, all medical schools will follow the example of these and other dental schools in the state.

What the Missouri Legislature is Doing

Politicians are already addressing the opioid crisis with bills, laws and regulations. Their perception is medical and dental professions are not doing enough and contributed in a major way to the opioid epidemic. The most recent data concerning overdose deaths demonstrates a national decrease for the first time in many years. While deaths from illicit opioids are still increasing, deaths from prescription opioids may be decreasing. Unfortunately, opioid associated deaths in Missouri are still increasing. Currently, the legislative efforts of Missouri are aimed at addressing opioid prescribing as a means to reduce doctor shopping for opioid prescriptions. Due to the current opioid epidemic and prior prescribing practices, politicians stepped in to legislate a solution. Often, their goals are admirable and appreciated but legislation can have unintended consequences or cause unanticipated barriers. In 2018, Missouri passed legislation limiting new prescriptions for acute pain to seven days. The seven-day limit is not an absolute but many pharmacies and insurers are treating it as such. Multiple other opioid related bills were debated this past 2019 legislative session. For instance, Missouri House Bill 491 prohibits physicians from prescribing opioids to patients less than 18 years of age unless admitted. While keeping appropriate patients opioid naïve is an admirable goal, the absolutes of this

legislation would be problematic, and fortunately, it did not pass. One since withdrawn amendment would have increased administrative burdens and possibly led to malpractice claims. A prescription drug monitoring program (PDMP) was on the docket again. The pros and cons of a PDMP are written about extensively in journals, including *Missouri Medicine*.[21–23] It once again passed the House, struggled to advance out of the Senate Seniors Committee, and then died on the floor of the Senate. Regarding dentistry, the Missouri Governor in 2019 signed SB 514, which limits opioid prescriptions to no more than 50 morphine equivalents a day, the equivalent of approximately 10 hydrocodone pills per day. Dentists can provide documentation should a patient require a higher dose of opioids. Dentists will not be permitted to prescribe extended release opioids. Additionally, this session legislators also passed legislation intended to increase addiction treatment. Missouri House Bill 904 prevents prior authorization or step therapy requirements when prescribing medication for addiction treatment (MAT).

The Opioid Epidemic is Everybody's Business

While strategies promoting non-opioid analgesics following procedures by dental clinicians are important, it is worth mentioning that patients present to other providers with dental complaints as well. Toothache is the fifth most common reason for patients to go to the emergency department.[24] In these settings, non-opioid alternatives should be used when appropriate. Non-dental providers including emergency physicians and primary care physicians need resources to efficiently make timely referrals to dental clinicians. Additionally, they should receive education regarding non-opioid treatment best practices such as the use of NSAIDS and how to perform simple nerve blocks. Otherwise, either these prescribers will continue to rely on opioids for patient's analgesia or this will just result in a bridge to nowhere.[25]

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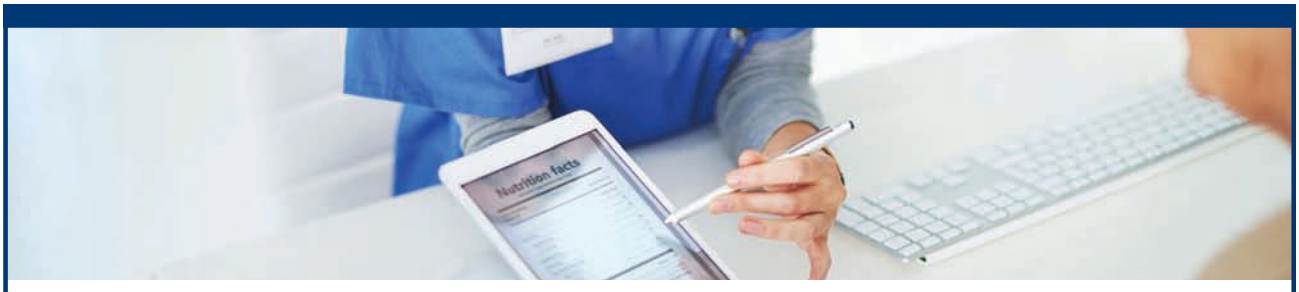
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Weeding Out Dubious Marijuana Science

by Alex Berenson

Some researchers find ways to minimize increases in crime and traffic deaths that followed cannabis legalization.

Academics depict the peer-review process as the gold standard for intellectual honesty, ensuring published scholarly work is unbiased and accurate. But ideological conformity makes peer review a far thinner defense than advertised.

In January 2019, I published a book about the mental-health and violence risks of cannabis. Several dozen scholars signed a petition expressing in unison their objection to my work. Thus, I've recently spent an inordinate amount of time reading papers seeking to prove that marijuana is a cure-all whose deleterious consequences are a figment of our collective imagination. The shoddiness of much of the work has shocked me.

Example: Driving deaths have risen more than 30% in Colorado and Washington, the first states to legalize marijuana for recreational use, since dispensaries opened there in 2014. That rise is more than double the national change. The Insurance Institute for Highway Safety reported in October that the number of vehicle accidents overall were up faster in legalized states than the rest of the nation.

Nonetheless, researchers have claimed legalization doesn't increase driving deaths. Last year, Benjamin Hansen of the University of Oregon and two other researchers wrote a paper looking at the rise in vehicular deaths in which drivers had THC in their blood. They found such deaths rose in Colorado and Washington at rates "similar" to those in other states.

In fact, the data showed that legalization explains about half the increase in Colorado and Washington. But because the data were limited, the results had wide confidence intervals, which means it's possible but not probable that the post legalization gap was the result of chance. A more honest way to report the results would have been to say that the paper had found a worrisome trend in cannabis-linked deaths, which more data might confirm.

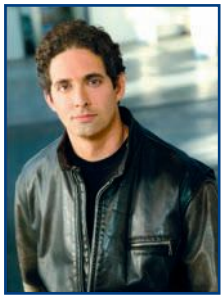
Violent crime has also soared in the legalized states since 2013. Yet last month two criminologists claimed in a *Seattle Times* op-ed that they had found "no increase in violent crime that can be directly attributed to marijuana legalization." That formulation makes the statement a trivial truth. Without examining every murder, no one can say legalization has directly driven the increase.

The authors explain in the op-ed that they based their statement on a paper they co-wrote. They don't name it, but the only published paper listing them as co-authors is a 2018 study called "Marijuana Legalization and Crime Clearance Rates." It didn't even examine whether crime had risen or fallen. It looked only at whether police were likelier to solve, or clear, crimes after legalization. But so what? If murders double from 100 to 200, and the police solve 50 the first year and 110 the second, the clearance rate has risen, but so has the crime rate.

Some of the research is comical. A paper published in March reported that cannabis use seemed to increase "satisfactory orgasms" in women. The paper divided subjects into three categories: nonusers, users who answered yes when asked if they used the drug "before sex," and users who answered no. But it presented results on sexual satisfaction only from the last two categories—not from women who don't use marijuana at all. The paper provides no data at all comparing users with nonusers.

I could offer a half-dozen other examples of dubious scientific practices—using nonstandard data sets, relying unnecessarily on "synthesized comparators" that are inherently vulnerable to manipulation, and "p-hacking" by looking at endless secondary outcomes until one pops up that reaches the threshold for statistical significance.

The tricks can be hard to find—and journalists, who are almost never trained in science or statistical analysis, often parrot the results unskeptically, especially when the findings confirm their own biases toward ideology or sensationalism. When car accidents and violent crime are involved, the results can be deadly. **MM**



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Impressions of a Father-Son Medical Mission to Haiti: The Father

by Stephen U. Stechschulte, MD

Decades ago my father, an academic immunologist and rheumatologist, once spoke about the possibility of a family sabbatical to Africa for medical mission work. Regrettably, that trip never occurred, but the thought of a mission trip with my own family resonated in my mind. What a singular experience I had missed with my now deceased father. When I first heard Bill White, MD, a Kansas City oculoplastic surgeon, speak about his mission trips to Haiti[1,2] and call for medical professionals to join him I was ready to go. However, it would take me, an accomplished procrastinator, another 13 years to finally pack my bags.

Dr. White, the 2018 the American Academy of Ophthalmology Humanitarian Award recipient, has traveled to Haiti for over twenty years. He and others have helped establish an ongoing ophthalmologic clinic and surgery service at the Northwest Haiti Christian Mission in Saint-Louis-du-Nord ("the mission") on the northwest coast of Haiti.[3] His efforts along with Andy Moyes, MD, Abe White, MD, and others have turned the Northwest Haiti Christian Mission into one of the most dynamic and important health care resources in all of Haiti. A point of focus creating self-sustaining, year-round medical care.



Stephen U. Stechschulte, MD, MSMA member since 2016, is a Board Certified ophthalmologist specializing in cornea, refractive and cataract surgery in Kansas City. He is married to Hannah Vargas, MD. They have four children. Left, Dr. Stechschulte and his son Henry, age 13 at the time, worked together in the Northwest Haitian Mission Hospital.
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The mission is one of the largest employers in the Northwest zone and serves the community of Saint-Louis-du-Nord in many ways. First established as a church and place of prayer, the mission now has a school, orphanage, a home for disabled children, an elder care facility, a full time general medical clinic, and one of the busiest birthing centers in Haiti. In fall and spring each year, for a total of ten weeks, two fully equipped operating rooms are staffed with surgeons, nurses, medical personnel and volunteers from all over the United States. They perform neurosurgery, general surgery, orthopedics, and ophthalmologic surgery (Figure 1).

The challenges of missionary work, visiting underdeveloped countries and providing on-going care are daunting. Travel to areas where typhoid, rabies, cholera, hepatitis, and malaria are prevalent requires extensive pre-planning for vaccinations and prophylactic medications. These endeavors involve risk to visiting medical professionals. Mental preparation is essential. Haiti has extreme economic and ecologic challenges and is still recovering from the 2010 earthquake that killed approximately 300,000. In 2016, Hurricane Matthew caused additional widespread devastation. More recently an earthquake on October 6, 2018, interrupted an eye team's trip.

I was privileged to travel with my oldest son Henry to the mission in October 2017 with a group of surgeons, and volunteers from all over the United States. Henry, age 13 at the time, shares his impressions of the trip in the accompanying article.

Flying from the U.S. to Haiti involves a flight into the capital, Port-au-Prince. Haiti is on the island of Hispaniola and less than 700 miles from Florida. It is surrounded by the Caribbean Sea and bordered to the east by the Dominican Republic. Port-au-Prince sits on a magnificent natural harbor where the Grise River enters the Gulf of Gonave. Verdant hills and mountains stretch beyond into the Dominican Republic. Henry and I had read some of the complicated, heart wrenching history of Haiti: Columbus's initial landing in 1492 on the north coast, the decimation of the indigenous Taino tribe, colonialism, slavery, Haiti's



The Haitian Mission Hospital is always crowded with patients as it is the main medical facility in Northwest Haiti.

successful slave revolt, and the ongoing ecologic and economic battles that continue to challenge. Roughly 20% of all Haitians live in Port-au-Prince. Regrettably, Haiti still is the poorest country in the Western Hemisphere. Our research did not prepare us for the poverty, population density, and cacophony of Port-au-Prince.

We flew north early the next morning, disconcertedly low over mountains to the coastal town of Port-de-Paix. The rudimentary, dirt airstrip functions as a road, a grazing area for scrawny pigs and goats, a community gathering center, and on one end as a garbage dump. Climbing into the back of another pickup, we bumped, banged and swerved for eight miles to the small town of Saint-Louis-du-Nord and the Northwest Haiti Christian Mission.

The mission truly functions as a spiritual and medical oasis in one of the poorest areas of the world. The starkly clean, walled and gated compound sits on five acres. It has its own generator, fresh water well, and dormitories. An incipient fish farm and plantain trees may soon offer food self-sufficiency. As a parent, I was pleased that Henry was holding up well.

After a brief orientation, Henry and I went to work screening patients and getting them ready for surgery. Henry helped screen hundreds of patients during the week's stay. Additionally, he helped in the operating rooms and interacted with the children in the orphanage and disabled center. I and other ophthalmic surgeons did complicated cataract, glaucoma, pterygium, pediatric, and retinal surgeries. Overall, our group did about 800 visual screenings and 150 major surgeries in the eye clinic-hospital. We also found time for group meals, prayer, singing, and outreach to the local jail and poorest sections of town. It was incredibly rewarding to help a community and people that, enthusiastically and appreciatively, value the mission's good works.

A criticism of medical missions is that the care is episodic and lacking in follow-up. Not so at the mission! An essential goal of the American medical teams visiting the Northwest Haiti Christian Mission is to train and equip a year-round residential medical staff. Ideally, medical missionaries work toward their obsolescence; toward a point where local physicians and staff are able to provide all clinical and surgical services. This laudable effort continues in Saint-Louis-du-Nord and every year shows incremental improvement. Local optometrists and physicians are more involved in care giving. Children from the orphanage leave and go to university. Some plan to return to the mission to work. Dr. White and his wife financed the education of a local boy who has returned to Haiti to practice.

At the conclusion of our trip, Henry and I had closer bonds of shared hardships and the mutual satisfaction of helping some of the poorest people on the planet become healthier and more self-sufficient.

Any physician or volunteer is welcome to participate and may contact the Northwest Haiti Christian Mission office in Indiana to get information, www.nwhcm.org, (317) 228-8770.

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Impressions of a Father-Son Medical Mission to Haiti: The Son

by Henry Stechschulte

When my dad first asked me to go to Haiti, I was a little nervous. He was asking me to go to a country I'd barely heard of and provide medical assistance for a week. Dad told me that I had been given a wonderful life with many comforts and blessings; that I should help others less fortunate than myself. So, after some intense consideration, five months later I boarded a plane from Kansas City to Port-au-Prince, Haiti.

We arrived on a Friday night with a group that consisted of eye doctors and technicians from Kansas City, Virginia and Texas. We left the austere Port-au-Prince airport loaded in the back of pick-up trucks that had been turned into buses, called tap-taps. Precariously weaving through the narrow, rough streets to our hotel, I got my first Haitian experience: heavy traffic, acrid truck fumes, tightly packed-colorfully dressed crowds, and a beautiful Caribbean sunset. After a welcome dinner at the hotel, a group of street vendors came to the courtyard. They had many native wares to sell: paintings, crucifixes, pottery, flags, trinkets and native souvenirs. I bought a painting from one of the vendors. It depicted a Haitian man leading two cows down to a river and two women carrying food on their heads. This is what I imagined rural Haiti would look like. I have grown fond of the painting which now hangs in my bedroom. Later, we enjoyed a meal of fried fish, rice, and beans. This is standard fare in Haiti. We stayed at the hotel in Port-au-Prince for one night before leaving for Port-de-Paix the next morning. Thus far my visit was going well.

To get to Port-de-Paix we could either take an all-day bus ride or a flight over the mountains. We reloaded onto the tap-taps to return to the airport. The roads were teeming with people riding motorcycles, hanging off the back of trucks, and little children calling us "Blancos". At the airport, we walked out on the tarmac to board extremely small planes seating only 5-7 people. Once in the air, I was struck by the extensive deforestation. There were very few trees on the land we flew over. The scariest part of the trip was when we landed on a rutted dirt and gravel road that doubled as



Traveling by "tap-taps" from Port-au-Prince to the Haitian Mission.

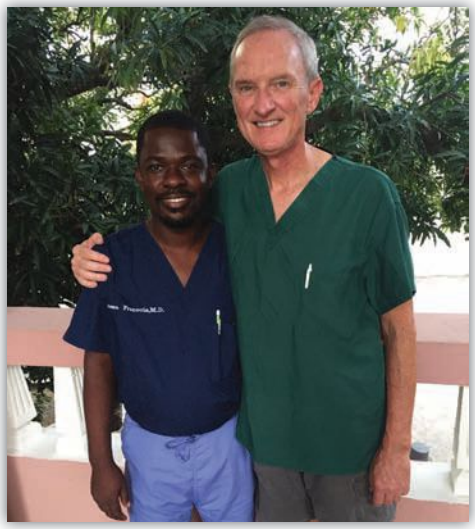
an airstrip. It was crowded with pigs and goats. One of the planes had to fly low over them to shoo them reluctantly off the runway. From there we traveled in tap-taps to Saint-Louis-du-Nord and the Northwest Haiti Christian Mission. When we arrived, tired but enthusiastic, we entered a large, quiet courtyard surrounded by the mission buildings. We met the full-time missionaries and were led to our dorms.

Immediately the next morning I started working in the mission eye clinic. There I did visual screening on the Haitian patients. Before we left Kansas City my dad had taught me the basics of visual acuity testing. Because the ophthalmologists only come twice a year, people come from all over northwest Haiti to get eye surgery. We had translators who helped us with the patients. I even learned a little Creole. We would line patients up and test their vision before sending them to the eye clinic. The Haitians arrived in their best clothes in respect for the doctors and medical staff. One man memorably showed up in a tuxedo with a top hat. I worked from 7AM to 4 PM. This was an incredibly long work day for me. When clinic was finally over, we went to dinner then headed to the chapel for devotions. Later, I would go to the mission orphanage and hang out with the kids. We played games and I got to know a few of them. I became close with one orphan named David. He told about his life in the orphanage and I enjoyed spending time with him. We talked until 10pm at night when the generators went off and the mission went dark.

On Sunday, we attended a three-hour service in the

Haitian Boy Completes Medical School with Financial Help from Dr. Bill and Lisa White

by William White, MD



Choose your words wisely as you never know who is really listening. During a medical mission trip to Haiti in 2002, I met Ifossa Francois. He was a young boy that my wife Lisa and I were supporting in a Haitian Christian mission. A missionary friend on site had specifically chosen him for his intelligence and compassion as worthy of our extra support. She chose well.

Upon first meeting Ifossa, I asked him what he wanted to do when he grew up. He immediately exclaimed either a pastor or a doctor like me. I had not expected this answer. I told him that if he really wanted to be a doctor, he would need to work hard in school and that my wife and I would help him financially. He never forgot that conversation. I discussed our exchange with Lisa, and she said that would be extraordinary if that came to fruition. But we both felt the chances of such were very slim.

Ifossa did extremely well all the way through high school. We approached the mission about sending him to college, with our financial support, and they agreed. Ifossa did superbly in college. So well in fact that he qualified to go to medical school on another Caribbean island: St. Kitts. Medical school was tough for Ifossa, but he again was a good scholar. He had to pass the same board exam that we do here in the US (the USMLE). And he did!

Upon graduation from medical school as a Haitian resident, the new doctor owes the government one year of service before entering practice or taking a residency. That is where Dr. Francois is now. Through a very strange series of events, he was assigned to the very mission in Haiti where we first met! His office is just a few feet away from where that our initial encounter took place. He plans on pursuing a residency in ophthalmology after he completes his service year. **MM**

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church across the street from the mission. The service was conducted in Creole which I did not understand. It was still a beautiful service and a moving experience. After church, we left the mission and walked around the town. We visited a market where people were selling all sorts of things such as dried fish, raw meat, and spices. On the north side of the market small homes lined the beach. Unfortunately, the beach functioned as a trash dump so the waves were full of plastic bottles. Pigs were sifting through the trash at the edge of the waves. We also went to the police station and gave some of the inmates food and soap. As we walked back towards the mission, we noticed a large, rapidly growing crowd of children following us. Someone stopped to give them candy. Not a good idea, we immediately were surrounded and could scarcely move. The candy supply was quickly exhausted. There are so many things we take for granted at home. I was becoming more appreciative for my Kansas City life. Back at the mission one of the nurses had long balloons and was blowing them up, twisting them into balloon animals for the kids in the disabled center. (Figure 2) The kids seemed so happy to have the attention and entertainment. We were having a great time, too.

Besides the eye clinic, I also worked in the birthing center, the orphanage, the disabled center, helping pre-op/post-op patients. I even got to watch a few surgeries. I enjoyed the trip, it was special time with my dad, and I made a lot of friends and memories. I have a better perspective on how different many people's lives are from mine. I feel it was equally rewarding on many levels for me. Before the trip I could not imagine how many people live a level of poverty unknown in the United States. I think a mission trip is really important to for young people. If they can go with a parent so much the better. If you have the opportunity then make it happen. I'm glad I did. **MM**

Why No Mandatory Retirement Age Exists for Physicians: Important Lessons for Employers

by Barbara Grandjean, JD & Chad Grell, JD

Does the law impose a mandatory retirement age for physicians? If not, may employers take it upon themselves to require physician-employees to retire at a particular age? And if mandatory retirement is not an option, what other options exist to remove underperforming, older physicians? An older physician whose skills, abilities, or competence may have worn away with time (or where there is simply the fear that has occurred) brings two central concerns into conflict: on the one hand, the paramount concern of public safety and professional competence, and on the other hand, fairly judging an employee's ability to work not by age, but by merit and demonstrated skill. This conflict plays out in every work setting, but it can be particularly heightened in the field of medicine.

In some professional work settings, the conflict is resolved on the side of public safety and competence, with mandatory retirement ages set by law. In the profession of law, many jurisdictions in the United States impose mandatory retirement ages for judges. For example, Missouri's Constitution requires state judges to retire at the age of 70; in Colorado, judges must retire at 72.[1] In the aviation industry, pilots cannot fly commercial airlines domestically once they turn age 65. Commercial pilots flying internationally must also abide by standards imposed by the International Civil Aviation Authority: a pilot who is 60 years or older may only serve as pilot-in-command if there is another pilot in the crew who is not older than 60.[2]

In at least one major way, these mandatory retirement ages are suspect: in analogous, or almost identical, settings, either no mandatory retirement age exists, or it is set much higher. If state court judges must retire at age 70, then surely United States Supreme Court Justices, who sit on the highest court in the land and decide legal issues of utmost national significance, must retire at age 70, too, correct? But the U.S. Constitution imposes no such requirement. Justice Oliver Wendell Homes, Jr. was 90 when he retired.[3] Similarly, although commercial pilots may not be able to fly past a certain age, a federal appellate court has held that similar mandatory retirement ages may not pass muster for an airline manufacturer's jet transport pilots.[4]

Physician-Employees are Protected from Age Discrimination

Lawmakers and professional regulators, perhaps implicitly recognizing the arbitrariness and unfairness in mandatory age retirements, have imposed no such requirements for physicians who are employees. To the contrary, physician-employees[5] may enjoy significant federal and state protections from age discrimination, and health care employers who may be tempted to require physician-employees to retire based on age would be strongly advised against doing so.

Under the Age Discrimination in Employment Act ("ADEA"), it is unlawful for a qualifying employer[6] to classify employees "in any way which would deprive





Barbara Grandjean, JD, (left), a partner, and Chad Grell, JD, (right), an associate attorney, both in Husch Blackwell's Denver office, wrote this article, with contributions from Tracey O'Brien. Barbara and Chad specialize in defending employers, especially hospitals and other healthcare providers, against allegations of age and other types of discrimination. The information contained in this article should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general information purposes only, and readers are encouraged to consult their own attorney concerning their specific situation and specific legal questions.
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or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual's age."[7] Almost every state has an ADEA analog.[8] These anti-discrimination laws recognize that chronological age is not an indicator of competency and should not be used to drive out older workers. As the U.S. Supreme Court has observed, "[t]hroughout the legislative history of the ADEA, one empirical fact is repeatedly emphasized: the process of psychological and physiological degeneration caused by aging varies with each individual."[9] As a result, "many older American workers perform at levels equal or superior to their younger colleagues."[10] Thus, the ADEA's baseline assumption is that age itself should not drive employment decisions.

Although the ADEA contemplates certain exceptions to its general rule, allowing employers to establish a legitimate age-based criterion referred to as a bona fide occupational qualification ("BFOQ"), employers would be very hard pressed to justify an age-based BFOQ for physicians. A physician's skill and competence cannot be reasonably measured by age, which is one legal requirement.[11] One article has reported that, while older surgeons were more likely to have poor outcomes in pancreatectomy, carotid endarterectomy or coronary artery bypass graft surgeries, there was no age effect for five other surgical procedures.[12] Further, there are numerous ways to test a physician's skills and competence on an individual basis, making it even more difficult to justify a BFOQ under the law.[13] Regardless, it does not appear that any court has upheld an age-based BFOQ for physicians.

To the extent an employer were to try to argue that public safety requires older physicians to retire, under regulations promulgated by the Equal Employment Opportunity Commission (EEOC), the employer will bear the burden to "prove that the challenged practice does indeed effectuate that goal and that there is no acceptable alternative which would better advance it or equally advance it with less discriminatory impact."[14] This is a very high burden.

In sum, age-based mandatory retirement plans for physician-employees are unlikely to be upheld in courts. The EEOC has obtained, and continues to obtain, settlements arising out of mandatory retirement policies, including large settlements against Johnson & Higgins for $28.1 million (forced retirement for employee/board members)[15] and Sidley and Austin for $27.5 million (forced retirement for law partners).[16] To date, Congress has not provided an exemption to the ADEA for physician-employees.

Contrasting Physician-Employees with Physician Owners or Independent Contractors

The picture may be decidedly more complex for physicians who are not classified as employees, but who are partners, members, or owners of physician practices, or who are classified as independent contractors. Just because a physician is a member, partner, or owner of a practice does not mean that anti-discrimination laws do not apply to that physician. Rather, courts generally examine six factors, such as the extent the practice supervises the physician and whether the physician can influence the practice, to determine whether the physician is actually an employer who does not enjoy the age discrimination protections described below, or whether the physician is an employee.[17] In at least one case, a court concluded that a physician-shareholder was not an employee because, in part, she had an equal right to vote on matters, shared equally in the firm's profits and liabilities, and participated in decisions to hire and fire employees.[18] But courts will analyze the "substance of the relationship rather than the label affixed thereto,"[19] and if a physician is more an employee than a bona fide partner, member, or owner, a physician may enjoy the same age-discrimination protections that apply to employees.

Similarly, as a general rule, physicians who are classified as independent contractors are not protected by age discrimination statutes.[20] But even if physicians agree to call themselves independent contractors, courts in Missouri, for example, will assess whether they actually fit the definition of an independent contractor, which is "one who contracts to perform work according to his own methods without being subject to the control of his employer except as to the result of his work," and who "are typically hired to complete a specific task, use their own tools in completing their work, are paid a fixed sum on a by-the-job basis, and are not provided with benefits."[21] A physician who does not fit this bill may be an employee who cannot be discriminated against on the basis of age.

Thus, although physician partners, members, owners, or independent contractors may not possess age discrimination protections, physician practices must fully explore and assess their liability before requiring such physicians to retire based on their age, especially since laws vary from state to state, contracts impose different obligations, and circumstances must be evaluated individually. Even if a physician practice is dealing with a bona fide owner or independent contractor who is forced to retire, that physician may still try to challenge the

practice's actions in court based on age discrimination and other laws. As a result, physician practices considering imposing mandatory age retirements for owner or independent-contractor physicians must proceed cautiously and thoughtfully.

This is so not just for legal reasons, but for pragmatic and fairness reasons, too. Apart from any legal obstacles, there is a pressing need for older physicians to continue to practice medicine. The AMA and the American College of Surgeons have acknowledged that approximately 26% of physicians are over the age of 65, [22] and "one-third of all practicing surgeons are older than age 55."[23] If physicians were subject to the same age requirements as commercial airline pilots, a quarter of the physician-workforce would vanish. Additionally, by 2025, the U.S. will have a shortfall of physicians from between 61,700 to 94,700.[24] Employers may not only face legal liability for imposing mandatory retirement, but they may be shooting themselves in the foot: by requiring skilled physicians to retire, employers may be depriving themselves of the individuals they need to perform work. And skilled physicians do not come cheap and are not quickly trained; jettisoning older, skilled physicians is a terrible waste, especially when society needs them and especially when they want to continue to work. In sum, a mandatory retirement age may not be fair to physicians and may not serve the best interests of physician practices.

Employers Should Work One-On-One with Physician-Employees to Improve Performance

If employers cannot mandate retirement for physician-employees, and if physician practices may not want (or may not be able to) require retirement for physician owners or independent contractors, what options exist to ensure that older physicians remain competent? How can employers strike the right balance between not discriminating against a physician on the basis of age while still ensuring patient safety?

Instead of imposing mandatory retirement, some employers may be tempted to impose mandatory skills testing or medical testing for employees of a certain age. This too would be ill-advised. In one federal case from New York, the plaintiff-employee was denied a promotion after he refused to submit to an EKG, which the employer required for candidates over the age of 40 seeking supervisory positions. The court held that the EKG requirement violated the ADEA, observing that although "medical testing" for "all those above a certain age is, perhaps, a practice less noxious under the ADEA than firing outright," because a "facial age classification is still involved," that classification has to be "justified as being reasonably necessary to the operations of the [employer's] business in order to withstand scrutiny."[25] Similarly, in another case, a court concluded that a law requiring all state employees over the age of 70 —regardless of position—to take and pass an annual physical examination violated the ADEA.[26] Although testing based on age is not permitted, if all employees in a particular position must be tested, then such testing may pass muster.

Since mandatory skills or competence testing based on age is not a viable solution for health care employers, to ensure patient safety and adherence to care standards, employers should scrupulously follow a quality assurance and improvement program. Further, employers should have procedures in place to conduct individualized medical inquiries of impaired physicians or physicians who are failing to meet the standard of care. For example, the Joint Commission's Ongoing Professional Practice Evaluation and Focused Professional Practice Evaluation processes, which strive to provide objective and accurate assessments, allow employers to identify physicians who may not be meeting the standard of care.[27]

But even here, employers must be careful: disability anti-discrimination laws prohibit employers from making disability-related inquiries or requiring a "medical examination"[28] from employees after employment has begun unless the inquiry or examination is job related and consistent with a business necessity.[29] The term "job-related and consistent with a business necessity" requires a reasonable belief based on objective evidence that an employee's ability to perform the essential job functions will either (1) be impaired by a medical condition or (2) pose a direct threat due to a medical condition.[30] A direct threat determination must be based on an individualized assessment of the employee's present ability to safely perform the essential functions of the job.[31]

All of this teaches a vital lesson for employers working with older physicians whose skills or abilities may have declined over time: employers must focus on performance—not age. Employers and physicians, who have an ethical duty to provide competent care,[32] should concentrate not on age, which is an unreliable indicator of performance, but instead on the quality of care a physician provides to patients. In those circumstances where an older physician's skills and competence are not meeting standards, employers should work with those physicians to

determine what steps, if any, can be taken to ensure those standards are satisfied. In doing so, age should never be used as a proxy for performance or talked about as such. Generally, this is also a best practice for physician practices dealing with physician owners or independent contractors, even if such practices may not be bound by the same legal anti-discrimination requirements.

For the same reasons that lawmakers and regulators have declined to impose a mandatory retirement age for physicians, employers should work with older physicians one-on-one to identify and correct performance deficiencies that may jeopardize patient safety. If those deficiencies cannot be timely and satisfactorily corrected, then employers may need to modify, or even terminate, physicians' employment. By focusing only on performance and communicating standards clearly and professionally, however, employers greatly improve their chances that their physician-employees will recognize that the time has come to make certain changes to their practice, or even to cease practicing. That momentous decision, however, is not one that employers can make for physician-employees based on their age. And even though that is a decision that physician practices may (subject to all the limitations described above) be able to make for physician partners, members, owners or independent contractors, the possible disruption, difficulty, and unfairness caused by mandatory retirement counsels against doing so.

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2. 49 U.S.C.A. § 44729(a), (c)(1).
3. https://www.supremecourt.gov/about/faq_justices.aspx
4. See EEOC v. Boeing Co., 843 F.2d 1213 (9th Cir. 1988).
5. The question of whether a physician-shareholder is also an "employee" for purposes of the ADEA is a fact intensive one that is based on a review of the totality of the circumstances.
6. 29 U.S.C. § 630(b) (defining an employer as a "person engaged in an industry affecting commerce who has twenty or more employees for each working day in ach of twenty or more calendar weeks in the current or preceding calendar year").
7. 29 U.S.C. §623(a)(2).
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27. OPPE and FPPE: Tools to help make privileging decisions, Robert A. Wise, M.D., August 21, 2013, available at: https://www.jointcommission.org/jc_physician_blog/oppe_fppe_tools_privileging_decisions/; see also Using OPPE as a performance improvement tool, Paul Ziaya, M.D., February 5, 2014, available at https://www.jointcommission.org/jc_physician_blog/using_oppe_as_a_performance_improvement_tool/
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29. 42 U.S.C §12112(d)(4)(A) (1994); 29 CFR §1630.14(c) (1998); See also, EEOC Enforcement Guidance: Disability Related Inquiries and Medical Examinations Under the Americans with Disabilities Act, Part B (July 27, 2000) available at: https://www.eeoc.gov/policy/docs/guidance-inquiries.html
30. EEOC Enforcement Guidance: Disability Related Inquiries and Medical Examinations Under the Americans with Disabilities Act, Part A (July 27, 2000) available at: https://www.eeoc.gov/policy/docs/guidance-inquiries.html
31. Id.
32. AMA Code of Medical Ethics I ("A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.")

MM

1 Picture = 1,000 Words



The Financial Cost of Smoking in Missouri

(1=Lowest, 25=Average)

- **Total Cost Over Lifetime per Smoker:** $1,413,082 (Rank: 2nd)
- **Total Cost per Year per Smoker:** $27,707 (Rank: 2nd)
- **Out-of-Pocket Cost per Smoker** – $86,001 (Rank: 1st)
- **Financial-Opportunity Cost per Smoker** – $946,449 (Rank: 1st)
- **Health-Care Cost per Smoker** – $158,651 (Rank: 28th)
- **Income Loss per Smoker** – $210,291 (Rank: 15th)
- **Other Costs per Smoker** – $11,689 (Rank: 23rd)

Source: https://wallethub.com/edu/the-financial-cost-of-smoking-by-state/9520/



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- Hematology and Oncology
- Hospitalist
- Infectious Disease
- Internal Medicine
- Maternal-Fetal Medicine
- Med-Peds
- Neonatology
- Nephrology
- Neurological Surgery
- Neurology
- Neurology - Neuroimaging
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- Obstetrics and Gynecology - OB Hospitalist
- Occupational Medicine
- Oncology - Gynecological
- Oncology - Surgical
- Ophthalmology
- Oral and Maxillofacial Surgery
- Orthopaedic Surgery
- Orthopaedic Surgery - Adult Reconstructive Surgery
- Orthopaedic Surgery - Hand Surgery
- Orthopaedic Surgery - Trauma
- Otolaryngology
- Pain Medicine
- Palliative Care
- Pediatrics
- Pediatrics - Emergency Medicine
- Pediatrics - Hospitalist
- Pediatrics - Ophthalmology
- Pediatrics - Surgery
- Pediatrics - Urgent Care
- Physical Medicine and Rehab
- Plastic Surgery
- Psychiatry
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- Radiation Oncology
- Radiology
- Rheumatology
- Sleep Medicine
- Telemedicine
- Trauma Surgery
- Urgent Care
- Urology
- Vascular Surgery

MSMA: Help Us Help You

by James DiRenna, DO

As I continue my proud journey representing Missouri medicine, I have been fortunate to relate and communicate many issues that challenge physicians. It is amazing that my road has taken me from Missouri to the states of California, Kansas, Kentucky, Nevada, and back to towns in Missouri. I find that lobbying on behalf of Missouri medicine, the words and resolutions are the same with a few variables that change when crossing the state lines.

What we debated and were concerned about in April and May (prior authorization, MOC and scope of practice, etc.) are presently not high priorities on the radar. As I move out of the second quarter of my presidency, my efforts will be focused on the new American addiction: vaping.

From 2014 – 2018 there was a decrease in one or more tobacco products among youths (Source: CDC Morbidity and Mortality Weekly Report). Dr. Karen Cullen from the FDA determined the past prevalence of current use (past 30 days) of flavored tobacco products among U.S .middle schools (6th to 8th grade) and in high school (9th to 12th grade) produced a noticeable increase in the finding of severe lung illness tied to vaping. At print, the number of vaping cases was 1,080 with 18 deaths from 15 states. The median age is around 19 years old with most patients reporting a history of using THC containing products within three months of their symptoms. In all cases, histopathological findings show patterns of acute lung injury, acute fibrinous pneumonitis, diffuse alveolar damage or pneumonia. Foamy macrophages and pneumocyte vacuolization were seen in all cases. This is helpful in its clinical diagnosis.

I feel that it is imperative that the development of an aggressive anti-vaping marketing movement with Public Service Announcements through social, print, and electronic media be considered and discussed by our membership

Another priority that continues my present mantra of communication and collaboration: I speak to my young student and resident physicians that if you haven't joined my journey with membership, to please consider the benefits of MSMA. I constantly want you to remember advocacy, education, influence, professional networking, and time and money. These attributes and reasons will assist you in becoming enlightened physicians.

It's very basic – help us help you. **MM**



James DiRenna, DO, 2019-2020 MSMA President and member since 1996, is from Kansas City, Mo., and practices Family Medicine for the Blessing Health System.
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External Intensivists Versus In-House Intensivists

I enjoyed this article, "External Intensivists Versus In-House Intensivists: Analysis of Outcomes of Nighttime Coverage of ICUs by External On-Call and In-House On-Call Intensivists" by Madhuri Ramakrishnan, MD, et al. published in the July/August 2019 issue of *Missouri Medicine*.

Many small and medium-sized hospitals struggle to provide 24-hour continuous itensivist and hospitalist staffing. The EHR is available remotely, and this article shows that being at bedside continuously is not always necessary to provide excellent care for intensive care unit patients. Of course, availability by intensivists for necessary procedures and family consultations remains necessary.

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Why Marijuana Won't Fix the Opioid Epidemic

Since published in May/June 2018 issue of *Missouri Medicine*, "Why Marijuana Will Not Fix the Opioid Epidemic by Ken Finn, MD," there have been several other publications which support the fact that marijuana has not been proven to be an effective pain medication or opioid substitute. *The Journal of Pain*,[1] October 2018, published an analysis of the literature up to that point which included nearly 10,000 patients, and concluded that "it seems unlikely that cannabinoids are highly effective medicines for chronic non-cancer pain." The European Pain Federation[2] also published a position paper which may have supported the use of cannabis for properly selected and supervised patients, after cannabis-based medications have failed; however, it is important to note the do not recommend using any products more than 12.5% THC. Products currently available are over 30% for smoked flower, 50% for concentrates, and nearly 100% for other extracts with emerging and documented negative health effects.

Although earlier inaccurate research suggested that there is a decrease in opioid overdose deaths in medical marijuana states, Stanford University published a paper[3] demonstrating that, using the same methodologies, opioid overdose deaths have increased by 23% in those medical marijuana states. Most recently, Columbia University[4] published a paper showing that U.S. "medical marijuana law enactment was not associated with a reduction in individual-level nonmedical opioid use, contradicting the hypothesis that people would substitute marijuana for prescription opioids."

In summary, there is growing and clear evidence that marijuana use as a medicine is not helping the opioid crisis and has not been proven to be an opioid substitute. It is critical that public opinion not trump science.

Note: This correspondence is also being sent to the Georgia State Medical Association that reprinted the Missouri Medicine article.

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MM



Letters to the Editor

Submissions reflect readers' opinions and may be edited for length.

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Missouri Medicine in the News

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



Congratulations to Jeffrey Carter, MD, MSMA member since 2002, on being appointed to the State Board of Registration for the Healing Arts. Dr. Carter, an MSMA member since 2002, is an anesthesiologist affiliated with Missouri Baptist Medical Center and Ballas Anesthesia, Inc.



Gary Gaddis, MD, PhD, a Professor of Emergency Medicine at Washington University in St. Louis School of Medicine, was elected by the membership of AMA's Academic Physicians Section to serve as Chair-Elect. Dr. Gaddis has been an MSMA member since 2002.

MSMA President-Elect George Hruza, MD, MBA, FAAD, recently presided over the dedication of a shade structure in the Purpose Garden at Campus YMCA in St. Joseph. The structure, made possible by a Missouri Dermatological Society donation, was installed to raise awareness about skin cancer. Dr. Hruza, pictured third from left, currently serves as President of the American Academy of Dermatology.



Stephen Malutich, DO, recently joined Golden Valley Memorial Healthcare, and he's one of MSMA's newest members. Congratulations, Dr. Malutich!



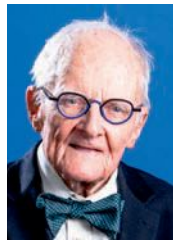
Lee's Summit Mayor Bill Baird has selected Jay Rapley, MD, as the 2019 Citizen of the Year, for his perseverance and strength when faced with extreme adversity; inspiring others with his story; and helping those who have faced injury or trauma in their own lives. Dr. Rapley has been an MSMA member since 2010.

Lisa Thomas, MD, has announced her candidacy for



State Representative of House District 124 comprised of portions of Camden and Miller Counties. The seat is currently held by Rocky Miller, who is term-limited and cannot run again. Dr. Thomas is a resident of Lake Ozark and has been involved in MSMA leadership since 2005. She currently serves as MSMA District 5 Councilor.

MSMA congratulates Charles Wheeler, MD, MSMA member since 1978, former mayor of Kansas City and a third-generation physician on receiving the Kansas City Medical Society's Lifetime Achievement Award; and Nathan Granger, MD, MSMA member since 1997, on receiving the KCMS's Innovator Award. Dr. Granger is with the Clay-Platte Family Medicine Clinic, founder of the Kansas City Metropolitan Physician Association and the KCMPA-ACO, and a board member of Centrus Health of Kansas City.







Robert Wilmott, MD, has been appointed Vice President for Medical Affairs and Dean of the Saint Louis University School of Medicine. Dr. Wilmott has been an MSMA member since 2007.



Hospitalist Maureen Weber, MD, MSMA member since 2016, recently joined Wright Memorial Hospital. MSMA wishes Dr. Weber all the best in her new endeavor.



Congratulations to David Wood, DO, for joining the medical team at Poplar Bluff Regional Medical Center. MSMA appreciates your membership support since 2016.



Laine Young-Walker, MD, has been named Chair of the Department of Psychiatry and Clinical Service Chief for all psychiatric services at MU Health Care. Dr. Young-Walker serves as the Secretary/Treasurer of Boone County Medical Society and has been an MSMA member since 2015.

MM

Free Health Clinic Receives Award from the AMA Foundation and Missouri Honor Fund

by Edmond B. Cabbabe, MD

Thanks to the generous donations from Missouri physicians and other donors established three years ago, the Missouri Honor Fund (MHF), in conjunction with the AMAF Community Health Program, granted over $40,000 to a clinic in St. Louis last year, and the MHF will support another clinic this year with a $10,000 award. The donors encourage qualifying clinics to submit their application to the AMAF for both the general AMAF and the MHF as they may qualify for one or both awards. Although the MHF has been established and operational, larger annual awards can be granted if the Missouri physician community and our patients are made aware of its effectiveness. I encourage you to seek and/or make a designated donation to the MHF at the AMAF. Your dollars will help promote our goal of providing needed care to the underserved and the uninsured.

The AMA Foundation's Community Health Program provides financial support to innovative programs targeting the prevention and reduction of type 2 diabetes and hypertension. This funding opportunity is awarded to community-based organizations such as free health clinics that provide services to vulnerable and underserved populations. Committed to fostering focused and measurable health improvements, Community Health Grants will be awarded in amounts up to $60K and are renewable for up to three years.

This grant fund opportunity is open to organizations that meet the following criteria:

- U.S. based Non-Profit Organization with 501(c)3 status*
- In operation for over three years
- Annual organization operating budget less than $3 million
- Provide services in the continental U.S.

The 2019-2020 Community Health Program Request for Proposals will open in late November/early December 2019 and can be found at https://amafoundation.org/programs/community-health. Organizations are not allowed to utilize third party foundations and/or fiscal agents to submit applications. This includes, but is not limited to, university and hospital foundations. Organizations with multiple sites are NOT allowed to submit for an individual site. In addition, the following organizations are ineligible to apply: Medical student-led clinics, hospitals, universities, elementary and high schools, state and specialty medical societies, local/city/state government entities.

*National affiliated organizations (utilizing the same EIN/501(c)3 status)

MM

Quality in Electrodiagnostic Studies: A Guide for Referring Physicians

by Chrissa McClellan, MD & Matt McLaughlin, MD

Many other diagnostic tests continue to be developed in the use of neuromuscular medicine, but none that can give as much physiologic information about muscle and nerve function.

Introduction

Electrodiagnostic testing includes nerve conduction studies (NCSs) and electromyography (EMG). NCSs involve applying electrical current to the nerves causing them to depolarize, inducing an action potential that is recorded, allowing the examiner to analyze various physiologic characteristics of the nerve, including latency, amplitude, and conduction velocity (Images 1 and 2). Electromyography involves putting a needle electrode into the muscle to determine to how the muscle is functioning at rest and with contraction. Different from an X-ray or MRI, electrodiagnostic studies are physiologic tests that give the examiner information about how the nerve, neuromuscular junction, and muscle are functioning.

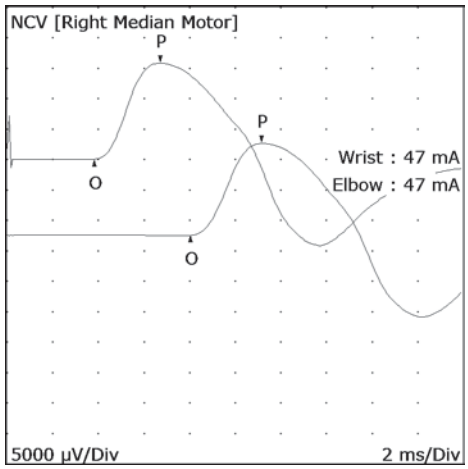
Prior to initiating testing, the electrodiagnostic physician should take a brief history, perform a focused physical exam, and develop a differential diagnosis to guide the appropriate selection of nerves and muscles to be evaluated. This allows the studies to be comprehensive yet minimize discomfort for the patient. The physician comes to a diagnosis based on the pattern of abnormalities (or lack thereof), and frequently alters the testing of various nerves and muscles in real time based on the analysis of the results. Electrodiagnostic studies are very much like an investigation, with the outcome of the investigation dependent on the knowledge and experience of the investigator. Electrodiagnostic studies can help localize the lesion that may be causing the patient's symptoms, rule out other diagnoses that could be causing similar symptoms, determine the severity of the lesion, and help to guide additional workup. These studies are frequently part of a complex clinical decision making process that may ultimately initiate invasive surgeries or other expensive medical treatments; therefore, its use and validity must be scrutinized.



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Challenges in Electrodiagnostic Medicine

Many referring physicians are unaware that non-physician providers are performing electrodiagnostic studies in their communities. In 1999, the American Association of Electrodiagnostic Medicine (AAEM), which is now the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), published "Guidelines in Electrodiagnostic Medicine: the Scope of Electrodiagnostic Medicine,"[1] which recommended that electrodiagnostic consultants be physicians with residency training in physiatry (Physical Medicine and Rehabilitation) and neurology. Despite this recommendation, it was noted in 2004 that 16.9% of electrodiagnostic encounters billed in the United States were provided by non-physician providers, including physical therapists, podiatrists, and chiropractors.[2] These non-physician providers were found to be performing electrodiagnostic examinations on younger patients with fewer comorbidities. Non-physician providers used fewer electrodiagnostic studies (only one study per encounter) than physiatrists and neurologists (three studies per encounter), possibly leading to under-recognition of more complex diagnoses.[2] It was later found that non-physician providers performing electrodiagnostic exams identified polyneuropathies in persons with diabetes only at a





Nerve conduction studies involve applying electrical current to the nerves causing them to depolarize, inducing an action potential that is recorded, allowing the examiner to analyze various physiologic characteristics of the nerve, including latency, amplitude, and conduction velocity.

rate one-sixth that of physiatrists and neurologists, likely due to underutilization of NCSs.[3] Substandard electrodiagnostic studies may lead to undependable results that may need to be repeated or cause unnecessary surgeries and procedures that are not successful, wasting healthcare dollars. Physical therapists, chiropractors, and podiatrists frequently lobby at the state level,[2] and they continue to be permitted legally to perform electrodiagnostics in many states. In the state of Missouri, for example, under Revised Statute 334.500, physical therapists may perform electromyography and nerve conduction tests, but may not interpret the results of the electromyography or nerve conduction test; under Missouri Code of State Regulations 20 CSR 2070-2.020(1), chiropractors are allowed to perform electromyography.

As with many other medical technologies that have been developed to improve the lives of our patients, electrodiagnostic studies have been plagued with fraud, waste, and abuse. Unfortunately, there has been unnecessary use of electrodiagnostic studies for financial gain, which prompted the department of Health and Human Services Inspector General to issue a report titled, "Questionable Billing for Medicare Electrodiagnostic Studies" in April of 2014, examining billing for the year 2011.[4] The most heavily scrutinized areas were New York, Los Angeles, and Houston; however, St. Louis, Missouri, was also named in this report. Since May of 2012, the Office of Inspector General has leveled penalties of almost $13 million in restitution and fines, along with 70 years behind bars for providers who have been guilty of fraudulent billing for electrodiagnostic exams.[5] Because of the increase in fraudulent billing, the Centers for Medicare and Medicaid Services (CMS) significantly reduced the reimbursement for electrodiagnostic studies in 2013, ranging from 40-70%.[6] These cuts in reimbursement forced many physicians performing electrodiagnostic studies to discontinue these services, which limited patient access to physicians performing these important tests. This was a big wake up call to many in the electrodiagnostic community that improvement in quality of electrodiagnostic laboratories was vital.

Recommendations for Referring Physicians

In May of 2012, AANEM updated its position statement regarding whom is qualified to perform electrodiagnostic examinations to include physicians whom have completed American Council for Graduate Medical Education (ACGME) accredited physiatry or neurology residencies and or fellowships, with direct supervision under an experienced electrodiagnostic physician for six months, and documentation of two hundred electrodiagnostic exams performed during this time.[7] Physiatrists' residency training commonly encompasses these requirements,[8,9] and generally physiatrists go on to perform electrodiagnostics independently after residency. Physiatrists may additionally become board certified through the American Board of Electrodiagnostic Medicine (ABEM) or the American Board of Physical Medicine

and Rehabilitation (ABPMR) Neuromuscular Medicine subspecialty. Neurologists' exposure to electrodiagnostics in residency is variable,[9] and those interested in this specialty go on to perform a one year neuromuscular or clinical neurophysiology fellowship. Neurologists may become board certified through the ABEM or the American Board of Psychiatry and Neurology (ABPN) Neuromuscular Medicine Subspecialty. We recommend getting to know the physician to whom you send your patients for electrodiagnostic studies, including their qualifications, as the quality of your electrodiagnostic examinations highly depends on the experience of the examiner.

Currently the gold standard in electrodiagnostic testing is performed in electrodiagnostic laboratories accredited by the AANEM.[10] In response to the unfortunate electrodiagnostic fraud, waste, and abuse, and subsequent reduction in reimbursement of electrodiagnostic testing, the AANEM took it upon themselves to improve standardization and quality of electrodiagnostic testing throughout the United States by offering an electrodiagnostic lab accreditation process. To become accredited, electrodiagnostic laboratories must use only physicians that are either physiatrists or neurologists with appropriate residency and or fellowship training as the medical directors and the practicing physicians. The accredited laboratory must demonstrate appropriate safety standards, including records of preventative maintenance of the equipment, as well as ongoing quality improvement projects to ensure continued advancement. The accredited laboratory must show appropriate documentation of electrodiagnostic exams by submitting reports that are peer reviewed for: evidence of history and physical exam, appropriate choice of NCSs and EMG, suitable reference data for comparison, proper documentation of raw data, and correct conclusions based on the data collected. Each laboratory must undergo reaccreditation every five years to show that these criteria continue to be met. The authors of this paper have both been through this accreditation process and feel that, although tedious at times, it has been very gratifying to know we are striving to meet the highest quality standards. It is the authors' recommendations that referring physicians look for AANEM accredited electrodiagnostic laboratories in their areas to refer their patients.[11] If you are currently performing electrodiagnostic studies in your practice, the author's highly recommend initiating the AANEM accreditation process in your laboratory to reassure your referral sources of your commitment to providing the highest quality electrodiagnostic testing for your patients.[10]

The Future of Electrodiagnostic Medicine

We believe the future of electrodiagnostic medicine is optimistic. Many other diagnostic tests continue to be developed in the use of neuromuscular medicine, but none that can give as much physiologic information about muscle and nerve function. After going through a very difficult growing period of uncovering fraud, waste, and abuse, the field of electrodiagnostic medicine has persevered and cultivated a culture of quality improvement, advocacy, and self-policing through recent efforts in AANEM accredited laboratories. This process, although difficult for those of us who strive for the gold standard already, has only strengthened and united many in the electrodiagnostic community to improve quality of care for our patients.

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Education • Research • Advocacy • Care

Optimizing the Health Care Needs of the Patient

by Darrin D'Agostino, DO

This edition of *Missouri Medicine* highlights the amazing work pre-doctoral educators are performing every day in the United States. Medical education has taken on a burden the last two decades and has struggled to optimize its role in the health care needs of the patient.

Medical education has historically been segregated into pre-doctoral and postgraduate education. Additionally, due to the need to continually learn and improve, physicians have traditionally taken Continuing Medical Education, based on a set of standards generated by their specialty colleges to maintain certification. Although an extremely sensitive topic these days, it, along with the separation of medical school and residency education, highlights the lack of integration between our learning systems. Creating a culturally sensitive and interprofessional foundation for health care learning can create opportunities to improve health care and the outcomes of the services and interventions we provide to our patients.

The articles we present include information and tools that can be used to improve a strained system. In this edition we highlight the wonderful and innovative programs at Kansas City University, and some the changes that are happening all around us as we prepare the next generation of physicians.



KCU's future Center for Medical Education Innovation will provide new opportunities for advanced medical education for KCU students as well as local and regional health care professionals.



At the center of the Joplin campus, an indoor/outdoor quad provides students with a communal social and study space.



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This is Not Your Grandfather's Medical School: Novel Tools to Enhance Medical Education

by Ryan Sheehy, PhD

Being able to integrate technology into medical education materials will close the professional gap between students and professors.



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Abstract

As new medical students start their journey to become the next generation of physicians, they are in awe of the wealth of knowledge at their fingertips as they begin medical school. Every student brings with them a unique story, and most bring with them a high tolerance for technology. The internet, smart phones, and the personal computer have shrunk the academic world and allowed students access to entire libraries that fit within their pockets. Medical school curricula continues to try to evolve to meet students in their increasingly technology filled world. How are medical schools evolving to integrate technology into their curricula? What follows is a review of the application of different technologies in medical education and a close look at the most efficient uses of technology within medical school curricula. This discussion is followed by perspectives from professors and a student on the use of a variety of different technologies for teaching and learning including podcasts, YouTube, Twitter, and varying online resources.

Teaching Technology

Teaching with technology is not new. The advent of the personal computer and the internet has changed medical education. For many years now, educators have used technology to enhance their teaching and students have used it to enhance their learning. The internet itself has opened up many opportunities to enhance learning. The ubiquity of the internet positions it nicely to provide creative learning opportunities that build collaboration, problem solving, critical thinking, and written communication skills.[1] The internet is the catalyst that accelerated, and continues to shape, the use of many of the technological methods used in today's medical school classrooms. Active learning is at the forefront of many of these technology-based methods as a metanalysis of undergraduate science, technology, engineering, and mathematics (STEM) courses found that active learning enhances student performance.[2] Active learning both in the classroom and beyond the lecture hall can be promoted by the creative use of technology within the medical school curriculum.

In-Class Technology Promotes Active Learning

The classic use of technology in the classroom is the use of slide sets in a lecture format. Slides can be used in a multitude of ways to influence the direction and course of in-class learning. Presentation format matters. A study done in the peer-reviewed journal *PLOS One* shows that slide software programs such as PowerPoint

and Prezi can lead to different amounts of audience engagement and enhanced presentation effectiveness when compared to an oral presentation.[3] The presentation software Prezi is unique in that it takes advantage of spatial relationships to give a lecture more of a story format.[4] Story telling is a great way to enhance learning and communication because stories are relatable. These are the reasons why stories make up nearly two-thirds of our daily conversations.[5] When directly compared to PowerPoint, results found Prezi to be the most engaging and effective medium.[3] Results further showed that Prezi use resulted in audience perception of a more organized, professional, and knowledgeable presenter.[3] However, it still takes significant effort to make a slide-based lecture result in active learning. One way is the use of an audience response system that allows all students in attendance to participate in lecture. iClicker is one of many audience response systems that allows students to respond to in-class poles, questions, and cases right from their laptop or phone. The beauty of iClicker is the ability for an instructor to look at student responses live in-class and for the instructor to adjust teaching to match any deficits or questions raised by the in-class poll.[6] Looking at student feedback regarding the use of clickers, 71% of respondents believed that clickers made lectures a more enjoyable experience, and 77% of respondents believed that clickers improved their ability to retain the lecture content.[7] In addition to iClicker, small group work within a large lecture format is another way to stimulate active learning. In undergraduate education, active learning has the greatest impact in classes of less than 50 students.[2] These results suggest that dividing large lecture classes into small groups to facilitate active learning will allow the educator to have the greatest positive impact on learning outcomes. Lastly, the application of expert tutor instruction into the large lecture hall increases active learning. A lecturer captures a one-on-one teaching experience in a large lecture class by implementing parts of the INSPIRE model. The INSPIRE (Intelligent, Nurturant, Socratic, Progressive, Indirect, Reflective, Encouraging) model was conceived by Lepper and Woolverton when they identified the seven characteristics of the most successful tutors.[8] In their article, Wood and Tanner apply the INSPIRE model to the lecture hall teaching format.[9] Focusing specifically on "indirect" from the INSPIRE model, one tactic an instructor can take would include telling the class that they all need to work together to come to a consensus on a case question rather than stating that 70% percent of the class answered wrong. Allowing students to reflect and turn in writing assignments about course material or specific questions can both allow the instructor to gain insight into how the students are thinking about the material and promote student metacognition.[9] Engaging students in a large lecture is not easy. It takes work and commitment on the part of the educator. As shown here, there are many ways to engage students and promote active learning within a traditional large class, lecture format.



Implementing podcasts into medical education allows for multitasking, helps learners overcome barriers of reading comprehension and language difficulties, allows the learner to grasp the information without a book, and enables the learner to further understand the in-class material.

Podcasts, Instructional Videos, and Video Streaming

Several technological mediums have also grown in popularity in medical education and these include podcasts, instructional videos (vodcasts), and video streaming applications. Podcasts are serial audio files recorded as an on demand radio show. Podcasts and instructional videos have been increasing in use in medical education.[10-14] However, their increased use has not led them to

completely replace in-class instruction. Schreiber, et al., found no significant difference in learning outcomes when instructional videos replaced traditional lecture indicating that there is not a significant rationale to completely replace in-class instruction with instructional videos.[15] The study went on to find that students enjoyed having the ability to pause, rewind, and speed up the video, however the students found watching only instructional videos to be a less engaging teaching method.[15] Even though completely replacing lectures does not seem to be the answer, podcasts and instructional videos have several benefits for learners. Specifically, implementing podcasts into medical education allows for multitasking, helps learners overcome barriers of reading comprehension and language difficulties, allows the learner to grasp the information without a book, and enables the learner to further understand the in-class material.[16] However, it is not enough to simply record a lecture and label it a podcast or an instructional video. An analysis of instructional video qualities most desired by students found that videos that are well organized and concise with high quality sound and images have the most favorable impact on the learner.[17] Concise and well organized videos help instructors avoid the "prof cast," as simply recording ones lecture and releasing it as a podcast or as an instructional video does not optimally take advantage of the medium. Video streaming is another technological medium that is growing in use in medical school. Many classes in a given curriculum can be recorded and made available to the student on demand after a lecture has taken place. Streaming recorded lecture material gives students the option to physically attend lecture, and a fraction of the students may choose not to attend due to the convenience of viewing lecture material from anywhere in the world at the student's desired pace. A recent study from the College of Medicine at the University of Central Florida found that a student's ability to self-regulate his or her effort was predictive of low attendance levels at a recorded lecture.[18] This indicates that self-sufficient students find more value in the advantages of streaming recorded lectures versus attending lecture in-person. The study went on to identify that attendance at a lecture was found to be higher in those students who orient more towards peer learning and help-seeking behaviors.[18] Most interestingly there was no correlation between performance on the final exam and the percentage of classes attended by the student.[18] This finding of no correlation between student performance and attendance is a result that has been collaborated by another study.[19] Additionally, research has been conducted on the use of interactive video conferencing systems to stream lectures live to locations outside the classroom. The literature on interactive video conferencing varies. Video conferencing has been found to have a positive effect when teaching clinical examination objectives to students located at remote sites.[20-21] However, another study found a neutral effect where video conferencing a class was just as effective as a traditional in-person lecture.[22] When done right in the correct context, podcasts, instructional videos, and streaming videos have great potential to increase the opportunity for active learning to occur within the classroom.

Simulation, Augmented Reality, and Virtual Reality

Exciting new developments in the areas of simulation and augmented/virtual reality have added new opportunities to engage students in active learning in medical school curricula. Simulations mirror real life scenarios and allow for imitations of real patients, anatomic regions, or clinical tasks.[23] Effective medical school simulations include timely student feedback, opportunities for repetition, ranges of difficulties, individualized and team based learning opportunities, defined outcomes, and simulator validity.[23] Research in the field of simulation is continuing to develop, however one study in particular reviewed literature from 1969 to 2003 and found that simulations are effective at enhancing and complementing medical education.[24] Simulation centers can be used to mimic operating rooms, patient rooms, intensive care units, or emergency departments.[23] Simulations have the unique ability to allow students to simulate the touch and feel of medicine through haptics and simulations can allow students to experience a clinical scenario at high fidelity with robotic mannequins and sophisticated computer algorithms. Haptics are defined as the ability to feel and sense motion during a simulation. One of the first blends of simulation and augmented reality came with the advent of the simulation PalpSim. Augmented reality involves the use of real world objects that are augmented visually by computer generated images. PalpSim provides training for femoral palpation and needle insertion, which is a common opening intervention in many radiology procedures.[25] What makes PalpSim unique is that students feel and sense the motion of the feedback devices with their hands and see a computer generated patient and needle with their eyes.[25] Augmented and virtual reality go hand in hand as new teaching methods in medical education. The biggest difference between the two is that virtual reality transports the user to a completely computer generated environment where the user sees, hears, and interacts with computer generated sights, sounds, and objects. One study reviewing virtual reality literature states that, "The possible impact of VR [virtual reality] on health care could be even higher than

the one offered by the new communication technologies like the Internet."[26] Virtual reality research has generated interest in the field of anatomy education. Nicholson, et al. found that a three-dimensional anatomical model of the ear enhanced student knowledge of three-dimensional relationships of structures within the ear.[27] However, the authors go on to acknowledge that future studies are needed to validate their results.[27] Both virtual and augmented reality seem to possess predictive validity in that skills acquired within the medium appear to be transferable to real situations.[28] More randomized control trials comparing virtual reality programs with augmented reality programs, high-fidelity simulations, or differing virtual reality programs are needed to assess the overall effectiveness of virtual reality programs.[28] The potential of virtual reality is only beginning to be tapped with the recent emergence of consumer accessible hardware. Simulation, augmented reality, and virtual reality will continue to shape medical school curricula for years to come.

Using Technology to its Highest Potential in Medical Education

Technology in medical education truly arose due to the increasing prevalence of technology in the lives of today's students and the changing societal expectations surrounding patient safety. Today's focus of many medical schools is to create the best physician possible and to promote patient safety in the training of student doctors. Ethical issues were raised by society including learning interactions and procedures on live patients.[23] Thus, the advent of technological means to learn medical processes and apply this knowledge prior to using it on a live patient became paramount. This further prompted medical schools to seek out and create curricula that teach lifelong learning to accommodate the explosion of medical knowledge accumulated over the lifetime of the profession. In the 21st century, the focus of medical education has shifted from knowledge-based medical education to competency-based medical education. Scientific facts and data learned in medical school may be outdated by graduation and memorizing facts does not prepare students to learn and practice in a clinical environment that is prone to change.[29] Sherwin writes that, "Competency-based medical education focuses on what a physician should actually be able to do."[29] In order to remain competent and up to date, today's physicians must have skills that ensure they continue to be lifelong learners. In order to become an effective physician, medical students need to be given more responsibility for their own learning and they need to learn to assess a situation and draw effective conclusions.[29] More responsibility and autonomy will help hone a student's intrinsic motivation and help them focus more on becoming the best physician they can be and less on extrinsic motivators such as specific course grades. The expense, work hours, and change necessary to implement technology into medical school curricula is worth the effort to create better physicians. By doing this medical schools can improve patient safety and prevent undue patient harm.

Today's medical students have high expectations for technology to be integrated into their medical education. Students expect efficiency and proper integration as today's medical student is accustomed to technology and they expect their instructors and learning materials to seamlessly integrate into their learning experiences.[23] "Today's students are no longer the people our educational system was designed to teach," writes Prensky in his article about digital natives and digital immigrants.[30] Medical students of today have spent countless hours using and surrounded by technology including cell phones, video games, and personal computers. An average college graduate has spent over 10,000 hours playing videogames and 20,000 hours watching TV over their lifetimes.[30] As a result of student's interaction with technology from an early age, it makes sense that, "today's students think and process information fundamentally differently from their predecessors."[30] Prensky describes these students as "digital natives" as they natively speak and represent the culture of the digital age because they've been immersed in it their entire lives.[30] This information is essential for an effective medical educator to understand, because a failure to integrate technology into the education of medical students would be doing the student a disservice in their long-term future growth as a lifelong learner.

Despite all of the good things technology brings to medical education, educators need to proceed with caution when planning to shape curricula around technology. Technology is a tool that helps an educator achieve the end goal of having his or her learners meet certain learning objectives. It is easy for an educator to become caught up in the excitement and attractiveness of technology and, therefore, it is essential for educators to remember that teaching should drive technology use. The use of technology should not drive teaching. When educators first begin to explore the insertion of technology into their teaching methods, they need to ask themselves, "How will technology enhance teaching and learning?"[31] Greenhalgh writes, "New technologies may have important educational advantages, but without support and training for staff and students they could prove to be an expensive disaster."[32] This statement effectively illustrates the commitment needed by both

educators and administrators to effectively train for precise and specific use of new technologies in the classroom in order to utilize the new tools to their greatest potential. As stated previously, integrating new technological teaching methods is a time consuming and work intensive process. Both educators and administrators must work together to find technology that fits the teaching philosophies and teaching styles of individual educators. This process will not be a "one size fits all" solution as educators need to feel motivated and safe if they are to integrate new teaching methods into their educational repertoire.[33] Svinicki writes, "Successful incorporation of technology tools will depend upon the extent to which they are connected to course goals, combined with effective pedagogies, and designed to improve student learning, rather than being used for their own sake."[31] This is the golden rule when it comes to incorporating technology in teaching, and for that matter into medical education. If a technological medium cannot be linked back to teaching objectives and cannot be combined with effective pedagogy, then the technology will not be an effective tool in medical education.

The future of technology in medical education is bright. Years from now this article will feel antiquated and out of date as new technologies become common place in medical schools across the nation. Building connections between technological savvy students and their educators is vital. Any small connections that educators can make with their students helps to build cohesiveness and community within the classroom. Being able to integrate technology into medical education materials will close the professional gap between students and professors. Closing the gap has the potential to result in cohesive, integrated educational experiences and the achievement of improving learning outcomes by creating in-class opportunities for active learning and skills building to create lifelong learners.

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None reported.

MM

Enhancing Culturally Sensitive Curriculum in an Osteopathic Medical School

by Gretchen Y. López- Hernández, PhD

Medical students need to demonstrate their ability to show cultural sensitivity and responsiveness to those non-native English-speaking patients.



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Abstract

Considering changing demographics in the United States, future physicians need exposure to specialized training ensuring effective communication with non-native English-speaking patients, particularly Spanish-speaking patients. We examine the impact of a medical Spanish terminology module on the linguistic competence of second-year osteopathic medical students participating in Kansas City University's Score 1 for Health program. Our goal is to enhance Spanish communication in clinical settings and to improving the quality and value of care delivered to patients.

Introduction

One of the challenges that medical students will face as future physicians is ensuring effective communication with non-native English-speaking patients. Medical students need to demonstrate their ability to show cultural sensitivity and responsiveness to those non-native English-speaking patients. Effective communication needs to be maintained even when health care providers and patients do not share the same language.[1] Incompatible language skills represent a communication barrier that could negatively impact patient care and health outcomes.[1-2] Enhancing language concordance between physicians and patients can potentially improve doctor-patient communication, patient satisfaction and trust, health outcomes, and reduce health disparities.[3,4,5]

One example that highlights the benefits of enhancing language concordance between physicians and patients was described in the study of Fernández and collaborators.[6] Physician self-rated Spanish-language ability and cultural competence enhanced elicitation and responsiveness of Spanish-speaking diabetic patients at a public hospital outpatient department.[6] This study demonstrates the importance of linguistic and cultural competency in the care of patients with limited English proficiency. Therefore, early training in linguistic competence can enhance medical education and have a positive impact on doctor-patient interactions.

Linguistic training of medical students, with a goal of competence, is of particular importance given the growing population of Hispanics in the United States (U.S.). Between 2000 and 2010, the Hispanic population grew by 43 percent, which was four times the growth in the total population of the U.S.[7] Furthermore,



Effective communication needs to be maintained even when health care providers and patients do not share the same language.

the Hispanic population grew in every region of the U.S. during this time period; most significantly in the South and Midwest regions.[7] Hispanics accounted for seven percent of the Midwest's population (10.5 percent of Kansas' population; 3.5 percent of Missouri's population) during 2010.[7] During 2011, in Missouri, six percent of people five-years-old and older reported speaking a language other than English at home; in Kansas, the number was 11 percent.[8] In Missouri, 17 percent of those who spoke a language other than English at home reported speaking English "not well" or "not at all".[8] Whereas in Kansas 22 percent of those who spoke a language other than English at home reported speaking English "not well" or "not at all".[8] While the Hispanic population is growing significantly in the US, Spanish-speaking physicians are underrepresented.[9]

Spanish language training programs already exist within predoctoral medical education.[5] In a national survey of U.S. medical schools, it was found that 66 percent (out of 110 surveyed medical schools) offered some version of Spanish medical curriculum.[5] However, the details about how these programs are incorporated within the medical curricula and the impact of Spanish language training on student medical competencies are not extensively described.[9-10] To address the need for linguistic competency training within Kansas City University, a basic Spanish medical terminology module was designed for second-year osteopathic medical students participating in Score 1 for Health.

Kansas City University's Score 1 for Health program provides free in-school health screenings to children in the Kansas City area. This program serves an ethnically diverse population of children, of which approximately 36% are Hispanic. Score 1 also provides early experiences in clinical medicine to Kansas City University's first- and second-year osteopathic medical students. Through the participation in Score 1's health screenings, Kansas City University's students have the opportunity to interact with children from diverse ethnic and language backgrounds enhancing their understanding of culturally sensitive clinical care.

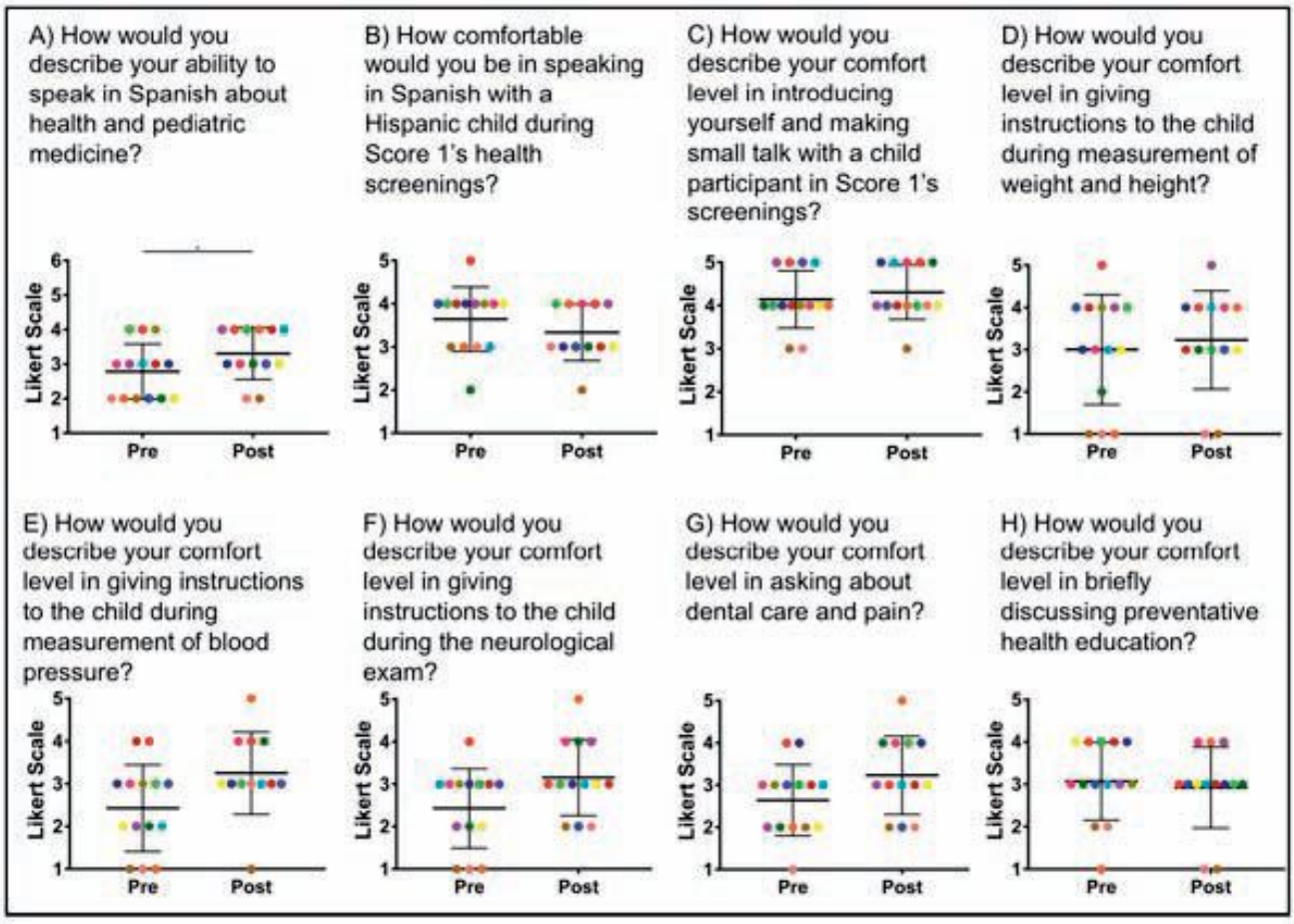
School-aged children from the Hispanic population in the Kansas City area represents one of the three major race/ethnicity groups participating in Score 1's health screenings. According to the 2008-2010 Community Report from Kansas City University's Score 1 for Health, one of the biggest obstacles identified by parents for accessing health services is a language barrier.[11] Using Score 1 for Health's screenings as a study setting for this module provides a unique opportunity to examine how Spanish linguistic enhancement of Kansas City University's osteopathic medical students will promote patient-student doctor interaction, patient satisfaction, and patient trust within the Hispanic population of Kansas and Missouri. Our goal is for the students who participate in the Spanish module to be encouraged to speak Spanish and use Spanish medical terms with the Hispanic patient population with which they are interacting. This will likely enhance doctor-patient communication and trust, thus strengthening the overall experience during the Score 1 screening for Spanish-speaking children.

Methods

Study Participants

Twenty volunteers were recruited from Kansas City University's Class of 2020 who, at the time of the study, were entering their second year of osteopathic medical education. This sample size represents approximately 10%

Figures 1A-1H. Likert scale for figure A: 1) None, 2) Rudimentary; 3) Basic; 4) Conversational; 5) Proficient; 6) Fluent. Likert scale for figures B – H: 1) Not at all; 2) Slightly; 3) Moderately; 4) Very; 5) Extremely. A total of 14 study participants submitted both pre- and post-questionnaires. Thirteen study participants reported using Spanish in their interactions with children during the Score 1's health screenings (1 participant did not answer).



of the Class of 2020. This research was conducted under an IRB approved protocol.

Inclusion Criteria

The study participants were student-volunteers self-identifying as possessing an intermediate or advanced Spanish speaking skillset, who were in good academic standing, and achieving a minimum cumulative grade point average of 2.0 after the completion of their first year of medical school. The module was focused on a short introduction to medical terminology in Spanish, rather than teaching basic Spanish, so participation in the study was limited to students that self-identified as intermediate or advanced Spanish speakers.

Pre-Questionnaire

The survey assessed participants' current opinions regarding their Spanish speaking abilities and their comfort and interest in utilizing the language in a clinical setting, that being Score 1's health screenings. The questionnaire was a hybrid survey based on published studies by Lion, K. C. et al. and Burbano, S. C. et al.[1-2]

Basic Medical Spanish Terminology Module

The module duration was a total of four hours divided equally over two days.

Score 1's Health Screenings

Participation in the Score 1's health screenings is a required element of the College of Osteopathic Medicine's (COM) curriculum and is not part of the study procedures. COM students participated in eight curriculum-based health screenings after the training module.

Post-Questionnaire

The survey assessed the participant's current opinions regarding their Spanish speaking abilities and their subsequent comfort in utilizing Spanish in the clinical

setting after completing the training module and after having had the opportunity to utilize Spanish and Spanish medical terminology in the Score 1's health screenings.

Data Analysis

For each student, both questionnaires were compared to determine if there were changes in the responses prior to, and after, completion of the basic medical Spanish module. Most responses were recorded using either a five-point (1-5) or six-point (1-6) Likert scale. Statistical analyses were performed using GraphPad Prism (GraphPad Software Inc., San Diego, CA, USA). Wilcoxon matched-pairs signed rank test was used to analyze the data from pre- and post- questionnaires. Statistical significance was designated at $p < 0.05$ and most of the data are presented as mean $\pm$ standard deviation.

Results and Conclusion

The desired outcome of this study is the enhancement of the linguistic competency of the participant osteopathic medical students through the introduction of the basic Spanish medical terminology module. The four-hour Spanish medical terminology module significantly enhanced the perceived ability to speak in Spanish about health and pediatric medicine of those medical students participating in this study (Figure 1A).

The survey also addressed students' perceived comfort level while performing the health screening while participating in Score 1 for Health. During the health screenings the osteopathic medical students interacted with Spanish-speaking children to gather general information (Figure 1C), measure weight/height (Figure 1D) and blood pressure (Figure 1E), perform basic neurological examination (Figure 1F), and assess dental care and pain (Figure 1G). The perceived comfort level of the medical students when performing these assessments showed increasing trends following participation in the basic Spanish medical terminology. A longer duration module as well as refresher sessions during the time period of the health screenings would potentially enhance the perceived comfort level when communicating in Spanish in different non-clinical and straightforward clinical scenarios related to Score 1's health screenings.

Currently, another cohort of study-participants was recruited from Kansas City University's Class of 2021 who, at the time of the second year of this study, were entering their second year of their medical education. This new cohort of volunteer students had an additional two-hour refresher session that included both a review of basic Spanish medical terminology as well as more interactive activities where the students could practice the use of Spanish while performing Score 1 clinical encounters. This refresher session was offered during the time period when the students were participating in the Score 1's health screenings. It is anticipated that the addition of the refresher session will further enhance the perceived comfort level when communicating in Spanish in both non-clinical and clinical scenarios related to Score 1's health screenings. One of the long-term goals of this study is to generate a validated model for the incorporation of Spanish medical terminology as a modality of linguistic competency training within Kansas City University's medical education curriculum.

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Disclosure

None reported. **MM**

Linking Diagnostic Skill Development, Communication, and Empathy Through Art and Observation

by Schoen W. Kruse, PhD & Monica N. Kinde, PhD

Some U.S. institutions have begun to include formal art training as a component of the medical school curriculum and many of these institutions have formed professional partnerships with area art museums.





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Introduction and background

Diagnostic skill development is an essential, and historically central, driving force of medical education. Teaching future physicians how to think critically and deliver a correct diagnosis, in addition to instruction of procedural ("doctoring") skills, is what has been at the core of medical education for close to a century. After all, making an accurate diagnosis sets off a chain of events, investigations, and therapeutic treatments, which likely will lead to appropriate management. However, patient care and positive patient outcomes require more than abilities that are often reflected in academic achievement, performances on examinations, declarative knowledge, and procedural skills (i.e., cognitive abilities). These additional and essential skills are often described under the rubric of "personality" and includes features such as personal qualities, attitudes, interests, values, and other psychosocial.[1] These skills help to shape and strengthen the health provider-patient relationship, which is positively correlated to higher satisfaction rates and health outcomes in patients.[2] Naturally, then, the ultimate goal of medical education is to graduate physicians that demonstrate excellence in their cognitive abilities as well as personality.

Although medical education has placed strong emphasis on diagnostic skill development, some experts estimate that 75% of diagnostic failures can be attributed to clinician diagnostic thinking failure from multiple causes including inadequate knowledge, faulty data gathering, and/or faulty verification.[3]

Decision-making is complex. It is partly based on a dual-process theory[4] which describes two families of cognitive operations called System 1 (intuitive) and System 2 (analytical) thinking. System 1 thinking is often described as a reflex system that relies heavily upon "pattern recognition." System 1 thinking, often described as the "gut feeling," is an automated mode of thinking, generated without much conscious effort, and channels the available information through a subconscious pattern recognition based on similar past situations. Alternatively, System 2 is the more "analytical," "deliberate," and "rational" side to the thinking process. It is a combination of logical judgment and additional information acquired through past learning and experience.[5,6] Through a conscious application of rules, this information is carefully processed, making System 2 thinking a much slower and cognitively demanding process, but one that is more likely to lead to better decisions. If there is adequate time to think, this process is usually engaged when there is uncertainty, complexity, or if the outcomes give little room for error.[7,8] Most matriculating medical students have mastered System 1 thinking but struggle with System 2 thinking. Medical education is called upon to develop opportunities for learners



Michael #145973 by Rick Ashley. This photo was finalist of the Outwin Boochever Portrait Competition in 2016. This tri-annual competition is supported by the Smithsonian National Portrait Gallery and traveled nationally and internationally. The Kemper Museum of Contemporary Art hosted the traveling gallery of finalists in the fall of 2017.
Reprinted with permission. Source: https://portraitcompetition.si.edu/content/rick-ashley

to practice balancing these two systems in order to refine critical thinking skills. Deliberate practice of advanced critical thinking skills will help to ensure graduates are ready to meet the demands of patient needs as diseases and disorders increase in complexity.

Educators in health professions are also called upon to identify and implement curriculum that will develop positive personality attributes that will result in improved healthcare delivery and patient outcomes. Empirical research suggests that a number of personality attributes, including empathy, are among significant predictors of clinical competence of physicians-in-training[9,10] and of positive patient outcomes.[11,12] Empathy has been described as one major element of professionalism in medicine,[13] and the most frequently mentioned personality attribute of the humanistic physician.[13] As such, cultivating empathy is among the goals of medical education, endorsed by professional medical organizations.[1]

Recognition that strong communication, observation, and emotional skills are essential for health care professionals is virtually universally accepted in the medical education community, yet there are limited opportunities to cultivate these skills given the intensity of the curriculum designed to deliver knowledge and practical patient care skills to the learner. This challenge is further complicated by the increasing emphasis on national board exam performance among medical students and residency programs. Even with time allocated for targeted practice of these skills, challenges remain in creating curriculum that comprehensively addresses and allows development of communication, observation, and emotional skills in addition to teaching diagnostic decision making and critical thinking.

In the past 15 years, increasing evidence has shown that health professionals benefit from exposure to the visual and performing arts.[14–17] Because of this, some U.S. institutions have begun to include formal art training as a component of the medical school curriculum and many of these institutions have formed professional partnerships with area art museums. Delivery of this curriculum has been varied, ranging from one class period[18] to weekly museum sessions over eight weeks.[19] The majority of these programs utilize Visual Thinking Strategies (VTS) as the andragogical approach and prioritize its effect on students' observations skills.[16,19–21]

At KCU-COM, we have created a course we believe can address the curricular needs described above; one that will teach diagnostic skill development, enhance communication skills, and emphasize the importance of empathy and relationship building. The Art, Observation, and Medicine (AOM) course for Year 1 Osteopathic Medical Students aims to help forge connections between active art examination and diagnosis, awareness of tolerance for ambiguity in healthcare, teamwork, communication skills, and empathy. As a required course in the first year of the osteopathic medical curriculum and through collaborations with the

Kemper Museum of Contemporary Art (Kansas City, Mo.) and Crystal Bridges Museum of American Art (Bentonville, Ark.), all KCU-COM students, from both Kansas City and Joplin, gain new perspective of the skills needed to deliver healthcare and address patient needs.

Description of AOM Sessions

First year medical students participate in small groups (10-15 students) at each museum under the guidance of a museum educator (docent). Prior to entry into the art galleries, students are reminded to respect one another's thoughts and opinions. Establishing a safe environment for communication and idea sharing is critical to the process. Three questions are asked at each piece of art: (1) What is going on in this picture? (2) What do you see that makes you say that? (3) What more can we find? The specific language used and order of questioning represent Visual Thinking Strategies (VTS), a research-based methodology that utilizes art discussion to develop growth in aesthetic and cognitive skills. Through VTS questioning, students are afforded the opportunity to comment on what they perceive is occurring in the piece and are asked to provide reasoning and information that supports their claims. The small group setting creates an opportunity to listen to the thoughts and opinions of their colleagues. The opportunity to share and listen in a collaborative environment helps foster an open and safe setting to practice communication skills and learn the value of teamwork to create a common narrative.

The VTS process aligns with the practice of System 1 thinking and development of System 2 thinking. Students often describe how they make an initial conclusion of an image based on their initial impression or snap judgement (System 1 process). It is only after listening to their peers, understanding the reasons that support their peers thoughts and opinions, and gaining perspective of the value others bring to the discussion of the piece of art do the students begin to change their opinions. By asking: What more can we find? students are asked to take a deeper dive into the image. The reshaping of their initial reactions into new ideas and opinions, based on more information, replicates a process that aligns with System 2 thinking. Through the AOM course, we've been able to create opportunities for students to practice their critical thinking skills and, in part, develop diagnostic skills.

After each image, students are asked to reflect on the process and share their thoughts with the group. Typical reflection questions are outlined below.

- What was the experience like for you? Pros? Cons? (This is a safe environment to provide feedback.)
- What did you notice about your observations?
- What did you notice about your peer's observations?
- Did you ever change your mind about your initial impressions during the course of the viewing?
- What did you notice about yourself when you encountered something that was confusing, vague or ambiguous?
- What did you notice about the process when you discussed vague and ambiguous aspects of the work?
- What kind of connections can you draw from this experience and working with a patient?
- Will patients present with a similar ambiguity or vagueness?
- How can we relate this experience to patient care? To team-based patient care?

Through these questions, students have an opportunity to discuss concepts related to communication, empathy, collaboration, diversity, ambiguity, burnout, interprofessional teamwork, and other topics that are difficult to teach in a lecture-based format yet are all recognized as essential for practicing healthcare providers.

After viewing up to five images at the museums and using the VTS process as the foundation of each discussion, the student groups reconvene and participate in a large-group debrief sessions. These sessions are composed of up to 45 students and are facilitated by KCU faculty within the College of Osteopathic Medicine and, when possible, the Clinical Psychology Program. Discussion at the large-group debrief reemphasizes the principles of communication and listening skills, collaboration and teamwork, changing opinions, ambiguity. Students also spend time discussing concepts of working on interprofessional teams. Some of the AOM sessions include both medical and clinical psychology students; these sessions offer great potential to discuss the benefits of multi-disciplinary teams and their positive impact on patient outcomes.

Measurements of Student Outcomes and Next Steps

In conjunction with the delivery of the AOM curricular content, we are associating a student outcomes study based on the museum experiences to evaluate the impact of the arts curriculum. The study focuses on measuring changes in observational skills, empathy, and tolerance for ambiguity. These variables are closely interrelated, and this study presents a unique opportunity to analyze the impact of one AOM session on factors that contribute to a strong doctor-patient relationship. Pre- and post-session surveys use the Interpersonal Reactivity Index subscales to measure empathic concern and perspective-taking[22] and Tolerance for Ambiguity Scale.[23]

We chose to study changes in observational skills, empathy, and tolerance of ambiguity in order to build

upon and expand prior research of arts-based strategies in medical education, which prioritized the skill of observation. Observation plays an important role in the practice of medicine given its role in clinical diagnosis. Some institutions have begun to include formal art training as a component of medical curriculum to help their learners develop observational skills[19] or to provide additional training in specialties for which visual skills are imperative, such as ophthalmology.[24] Teaching students to see visual details in clinical settings laid the foundation of using arts-based strategies.[14,25,26] Tolerance for ambiguity (TFA) is said to be a necessary skill of medical professionals as it enables them to deal with situations in which there is incomplete information or multiple answers.[27,28] In addition, one study using arts-based training in the context of classroom learning further explored the connection between TFA and empathy.[18] Empathy is inherently related not only to TFA, but also to communication, given that better communication can impact the extent to which an individual is able to participate in the perspective-taking necessary for empathy. To date, evaluation of empathy primarily exists in studies exploring arts-related training of medical students as a correlation or through elective coursework.[29] Our AOM course responds to the call for "empathy training" to be added to medical school curricula.

This year's curricular AOM offerings will be complete in June 2019 and outcomes will be analyzed soon after. We look forward to evaluating and reporting our findings from this year's curriculum. Our future directions include building upon the existing arts-based AOM curriculum. There are opportunities to create a thread of curriculum within the AOM course that focuses on diversity and cultural competency. We plan to increase interprofessional education in the AOM sessions for all of our students by collaborating with students in other health-professions programs. Additionally, we have opportunities to build in 'booster' sessions to reinforce skills learned in previous AOM sessions, both in the museum setting as well as campus-based setting using virtual technology.

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MM

Advancing Integrated Healthcare: A Step by Step Guide for Primary Care Physicians and Behavioral Health Clinicians

by Sarah E. Getch, PhD & Robynne M. Lute, PsyD

Interprofessional practice is crucial to achieve the best patient outcomes, reduce costs, improve population health, and improve the work life of health care providers.





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Introduction

Primary care providers (PCPs) often act as the first line of response for their patients who present with mental health concerns and many individuals with chronic illness also suffer from behavioral health issues.[1] However, primary care providers frequently lack the time and training to be able to effectively diagnose and treat behavioral health issues. Thus, the fields of medicine and psychology have moved to integrating behavioral health providers within primary care settings and team-based approaches in primary care. How a PCP practices integrated medicine can vary by levels of integration ranging from standard referrals for behavioral health needs to full integration of a behavioral health clinician within a an integrated health care team. Research has shown that a team-based approach to care delivery can not only result in improved quality of care, productivity and efficiency, but also an increase in satisfaction among both patients and clinicians.[2,3] The importance of a behavioral health clinician (BHC) on an integrated health care team cannot be understated. Experienced BHCs offer a broad and deep range of clinical and research interventions and skills that benefit patients, providers, and health care systems. In fact, many of the interventions and skills offered by BHCs address some of the most prescient medical and psychological needs of our patients including chronic pain and nutritional health. Further, BHCs bring a skill set aimed at addressing the programmatic and practice outcomes necessary for practice improvement. Despite the evidence-base supporting interprofessional practice (IPP), providers are often hesitant to incorporate BHCs due to multiple factors, which we discuss.[4,5] However, the move toward IPP is crucial for all PCPs in order to provide best care. Our aim with this article is to help PCPs who work at any level of integration to take steps toward increased IPP by utilizing critical clinical examples.

What is Interprofessional Practice?

Interprofessional practice (IPP) is defined as collaborative practice that occurs when healthcare providers work with others from their own profession, with others from outside their profession and with patients and their families.[6] IPP serves as the umbrella under which multiple levels of interprofessional care exist. Providers who work collaboratively should share common goals and more effectively coordinate care according to patient needs thus resulting in higher quality care. Many PCPs utilize some kind of interprofessional practice by working with nursing staff, providing referrals for patients, or seeking

consultation from individuals outside of their profession. However, true interprofessional team-based care occurs when care is delivered by intentionally created, work groups who are recognized by themselves and others as having a collective identity and shared responsibility for a patient or group of patients.[7] Today, many organizations are moving to an integrated care model where tightly integrated, on-site teamwork operates with unified care plans as a standard approach to care for designated populations. An organization that is providing integrated care would utilize organizational integration involving medical, psychological, social, and other services. Such care would also include 'altitudes' of integration (i.e., integrated treatments; integrated program structure; integrated system of programs; integrated payments.)[8,9]

What are the Benefits of IPP?

The benefits of IPP have been well documented and reported over the last 50 years of study. Research has demonstrated that in acute and primary care settings patients are more satisfied with their care, more accepting of care, and demonstrate improved health outcomes when they receive care from an interprofessional team.[10] Additional benefits of IPP include improvements in access to healthcare, appropriate use of specialists, and outcomes for individuals suffering from chronic diseases as well as declines in patient complications, length of hospital stay, provider tension and conflict, turnover, hospital admissions, clinical error rates, and mortality rates.[10,11,12,13,14,15]

The benefits of IPP can be summed up easily by the Institute for Healthcare Improvement's (IHI) Triple Aim Framework. The IHI Triple Aim is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions: improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care. However, as institutions began to adopt the Triple Aim model, it quickly became clear that good patient care was dependent upon providers also being properly cared for. High rates of burnout among clinicians and staff remain widespread.[16] In 2014, Bodenheimer et al.[17] proposed the Quadruple Aim Framework in which organizations optimize health system performance by simultaneously pursuing improving the patient experience, improving the health of populations, reducing the per capita cost of health care, and improving the work life of healthcare providers.

While many organizations have turned toward the Quadruple Aim to improve health system performance, many PCPs continue to look to improve their own practices or organizations but often find themselves at a loss of where to start. Because PCPs often act as the first line of response for their patients who present with mental health concerns, the introduction of a BHC to primary care practice would have immediate benefits for providers and patients alike and thus is a logical place to start with IPP. One of the most fundamental aspects of successfully enhancing IPP includes understanding the difference between the roles and functions of traditional therapy versus behavioral health care in integrated practices. Traditionally, the terms "mental health" or "behavioral health" conjure the idea of outpatient care located in a siloed environment away from the primary care practice. Traditional therapy can be time-limited, yet is often a longer-term commitment that tend to conjure images of Freud, couches, hour-long sessions, and unscientific talk therapy that has little to nothing to do with one's medical care. Not only is this view of therapy inaccurate, it reflects very little of what a BHC does within a primary care practice. According to Robinson & Reiter,[18] when electing to hire or work with a BHC, the ideal knowledge, skills, and attitudes may be summarized as: "The BHC works in the primary care clinic as a regular team member and delivers brief, consultation-based services to patients and primary care providers (PCP). The BHC works with individuals, groups and families, providing evidence-based behavioral interventions for both mental and physical health conditions in patients of all ages." The sample roles elucidated above fit with this BHC definition.

How are Levels of Integration Defined?

Integration of health care can occur at multiple levels and is often used to describe how health care components are brought together.[9] The original levels of integration framework was proposed by Doherty, et al.[19] and served as a foundation for classification of integration levels based on how and where services and collaboration took place. This framework established a continuum that moves from collaboration to integration of healthcare delivery. More recent work has built upon this framework to propose six levels of collaboration that lead to integration of care beginning with coordinated care, moving to co-located care, and ending with integrated care. Within each of these main categories there are two levels, illustrated in Table 1.[9]

PCPs can begin to utilize these levels of integration by assessing their own practice using this collaboration-to-integration table as a template. At Level 1, BHCs and

PCPs work at separate facilities, separate systems and rarely communicate about cases. When communication occurs, it is usually based on a particular provider's need for specific information about a mutual patient. Basic Collaboration, or Level 2, occurs when PCPs and BHCs maintain separate facilities and separate systems while utilizing each other as resources. Communication may occur periodically and is generally driven by specific issues. Levels 3 and 4 comprise Co-located Care. At Level 3, BHCs and PCPs are co-located in the same facility, but may not share the same practice space. Because of increased proximity, communication occurs more regularly and occasionally providers will meet to discuss share patients. At this level, the referral process is often more successful due to the co-location of providers. Providers may feel as if they are part of a larger team, however, decisions are still made at the individual provider level. Level 4 is marks the beginning of integration through some shared systems. This level also includes closer collaboration among PCPs and BHCs, all appointments being scheduled by the primary care front desk, and shared medical records. The move into fully Integrated Care involves Levels 5 and 6. At Level 5, providers begin to function as a true team, with frequent communication between team members. As a team, they will purposefully seek to recognize and address any barriers to care that currently exist for their patients. Full integration may not yet be possible for the team, however, all providers have knowledge of the different roles team members need to play and have begun to change their own practice based on this knowledge. Full Collaboration in a Transformed/Merged Practice, or Level 6, involves the greatest amount of practice change as multiple practices will have combined into a single transformed or merged practice. Both providers and patients view a level 6 organization as a single health system and have applied the principle of treating the whole person to all patients.[9]

Table 1: Levels of Integration Defined

Coordinated Care Key Element: Communication		**Co-Located Care** Key Element: Proximity		**Integrated Care** Key Element: Practice Change	
LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
Minimal Collaboration	Basic Collaboration at a Distance	Basic Collaboration Onsite	Close Collaboration Onsite with Some System Integration	Close Collaboration Approaching an Integrated Practice	Full Collaboration in a Transformed/Merged Integrated Practice

Table 2: Levels of Integration and Non-drug Pain Management

Coordinated Care Key Element: Communication	LEVEL 1	Begin to ask: • Who do I know in the community? • How do I find them?
	LEVEL 2	• Know what qualifications you are looking for in BHC • Identify qualified BHCs accepting patients in community • Consider if patients follow up with referral and how you will get feedback from referral source
Co-Located Care Key Element: Proximity	LEVEL 3	• Build infrastructure for feedback and integration into patient's healthcare plan • What is access like? • How to increase access?
	LEVEL 4	• Have feedback infrastructure • Explore reimbursement options and what costs would be of having BHC within practice • Have administrative conversations • Develop vision for full integration
Integrated Care Key Element: Practice Change	LEVEL 5	• BHC in practice • BHC shares CBT techniques with the core team in psychoeducation sessions (i.e., motivational interviewing, symptom management) • Physicians begin to use some of techniques themselves patient visit (i.e., reframe, identifying catastrophic thinking)
	LEVEL 6	• BHC in practice • Shared medical record • warm hand offs • Team has shared knowledge of how to use behavioral goals, self-management skills, reinforce pacing, etc.

Behavioral Health Needs in an Integrated Health Care Model

Each year the *Monitor on Psychology* produces a Trend Report as an annual guide to changes ahead for psychologists in patient care, research, technology, social justice and more. These trends, put together within an integrated care model, can provide a stepwise model of integration for PCPs looking to improve patient and provider outcomes by increasing IPP through the addition of a BHC. In order to aid PCPs in their attempts to increase IPP, three significant and time consuming

Table 3: Levels of Integration and Nutritional Health

Coordinated Care Key Element: Communication	LEVEL 1	• Assess what you know about nutritional health. • What resources available in clinic? • What free technology is available?
	LEVEL 2	• Ask who do I know in the community and how do I find them? • Know which providers have a background in nutritional health: Board Certified Specialist in Renal Nutrition (CSR) Board Certified Specialist in Pediatric Nutrition (CSP) Board Certified Specialist in Sports Dietetics (CSSD) Board Certified Specialist in Gerontological Nutrition (CSG) Board Certified Specialist in Oncology Nutrition (CSO) • Identify qualified RD/RDN accepting patients in community • Consider if patients follow up with referral and how you will get feedback from referral source
Co-Located Care Key Element: Proximity	LEVEL 3	• Build infrastructure for feedback and integrate into patient's healthcare plan • What do you know about coverage for nutrition? • What specific behavior change do you want the BHC and patient to work on and how will you follow up with that?
	LEVEL 4	• Have feedback infrastructure • Explore reimbursement options and costs of having BHC within practice • What does your feedback from BHC look like? Does it include electronic communication with patients? Can they upload photos of meals? Share healthy meal plans and recipes?
Integrated Care Key Element: Practice Change	LEVEL 5	• BHC in practice • BHCs use knowledge of process of behavioral change, • Consider how barriers and routines in patient environment can accelerate to decelerate change • Barriers are shared in treatment planning
	LEVEL 6	• BHC in practice • Shared medical record • Warm hand offs • Team has shared knowledge of how to use: Motivational interviewing How to monitor antecedents, behaviors, and consequences • Physicians using some techniques themselves in the visit: Addressing barriers Discussing electronic communication and behavior tracking

psychological trends, non-drug pain management, nutritional health, and programmatic outcomes/ data management, will be explored at each level of integration. To demonstrate how integration could occur, three collaboration-to-integration tables are created to describe this process.[20,21,22]

Non-Drug Pain Management

The over prescription of opioids to manage chronic pain has created increased incentive for physicians to examine non-drug treatments for pain. BHCs, and in particular psychologists, are prepared to treat chronic pain patients in a biopsychosocial model using an integrated approach.[20] Table 2 examines how PCPs can assess their current level of integration and how to take steps toward increased integration specifically with non-drug pain management.

Nutritional Health

What we eat and how we eat it can influence our physical and our mental health. BHCs are prepared to address nutritional health through the assessment of behavioral patterns in order to help patients make successful changes.[21] Table 3 examines how PCPs can assess their current level of integration and how to take steps toward increased integration specifically with nutritional health.

Programmatic Outcomes and Data Management

While psychologists are easily accepted as experts in behavioral health, they are often overlooked when it comes to evaluating outcomes and managing data. Doctoral level psychologists receive training in research methodology and statistical analysis that prepare them to be able to answer important evaluative questions when it comes to practice and patient outcomes. Table 4 illustrates how PCPs can assess their current level of integration and how to take steps toward increased integration specifically with regard to evaluating outcomes and data management identifying and influencing change in practice operations.

Conclusions

The evidence supporting increased interprofessional practice has clearly demonstrated that IPP is crucial to achieve the best patient outcomes, reduce costs, improve population health, and improve the work life of health care providers. This article encourages PCPs to begin to assess their current level of health care integration within their organization and then to predict the growth in integration with the addition of a BHC to their healthcare team. Many of the interventions and skills offered by BHCs address many of the most prescient medical and psychological needs of our patients including chronic pain and nutritional health. Further, BHCs bring a skillset aimed at addressing the programmatic and practice outcomes necessary for practice improvement. The tables provided allow PCPs to examine next steps in integration and therefore a pathway to improve the wellbeing of the communities they serve.

Table 4 : Levels of Integration and Programmatic Outcomes

Coordinated Care Key Element: Communication	LEVEL 1	• Assess what you know about how evaluate outcomes and manage patient data • What resources available in clinic? • What free technology is available?
	LEVEL 2	• Begin to track your referral data • How many referrals to BHCs are being made? • Which BHCs are being utilized the most?
Co-Located Care Key Element: Proximity	LEVEL 3	• How many patients are following up with the referral to clinician in the system? • Move beyond tracking usage and consider asking quality and satisfaction questions • Do your patients report satisfaction in working with this clinician?
	LEVEL 4	• Begin to work patient behavioral health goals into interactions with BHCs • What behavioral health goals have been set for your patients? • Is your utilization data positively correlated with better patient outcomes?
Integrated Care Key Element: Practice Change	LEVEL 5	• Develop a plan to review your IPP practices • Does the data reflect that warm hand offs are increasing utilization? • Are patients reporting that all team members have knowledge of their behavioral health goals?
	LEVEL 6	• Goals for patients (utilization, access, health outcomes) are set in a team meeting and tracked over time • Quality metrics for patient satisfaction are developed and analyzed along with patient outcomes • Team member satisfaction (burn out, perceptions, etc.) are also assessed and used to inform practice policy and procedure

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MM

The Crisis of Clinical Education for Physicians in Training

by W. Joshua Cox, DO & Gautam J. Desai, DO

A systematic approach to addressing the competitive challenges of clinical education training site distribution can create opportunities for national and international interprofessional collaborative clinical education.





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A significant challenge for medical schools in the United States is the clinical education of medical students after the largely didactic, and typically two years of pre-clinical education occur. Current trends in healthcare and educational processes have had a direct impact on medical education including 3rd year clerkship training. The number of allopathic medical students enrolled in the first year class has increased by 29% since the year 2002-2003, with over half of the growth occurring due to increases in class size of existing schools. This produces a cohort of over 21,000 allopathic medical students who require clinical education yearly. In 2016 over half of the MD schools surveyed mentioned the clinical training of students from other health care professional schools as a source of decreased availability of clerkship training spots for medical students, as compared to approximately 25% of schools reporting this in 2009.[1] In 2002-2003, there were 3,079 first-year osteopathic medical students. This number has increased in 2017-2018, in which 8,088 first-year students were enrolled.[2] Osteopathic growth is due to increases in class size as well as new school development. Combined osteopathic and allopathic first-year medical student enrollment has increased by 50% since 2002-2003, with almost 28,000 students per year entering medical school.

Although the number of osteopathic and allopathic medical students requiring clerkship spots has increased, there has not been a commensurate increase in the number of clerkship spots nor has there been an increase in clinical preceptors. There are several additional factors which compound this challenge. Many community-based hospitals have closed, or been acquired by larger organizations, decreasing the available hospital based rotations for students. Preceptors who have historically provided clinical education are retiring, and many preceptors are joining practices that limit medical students, or don't permit students at all.

Another source of additional competition for clerkship spots not included above is offshore medical schools with for-profit models. They often purchase large blocks of clinical clerkship spots in U.S. hospital systems.[3] When these partnerships are established with hospitals or health systems, there may be an ensuing shift of remaining clerkship availability toward outpatient sites. These typically require more sites in order to accomplish training. This has the resultant consequence of causing some medical schools to pursue new clinical or clerkship core sites, often extending outside of the desired geographic home region of the medical school.

Additionally, widespread occurrences of hospital and health system mergers have had a negative impact on current and potential clinical sites often due to a lack of experience with clinical education on

the part of the parent acquiring body. There has also been a notable shift to increase ambulatory health care. This shift includes outpatient surgeries as well as pre- and post-operative care, and overall shorter hospital stays. This shift directly impacts educational opportunities and preceptor capacity.[3, 4]

The transition of the physician workforce away from private or physician-owned practice settings to a hospital or health system employed scenario further contributes to preceptor shortages. The complexities of opening and maintaining a medical practice has been a driving force of this transition. There has also been a shift away from the concept or mentality of teaching the next generation as being a duty and privilege.[3] With large system and industry driven concerns, the focus often becomes a concern that teaching students in clinical education results in a loss of productivity. This is frequently combined with an expectation of monetary reimbursement (or increased incentives where payment is already taking place) on the part of the hospital, health system, and even individual preceptors, clearly impacting retention and recruitment.

In addition to the roughly 28,000 medical students mentioned above in need of clinical training, other allied health professionals such as Physician Assistant students and Advanced Practice Nurse students, often compete for the same clinical experience in the same training spots.[3] Some potential preceptors hesitate to participate due to concern for their ability to contribute to education while maintaining operational efficiency and high quality of care. One factor which makes precepting of students more challenging is the existence of so many different, non-communicating electronic health record systems. This is especially true during the first few months of clinical education, when the learner's exposure to electronic medical records may be nil to minimal. Preceptors and health systems have to decide between taking the time to train a new learner on their EMR system, taking the time to review, edit and augment the students' notes, or just not let the students document in the system. Even after training on one system, another office/hospital may have different systems with different complexities.

While these challenges did not develop overnight, and a simple, quick, fix-all solution has not yet been identified, there are some learning opportunities that may lessen the burden of the clinical education crisis. Although the use of simulation and virtual reality has been present for some time in medical education, their use has yet to be fully optimized. Simulation based education has in some models demonstrated advantages over the more traditional, but less available approach to clinical education. As it relates to certain skill sets such as advanced cardiac life support, laparoscopic surgery, cardiac auscultation, hemodialysis and central venous catheter insertions, and thoracentesis, simulation offers significant opportunity to create proficiency and improve safety when performing these procedures.[5] In general, a preceptor is more likely to take learners in their clinic if the learner has already practiced or even demonstrated competency with basic procedures in a virtual setting or on a human patient simulator.

One suggested solution to address offshore schools purchasing and using needed clinical sites includes restricting approval for federal loan programs to medical schools who have met COCA or LCME accreditation standards. There is also support for adding the expectation or requirement that these institutions have accountability to graduate medical education (GME) reporting and contribution to development.[3] One less exclusionary approach to the issue of competition for clinical education slots could be considering global educational exchange opportunities,[4] and taking advantage of existing interprofessional education (IPE) opportunities rather than directly competing with other healthcare learners for training and preceptors.

The implementation of standardized preceptor development measures may help address concerns related to efficiency, productivity, and quality of care. While many teaching models exist in the clinical setting, the One Minute Preceptor (OMP) is a clinical teaching strategy that has shown measurable improvement in medical student skills, abilities, and knowledge base as well as teaching performance from the preceptors.[6] Robust and consistent curriculum development by medical schools, creating preceptor manuals, consistent use of online modules for students, and self-directed learning strategies may prove useful as the preceptor's energy can be focused on clinical training and facilitating the student's learning. Improved preceptor recognition efforts, library access and support, and additional CME offerings can be helpful measures as well. Transitioning medical students to clerkship with consistent clinical readiness and recognized professionalism standards would lessen the burden on the preceptors.

While beyond the scope of this article, the topic of Graduate Medical Education must be addressed as it is

an equally challenging issue influencing the future of the medical profession. Although not always the case, the transition of medical students from clinical education into residency would be a seamless continuum. With the implementation of a single GME accreditation system, an increasing number of medical students will be in direct competition for the available residency training spots. With the given transitions and changes surrounding the health care system, challenges facing GME parallel many of those in clinical education. In fact, major restructuring of the GME system may be in order to better coexist with healthcare transformation.[7] The anticipated shortage of primary care physicians is another topic directly related to clinical education. The growth in non-primary care GME positions is much greater than primary care growth, and steps such as redirecting funding towards development of primary care positions have been mentioned as potential corrective measures.[7] As nurse practitioners and physician assistants increasingly provide the health care once delivered solely by primary care physicians, then the primary care GME needs become less critical.[8] A trend that concerns many medical students regarding post-residency opportunities and may ultimately influence the path they take during their clinical education experiences.[9] This poses a challenge given the extent of the projected primary care physician shortage. Perhaps a focus during both clinical education and residency on primary care physicians serving as supervisors of interprofessional teams, and expert clinical educators could lessen the burden since these roles will always exist for primary care physicians.[9] Using evidence of best practices and needs-analyses, models can be created to influence resident distribution in the US, creating allocation proposals of GME position growth and distribution. This can serve as an initial point of focus for decision makers when deliberating about post-graduate training of phsyicians.[8]

There is no easy solution for the many challenges facing clinical education for physicians in training, and what may work for one medical school may not work for another, depending on factors such as geographical region, class size, and the established preceptor network. Some of the burden may be lessened by requiring all medical schools to allocate part of their resources to preceptor development as well as planning for increased capacity. This is especially critical if the medical school is requesting an increase in class size from their accreditation bodies. Although this is done to some extent, heightening scrutiny on this process, as well as mandating evidence of clerkship capacity increases, can help medical schools thoughtfully increase their class size. A reduction in the number of U.S. based clinical training spots used for offshore schools may help some medical schools place students in clinical training environments especially if these institutions cannot compete with private, for profit entities who can afford to "purchase" clinical rotation spots. Giving preceptors well trained students who will enhance clinical services for patients, both in the office and hospital can also be addressed through additional and improved pre-clinical coursework focused on systems-based practice and patient-centered care. Additionally, a systematic approach to addressing the competitive challenges of clinical education training site distribution can create opportunities for national and international interprofessional collaborative clinical education. It is clear, that a multifaceted approach is needed to address the crisis of clinical education of our future physicians.

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Is Pre-Doctoral Medical Education Preparing Physicians for the Modern Workforce?

by Loren Meyer, MD, Laura Rosch, DO & Darrin D'Agostino, DO

Although generally (and historically) averse to change, physicians hold the key to health care reform given their intimate understanding of the needs of the end consumer of care.



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Today, the emphasis on physicians as team members supporting the care of populations is a different model of health care than that which supported autonomous physicians who use clinical evidence and experience to benefit each individual patient.

Taking care of patients is an awesome task and is often spoken about by patients – and worse, other health care providers, in mildly sarcastic and generalized terms focusing on inefficiencies, excessive cost and poor outcomes. Many physicians are saddened by this and often wonder if their career choice to serve the ailing patient was the right choice for them. What are the circumstances that lead to what some would consider the most critical time in the United States for health care reform? Are the challenges physicians, nurses, and other clinicians face changing the workforce of healers, or are the stagnant education models in the United States maintaining these challenges?

The physician of the future is a complex and alternate version of the physician of today. Critics of this statement rely on the belief that our past history of health care delivery is so engrained in the fabric of the United States that change is difficult at best and impossible at worst. The drivers for change are as complex as the system in which health care is delivered. Traditionally, medical education begins with pre-doctoral training in medical school. From here, successful graduates, now physicians, enter an apprenticeship which mandates training in a specific field of study which, upon graduation from this residency, gives validity and credibility to the health care this individual will provide in that specialty. This hyper-focus of training is a consequence of many factors that have developed over many decades in the United States and is now the foundation upon which all systems of practice and funding are created. Undergraduate Medical Education as we know it in the United States is based significantly on the Flexner report published in 1910. Standardization of the curriculum, licensing requirements, and Graduate Medical Education requirements have significantly influenced the evolution of the expectations for graduates from allopathic and osteopathic institutions.[1]

Although medical education delivery has not changed dramatically in the last 100 years, many institutions have attempted to improve the educational experience by altering the focus of the declarative knowledge, which is typically introduced in the first two years of medical school. Often unappreciated is the fact that since 1765 five major curricular models have been implemented and catalyzed significant changes in North American medical education: the apprenticeship model (1765-); the discipline-based model (1871-); the organ-system based model (1951-

); the problem-based learning model (1971-); and the clinical-presentation based model (1991-).[2]

According to a study from the Physicians Advocacy Institute and Avalere, reported in March 2018, hospitals employed 42% of physicians as of July 2016, up from 25% in July 2012 and 29% of practices were hospital-owned.[3] An American Medical Association study released in May 2017 noted that less than half of physicians had ownership stakes in a medical practice in 2016.[4] As early as 2014 a report from recruiting firm Merritt Hawkins noted that over 90% of the 3158 searches they tracked were for employed settings vs independent practice settings such as partnerships, concierge, or solo practices.[5]

Population based clinical (e.g. vaccination rates, chronic disease control) and utilization (e.g. Hospital admissions, Emergency room utilization, cost per episode of care) metrics, important to government and non-government payers, require a different mindset than physicians traditionally utilized, or were taught in their medical school or residency. While still accountable to the individual patient and their family, physicians are increasingly accountable to the payers and employers with whom they work with in managing populations of patients.

As we think about the future of health care in the United States, it is important to understand that not only has medical education evolved over the years, but practice models and location of the health care workforce has evolved as well.

An Effort to Merge Goals

The AAMC and AACOM have endorsed the philosophy of competencies (outcomes oriented approaches to instruction and assessment) in pre-doctoral medical training by recommending the adoption of Entrustable Professional Activities (EPAs).[6,7] One of the drivers behind the EPA initiative is the belief that their attainment by students prior to graduation from medical school would enable residency training programs to more efficiently and effectively develop specialty competencies that include domain specific milestones before their graduates enter clinical practice. In regards to the six broadly defined competence domains, undergraduate medical training programs appear to have initially focused their efforts upon the first four domains (i.e.- Patient Care, Biomedical Knowledge, Communications, Professionalism) as it has been difficult to more concretely define, train to, and assess Practice and Systems based competencies in the undergraduate arena.[8]

"Best Practices" (BP) is a term which is all too often used interchangeably with "Evidence-based practice" (EBP). However, the critical distinctions between these two terms are not always fully appreciated by practicing clinicians and medical educators. EBP describes clinical activities that produce an optimal outcome in a specific area of patient care and, provide evidence of the replicability of the specific outcome. Examples of EBP can include a particular medication, regimen or surgical intervention, which has been objectively documented to decrease the frequency, and severity of chest pain due to cardiovascular etiologies and/or the morbidity and mortality associated with coronary vascular disease. Cost based EBP's could include a particular regimen used to treat cardiovascular disease, which is equivalent to other regimens in terms of morbidity and mortality while significantly reducing the cost of care. BP are often clinical activities representing medications, regimens, techniques, methods or processes which become generally accepted, based upon observations, experiences and habits of a group of like-minded individuals who believe in the value of the practice at hand, but nonetheless lack the validation of a formalized, data-based evaluation process.[9]

It is clear that the need for undergraduate medical training programs to: 1) integrate instruction and assessment in service to Practice and Systems-based competencies within the curriculum, and 2) create a clinical learning environment in which faculty might role model Practice and Systems based competencies for students is essential. If graduates are to lead in the implementation of 21st century models of health care, health care education and systems-based practice need to communicate better and integrate seamlessly.

Health Care Systems

It is fair to postulate that many suboptimal health care outcomes have as a root cause: suboptimal approaches to instruction and assessment in both undergraduate and graduate training programs. Such concerns were core drivers in the formulation of the ACGME's, AOA's and NBOME's respective Competence initiatives with these organizations agreeing upon a core set of competencies (Patient Care, Biomedical Knowledge, Communications, Professionalism, Practice

and Systems) as separate yet interrelated 'domains' to be mastered by medical students and residents prior to graduation.[10, 11, 12] Subsequently, medical specialty colleges and residency programs developed specialty-specific outcomes or 'milestones' within each of these six broadly defined competence domains.[13] These more narrowly defined, highly granular outcome markers define the specific knowledge, skills and attitudes of greatest relevance and interest to each specialty college and their respective residency training programs.

Patient Care

Clinical Medicine is in the early stages of articulating how outcomes oriented initiatives can be used to concretely and reliably improve the health of individuals, communities and populations. For example, it was not until 2000 that the Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences) launched its Quality Chasm Series. This initiative continually identifies the 'gaps between what is known to be good health care versus current practice norms' so that today's providers can improve upon areas of suboptimal health care outcomes.[14, 15] In its twelfth report (2015), entitled Improving Diagnosis in Health Care, the IOM made clear that the frequency and severity of diagnostic errors represents an urgent health care system concern.

In a search for root causes of diagnostic errors, the IOM report stated that medical training programs and licensing boards are "not adequately preparing individuals to become skilled diagnosticians."[16] Subsequently, they recommended that diagnostic instruction and assessment at all levels of medical training (undergraduate, residency and continuing medical education) "employ approaches that are aligned with evidence from the learning sciences."[17]

Over the last decade, health care systems have been approaching the physician workforce and training issues in numerous ways. Research suggests that the ability to train physicians to provide high value care while keeping costs reasonable requires a number of events to occur during the learning cycle of physician training. Physician education is typically described as Pre-doctoral (medical school), graduate (residency training) and Continuing medical education. Three elements are important to ensure learning has occurred and will be practiced by the physician: knowledge transfer, reflective practice and a supportive environment.[18]

Increasing knowledge about high value, cost conscious care was previously thought to be knowledge that was obtained as a practicing physician. In recent years, the competency, Practice Based Learning has influenced the early acquisition of this information. Although there is no consistency in the transfer of this knowledge to medical students or residents, three specific cost focused topics are critical to influence cost effective care: price of service/general health economics, scientific evidence, and patient preferences.[19]

Critical reflection is a commonly used tool in the learning sciences since 1933 from the works of John Dewey who defined it as "active, persistent and careful consideration of a belief or supposed form of knowledge in the light of the grounds that support it and the further conclusion to which it tends."[20] It is not enough to rely on experience alone to learn a task, which is often the place that reflection is used as an anchor of knowledge, but rather a conscious realization must occur for the experience to become linked to acquired knowledge for the reflection to be a true source of learning. Reflection is a powerful learning tool and is intimately influenced by a learner's awareness of their actual understanding of a subject: metacognition. Metacognition is a person's awareness of his or her own level of knowledge and thought processes. Weaker students typically have poor metacognition; they can become overconfident in their level of understanding of subject matter.[21] In health care, this shallow, fragmented understanding of knowledge leads to errors and harm.

In a systematic review of the literature (2650 articles), 79 articles evaluating cost-effective, value-driven care were identified (for this review value = services or outcomes ÷ cost). A supportive environment for learning was cited in almost 35% of these articles as a critical necessity to understand value-based care. A supportive environment is one that integrates at multiple levels, value-based care. Macro-level support includes high level organization elements such as a supportive and transparent payment system, management policies that are accessible and easily understood and fair reimbursement systems for clinicians (including, but not limited to, risk-sharing and shared savings models). Additionally, the presence of clinical role models, educators and a values based culture within the organization help drive value-based care.[22] Clinical role models of cost conscious and value driven care is critical for a learner as well. Much of the health care learning

environment is predicated on modeling and learning from mentors. Consistency in modeling is challenging at the medical school level given the significant challenges with clinical rotations (clerkships) around the country. Unfortunately, inconsistency is the norm in clinical education and this mandates medical educators develop innovative learning experiences for health care professionals to improve this challenge.

In August 2011, the American College of Osteopathic Medicine (ACOI) prepared a white paper statement, The Phoenix Physician, that considered the rapid changes in health care delivery and how at milestones of innovation such as the discovery of penicillin or the invention of the computer, physicians at first resist adoption, and then adapted to change.[23] The following list of points made in this document almost nine years go highlighted the concerns healthcare professionals had for the future of health care in the United States. Although these concepts are packaged differently in various references, they persist as targets for reformation and improvement of the US health care system.

- Open Access to health care by using teams
- Understanding the strengths of allied health care professionals
- Better understanding and the use of population health tools and approaches to care delivery
- Education targeting the development of data-bases and the use of information in decision making
- Better training in disease management and a focus on disease prevention
- Development of physician leadership and communication skills

As stakeholders in the health care professions, physicians have a critical role in defining the future physician. Although generally (and historically) averse to change, physicians hold the key to health care reform given their intimate understanding of the needs of the end consumer of care. Although not typically thought of as a disruptive innovator, physicians have an opportunity to partner with health care systems and guide the integration of medical education with systems and practice based learning in order to create value in patient care, protect patients from mistakes and provide care to those most in need. The future physician is needed now.

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Disclosure

None reported.

MM

Rapidly Developing Large Bilateral Cataracts in a 58-Year-Old Woman After Only 46 Hyperbaric Oxygen Treatments

by John C. Hagan III, MD, James V. Maturo, MD & John P. Kirby, MD

As HBO_2 continues to grow as an important therapy option, updating the incidence, prevalence and severity of developing problems like cataracts incident to HBO_2 underscores the need for better data registries.





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Abstract

We are reporting a 52-year-old female that developed documented vision impairing, large, bilateral nuclear and cortical cataracts during therapy after 46 treatments of a planned 60 treatment course of HBO_2 for a non-healing post-radiation leg wound. A review of the available literature makes this one of the earliest cases of cataract formation.

Introduction

Hyperbaric oxygen therapy (HBO_2) was reviewed comprehensively in the May/June 2019 issue of *Missouri Medicine: The Journal of the Missouri State Medical Association*.[1,2,3,4,5,6,7] Cataract formation and induced myopia following longer term HBO_2 treatments have been a recognized risk of that therapy since at least 1977.[8] Although transient myopia after HBO_2 may be commonplace and short term as described by Lyne[9] and Anderson and Farmer[10], most cataracts develop after much longer treatment sequences often over a 100 or more. To date, the soonest that *de novo* cataract development attributable to HBO_2 therapy has been reported in the literature is eight weeks after completion of therapy. Those cataracts followed 48 treatments at 2.5 ATA (atmospheres absolute) for 90 minutes in a 49-year-old female. They were described as nuclear cataracts.[11]

We are reporting a 52-year-old female that developed documented vision impairing, large, bilateral nuclear and cortical cataracts during therapy after 46 treatments of a planned 60-treatment course of HBO_2 for a non-healing post-radiation leg wound. A review of the available literature makes this one of the earliest cases of cataract formation and underscores the need for better comprehensive data registries for wounds and HBO_2.

Case History

A 58-year-old, white female consulted one of the authors (JCH) for a routine eye examination on April 17, 2019. Her last eye exam was by a commercial optometrist several years prior and was normal. She had never had an abnormal eye exam. For physiologic presbyopia, she was using over the counter reading glasses of plus 2 diopter strength. She had a complex medical history: thymic carcinoma, sarcoma of left leg, radiation treatment to that leg sarcoma (59.4 Gy in 1981), post-radiation leg lymphedema and recurrent chronic leg ulcers, elevated

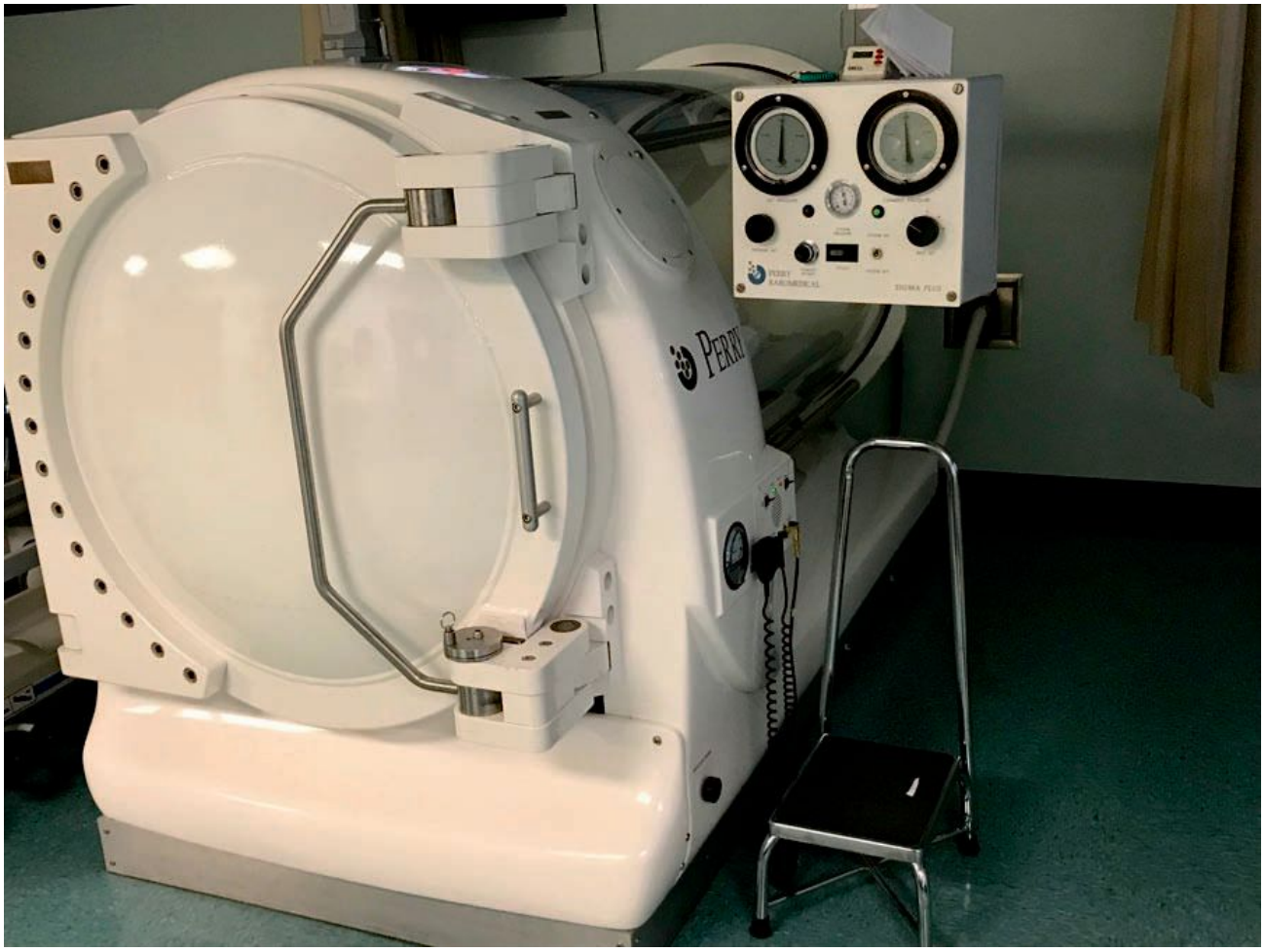


Figure 1
The instrument used for HBO_2 treatment in this case was a Sigma Plus manufactured by Perry Baromedical Corporation in 1999.
(Photo credit: James Maturo, MD)

cholesterol satisfactorily treated with statins, dilated cardiomyopathy, and controlled hypertension. She had no factors associated with early cataract formation: no heavy sun exposure, never on oral steroids, non-smoker, not a heavy alcohol drinker, not obese, good diet, not diabetic, not premature birth, no history of eye trauma. Her deceased mother had cataract surgery in her 80s and her father has cataracts but no surgery in his 80s; two brothers do not have cataracts.

Her uncorrected distance vision was: RE (right eye) 20/20 and LE (left eye) 20/25. Her refraction was; RE -0.75 + 0.75 axis 90 visual acuity 20/20, LE -1.25 +1.50 axis 90 visual acuity 20/20. With a +2.00 diopter reading add she was 20/20 OU (both eyes) at near. Abnormal findings in the dilated eye exam were limited to the LE lens. It had tiny amount of nuclear sclerosis and a small cortical lens cleft in the far periphery. The right lens had clear nucleus and cortex. A diagnosis of visually insignificant incipient cataract LE was made, multifocal glasses recommended and follow up yearly.

The patient returned to JCH 13 weeks later on July 31, 2019 complaining of severe blurring of vision in both eyes. She had consulted author JVM for non-healing post-radiation wound on her left leg on February 27, 2019. The wound measured 4 cm X 2.5 cm X 0.2 cm. For the non-healing wound, she was to receive 60 HBO_2 treatments of 90 minutes at 2 ATA, 100% oxygen with no air breaks. The HBO_2 unit was a Sigma Plus manufactured by Perry Baromedical in 1999 (Figure 1). Treatments were weekly, Monday through Friday. Her first treatment was April 22, 2019 but was quickly aborted due to pain from not being able to clear her ears. Her first complete 90-minute treatment was May 1, 2019. She noted some mild blurring of vision in

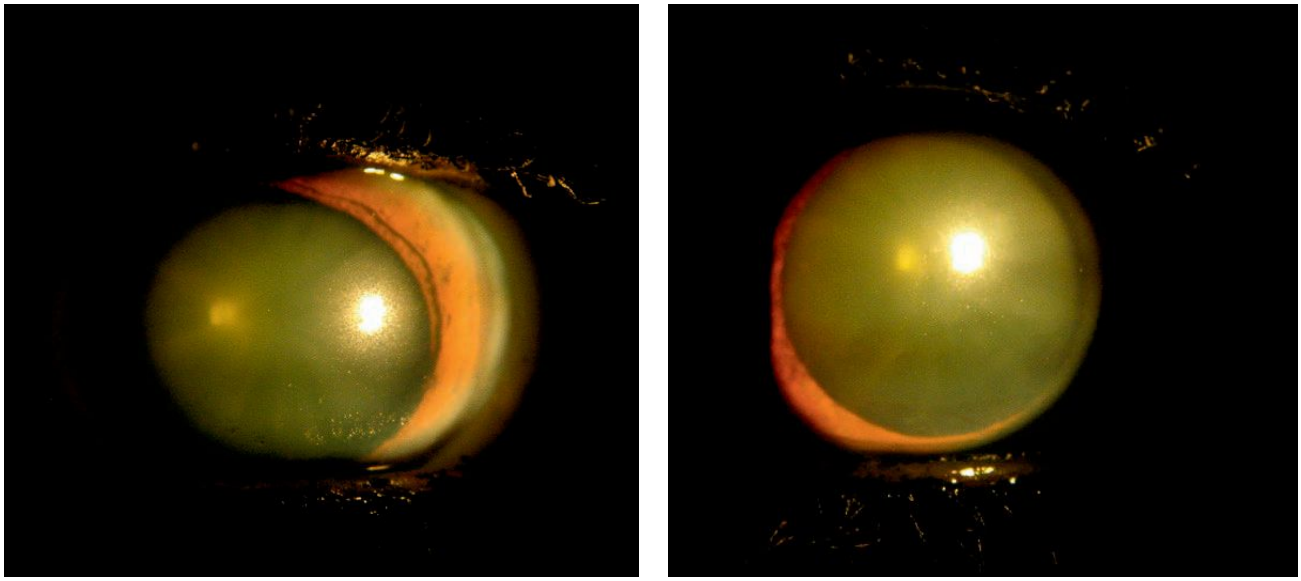


Figure 2. Left Eye, Right Eye. This 58-year-old female developed large, surgery requiring cataracts over a 13 week period while receiving 46 of a planned 60 treatment course of hyperbaric oxygen therapy for non-healing, post-radiation ulcer of the left leg. (photos Randy Jackson, MD)

both eyes after her initial treatments. She had been told prior to treatment that this was common and usually reverted to normal post therapy. HBO_2 treatments were continued. Towards the last of July 2019, she noted dramatic worsening of vision in both eyes. Treatments were stopped July 30, 2019 until she was seen by an ophthalmologist. She had received 46 of the planned 60 treatments.

She had not purchased multifocal glasses after her first examination because she was getting by with reading glasses and "didn't want to wear glasses all the time." Her RE uncorrected distance vision was now 20/80 and her LE 20/100. Her RE refraction was -2.00 + 0.75 axis 80 visual acuity $20/20^{-1}$. Her LE refraction was -2.50 + 1.50 axis 90 blurred 20/25. A complete dilated medical eye exam was repeated. Abnormal findings were limited to the lens of both eyes. Each lens (Figure 2) had extremely large, four quadrant nuclear and cortical cataracts. Additional testing included macular and nerve fiber layer optical coherent tomography (OCT) which were normal in both eyes. A diagnosis of HBO_2 accelerated advanced cataracts OU was made. It was advised the patient buy multifocal glasses for full time wear. Subsequently she reported unsatisfactory vision even with glasses. At the time this paper is published (September/October 2019) she has had phacoemulsification cataract removal and intraocular lens insertion on one eye with the second eye scheduled later. The leg ulcer was noted to be completely healed by JVM on July 31, 2019.

Discussion:
Oxygen and Ocular Physiology and Pathology

The toxic effects of oxygen on the eye were most importantly first noted in studies on the cause of retrolental fibroplasia (RLF), now called retinopathy of prematurity or ROP. RLF/FOP occurred occasionally in premature and low-birth weight infants in the 1940s and in epidemic numbers in the early 1950s. Terry, in 1942, first used the name retrolental fibroplasia to describe a blinding disease of premature infants in which large amounts of fibrovascular tissue developed from the peripheral retina that eventually blinded the child.[12] In 1951, brilliant research done in Australia by Campbell identified the role of oxygen exposure and subsequent development of RLF/ROP.[13] Subsequently oxygen exposure to the premature and low-birth weight infants immature retina has been shown to cause primary vasoconstriction due to hyperoxygenation and suppression of normal vascular development. This is associated with suppression of vascular endothelial growth factor (VEGF) and a secondary vaso-proliferative phase. This occurs when normal oxygen levels are present from non-oxygen enriched, room air inhalation. Mechanisms include vasodilation, and massive proliferation of neo-vascular, fibrous material into the eye's vitreous cavity as a result of high levels of VEGF.[14]

The myopia and blurred vision associated with HBO_2 therapy have a different etiology than refractive myopia which is due to longer than normal axial length of the eyeball or excessive curvature of the cornea or less commonly the lens. True refractive myopia is generally only permanently reversible with surgery to the cornea or human lens. The cornea may respond with usually temporary, but occasionally permanent, steepening (more myopic-less hyperopic) or flattening (more hyperopic-less myopic) to a variety of conditions such as contact lens fitting problems, medications, elevated blood sugar or hormonal changes. HBO_2 treatment sequences, most often more prolonged or deep ones, can commonly, but variably, aversely change visual acuity. These are most often temporary and self correct after the treatment sequence is completed.[15] It is hypothesized that for cataract formation, HBO_2 therapy produces oxygen free radicals which can damage many body tissues especially the delicate clarity of the human lens.[10,11] Cataract formation or acceleration can occur during HBO_2 therapy; although more commonly after prolonged treatments. Palmquist et al. reported in 15 patients given ophthalmological examinations prior to therapy and found to have no cataract formation that after 150 treatments, seven developed non-fully reversible cataracts (46.6%).[16] The subject of hyperbaric-related myopia and cataract formation has been recently and extensively reviewed by Gengel and Cooper, and will not be repeated here.[17]

Our patient is unique as she has no personal risk factors for the development of premature cataracts and had a relatively short course of HBO_2. She had a complete ophthalmological examination prior to HBO_2 therapy and had a normal RE and insignificant pre-cataractous changes in the LE. After only 46 HBO_2 treatments and 13 weeks, she developed extremely large nuclear and cortical cataracts in both eyes. This is the most rapid and largest HBO_2 caused bilateral cataract development in the literature that we have been able to identify. We submit this case report to confirm the seemingly idiosyncratic nature of this risk on behalf of patients and clinicians considering HBO_2 therapies as well as to invite clinicians to contribute any earlier documented cases of cataract formation.

Conclusion

The frequency of cataract formation during and after hyperbaric oxygen therapy is not known with certainty but can be permanent and progressive. Informed consent should include a discussion of highly variable cataract formation and consideration given to complete, dilated ophthalmological examination prior to HBO_2 therapy based upon applicability with the patient's presentation, history, and discussions prior to therapy. As HBO_2 continues to grow as an important therapy option, updating the incidence, prevalence and severity of developing problems like cataracts incident to HBO_2 underscores the need for better data registries. These would not only improve comparative effectiveness evidence, but also accumulate clinical experiences with the risks involved. Although it is assumed that corrective cataract surgery almost always solves these occurrences, better tracking of patients will be needed to delineate this.

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Disclosure

None reported.

MM

A Case of Recurrent Lobar Intracerebral Hemorrhage in the Setting of Phosphodiesterase-5 Inhibitor Use

by Scott A. Lucchese, MD, Arshdeep S. Dhaliwal, MD, Arpanjeet Kaur, MD & Laura Qi, MD

This case bolsters existing evidence that phosphodiesterase-5 inhibitors as a class should be viewed with caution. As of publication, FDA warns against possible cardiovascular adverse reactions, hearing loss, hypotension, and priapism, however does not warn that Intracerebral hemorrhage may be possible side effect.



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Astract

Intracerebral hemorrhage occurs when a diseased blood vessel within the brain bursts. We present a case of 69-year-old patient with two sequential episodes of lobar intracerebral hemorrhage occurring during sexual intercourse. Both episodes were associated with the use of phosphodiesterase-5 inhibitors. This is the first case reported which is temporally associated with isolated bilateral lobar bleeds with appropriate use of phosphodiesterase-5 inhibitor on two different occasions associated with sexual intercourse.

Introduction

Intracerebral hemorrhage (ICH) (code 431, International Classification of Diseases, 9th Revision) is a neurological deficit documented by brain CT or MRI showing the presence of an intracranial bleed in the parenchyma of the brain.[1] ICH is a serious cerebrovascular condition associated with high mortality and morbidity in adults. Etiological factors for spontaneous ICH include vasculopathies, such as, cerebral amyloid angiopathy, hypertension, aneurysms, vascular malformations; alcohol ingestion; coagulopathies; drugs; tumors; and genetics.[2-4] The risk of lobar ICH significantly increases with age, as well[5].

Oral phosphodiesterase-5 inhibitors are commonly used for the treatment of erectile dysfunction (ED). These medications are also thought to be possibly beneficial for treatment of cerebrovascular and pulmonary diseases. Sildenafil, a phosphodiesterase-5 inhibitor, has an expanding role in the treatment of pulmonary hypertension.[6] Common side effects include flushing, headache, nasal congestion, changes in pulmonary blood flow and ischemic manifestations, such as transient ischemic attack, ischemic stroke, cerebral infarction, or ischemic optic neuropathy. Since the approval of these medications in 1998, multiple reports have tied their use, both appropriate and inappropriate, to ICH and retinal hemorrhages.[2,7-20]

We present a 69-year-old male with clinical and radiological evidence of two (right and left frontal) incidences of lobar ICH occurring on two separate occasions during sexual intercourse, both associated with appropriate use of phosphodiesterase-5 (PDE-5) inhibitor for erectile dysfunction.

Case Report: History and Clinical Findings

The patient was a 69-year-old white male who experienced two episodes of intracranial lobar hemorrhage temporally associated with PDE-5 use. He had previous history of intracerebral hemorrhage nine months prior to presentation, coronary artery disease, colon cancer status post two resections, and subsequent chemo and radiation therapy, erectile dysfunction and hyperlipidemia. He presented to the emergency department with complaints of one-day history of headache, confusion, and inability to concentrate. The headache was bifrontal in location without radiation, 5/10 in intensity and squeezing in character. There was no associated photophobia, phonophobia, nausea, congestion or lacrimation. There was no slurring of speech, hearing loss, neck stiffness or significant weakness. The patient has been normotensive and non-diabetic throughout his life. He was on multi-vitamin, 81 mg aspirin, sildenafil (25mg) for his erectile dysfunction, and tamsulosin for benign prostatic hyperplasia.

He had strong family history of coronary artery disease and myocardial infarction. He had a daughter with brain aneurysm which was treated surgically. He did not smoke, drink, or use illicit drugs. His labs were within normal range without abnormal platelet count or INR.

On examination, he was well nourished and in no acute distress. The remainder of the general examination was unremarkable. On mental status exam he scored 12/30 on MMSE with deficits in all spheres except repetition and orientation to place. His executive functions were compromised with difficulty calculating and was also not able to follow three step commands. He was not able to repeat three objects consecutively and follow written commands. In addition, he had verbal and action perseveration. The remainder of the cranial nerve exam was unremarkable.

Motor exam was unremarkable. Deep tendon reflexes were symmetric. Sensation to all modalities was intact. He had no ataxia. Cortical sensations including graphesthesia and stereognosis were normal.

On fundoscopic exam, the patient had bilateral papilledema. The patient was hypertensive (160/90mmHg) and required intravenous (IV) hydralazine for control of blood pressure. While in the emergency department his headache resolved a few hours after presentation. He was started in emergency department on phenytoin for seizure prophylaxis after ICH.

Non-contrast computed tomography (CT) of brain showed acute left frontal lobe bleed and chronic right frontal encephalomalacia from prior ICH (Figure 1). About nine months prior to current presentation, he had presented with a similar syndrome and brain CT at that time showed large right frontal bleed (Figure 2—the remnant of this bleed is the source of chronic changes in Figure 1). Head Magnetic Resonance Imaging (MRI) exam showed a left frontal intracerebral hemorrhage with both a subacute and acute component with minimal mass effect on left lateral ventricle and no midline shift. The MRI was also notable for evidence of previous right frontal hemorrhage, mostly resolved, with resultant encephalomalacia. Periventricular T2 hyperintense signals were present in the frontal areas suggesting chronic small vessel disease (SVD) (see Figure 3 current bleed, Figure 4 for prior right bleed). Carotid duplex ultrasound demonstrated mild carotid plaques bilaterally without any significant stenosis. MRA angiogram of head and neck were negative for any aneurysm, arteriovenous malformations or other vascular anomalies.

On further discussion with the patient's wife on the second day of the admission, she noted that the patient's headache began while they were in engaged in sexual intercourse. She also noted they had been engaged in intercourse leading up to the previous episode of ICH approximately nine months prior when the patient had the initial right sided frontal intralobar hemorrhage (Figure 4). She noted the prior headache occurred during intercourse while using tadalafil for erectile dysfunction. She also noted he had taken sildenafil (25mg) and was engaged in intercourse just prior to development of the headache which led to the current presentation, and discovery of the new left intralobar frontal hemorrhage (Figure 3).

The temporal relationship of the two occurrences of ICH on two different occasions with the use of the PDE-5 inhibitors was concerning for possible causality. It seems likely that type PDE-5 inhibitor use and sexual activity in the setting of underlying vascular pathology, possibly amyloid angiopathy, contributed to the bleeds. He had used PDE-5 inhibitors several other times in the past, but not with a great deal of frequency. The wife could not give a detailed history of this and the patient wasn't aware at that point and time how often he had used them. He never reported a sexual headache prior to his first presentation of ICH. He was counseled to stop taking any

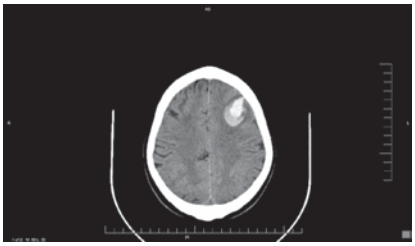


Figure 1. Computed tomography of brain showing second episode of left frontal bleed and right frontal encephalomalacia from the first episode.

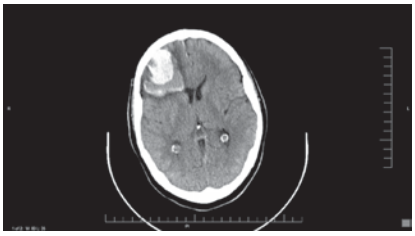


Figure 2. Computed tomography of brain showing first episode of large right frontal bleed.

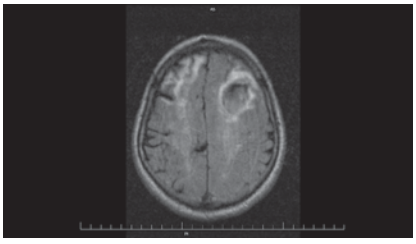


Figure 3. FLAIR image with second episode of acute bleed in left frontal lobe and sequela of prior bleed with gliosis in right frontal region.

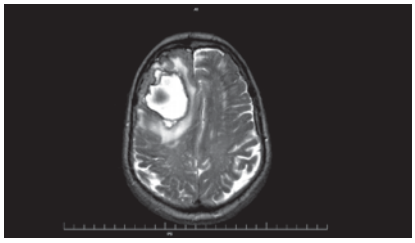


Figure 4. First episode of right acute frontal bleed with edema and mild midline shift; diffuse T2 signal hyper-intensity in the periventricular region consistent with small vessel disease.

PDE-5 inhibitors after his second episode. Unfortunately, he was not advised to discontinue use of PDE-5 inhibitors after his first episode of intracerebral hemorrhage.

The patient did well initially with conservative management after both bleeds. His phenytoin was discontinued at discharge. Approximately eighteen months after the second bleed, he developed partial complex epilepsy and was treated with levetiracetam which he tolerated very well. He had to give up his real estate business due to his executive dysfunction resulting from the bilateral bleeds.

Discussion

The overall incidence of intracerebral hemorrhage (ICH) is 12 to 15 cases per 100,000 individuals or about 40,000 cases per year in the United States. Spontaneous (atraumatic) primary ICH is a catastrophic form of stroke associated with high morbidity and mortality and a substantial recurrence risk. Lobar ICH location is associated with the risk of subsequent ICH recurrence, likely because of the type and severity of the underlying small vessel diseases (microangiopathies), which include arteriolosclerosis, lipohyalinosis, and cerebral amyloid angiopathy (CAA).[18]

Intracerebral hemorrhage mortality is about 40% at 30 days, similar to SAH in acute mortality.[3] The five-year mortality rate is over 50% (52% for males, 56% for females) in ICH patients older than 45 years, and the 10-year survival rate is 24.1%.[1,11] For those who survive a spontaneous ICH, the risk of recurrence is in the 2% range, annually.[1] Since our patient was normotensive and non-diabetic, it is highly suspicious that amyloid deposition might have played a significant role in altering the microstructure of the cerebral vessels.

Fourteen cases of adult intracranial hemorrhage associated with the use of PDE-5 were found on review of the English language literature. The case reports' subjects range from 33 years old to 70 years old. All developed cerebral hemorrhage symptoms (including headache, dizziness, blurry vision, decreased mentation, and nausea) 30 minutes to three hours after ingestion of PDE-5 inhibitor. None of these subjects had history of ICH. One report noted the patient described was found to have an arterial venous malformation, which was thought to be the causes of the hemorrhage[20]. None of the other cases reported known vascular malformations. Bleed location varied from cortical to subcortical without any appreciable correlation to age of subjects. Dosage varied from appropriate to excessive, but it remains unclear what the degree of dose related risk of ICH is associated with PDE-5 use.[2,7-10,12,13,15,17-19,21-24, 25]

The relationship between ICH and PDE-5 inhibitors is likely due to increased blood flow to the intracranial vessels during sexual intercourse which is further enhanced by concurrent use of these drugs. Sexual intercourse is known to produce a hyper dynamic circulatory state in both men and women, manifested by increased heart rate and blood pressure.[7,15] Following sexual stimulation, penile erection occurs through the release of nitric oxide (NO), which causes dilation of the blood vessels of the corpus cavernosum via an accumulation of cyclic guanosine monophosphate (cGMP). The PDE-5 inhibitors enhance this vasodilatory effect of NO-cGMP pathway by inhibiting PDE-5, the enzyme responsible for breakdown of cGMP. Studies have

also shown that sildenafil acts on phosphodiesterase-1, -2 and -5 receptors and leads to a secondary increase in intracerebral circulation and vasodilatory effects, leading to sympathetic over activity which increases the risk for intracranial bleeding.[25,26] Side effects of sildenafil, including flushing, headache, nasal congestion, and changes in pulmonary blood flow indicate the multisystem vasodilation caused by these drugs.[27,28]

Our case appears to be first one highlighting the temporal relationship between usage of two separate PDE-5 inhibitors and two separate episodes of ICH in different areas of the brain in one patient. This case bolsters existing evidence that PDE-5 inhibitors as a class should be viewed with caution. As of publication, FDA warns against possible cardiovascular adverse reactions, hearing loss, hypotension, and priapism, however does not warn that ICH may be possible side effect.

Conclusion

This case of recurrent lobar hemorrhages revolves around use of PDE-5 inhibitors and ICH likely associated with preexisting microvasculature pathology, precipitating ICH. It illustrates the risk of intracranial hemorrhage associated with the use of PDE-5 inhibitors during sexual intercourse. It would appear to be a particularly cautionary tale in the instance of prior intracranial bleed, or in the setting of known cerebrovascular disease. It is of utmost importance to discuss the risks and benefits before prescribing such medications to patients with possible underlying vasculopathies and/or prior bleed. If it is desirable to use these mediations, it is likely prudent to start at the lowest possible dose in these populations.

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Disclosure

None reported. **MM**

The Benefits of Marine Omega-3s for the Prevention and Treatment of Cardiovascular Disease

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

Studies providing approximately 1-2 grams of marine omega-3s in the secondary prevention setting have noted significant reductions in major coronary events and mortality. Additionally, providing 1-gram of marine omega-3s in those with chronic heart failure has been shown to significantly reduce mortality.





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Abstract

There has been a raging debate whether marine omega-3s are effective for the prevention of cardiovascular disease. Our review paper discusses the landmark clinical studies testing the benefits of marine omega-3s. Moreover, for the first time, the REDUCE-IT study tested a high dose of marine omega-3s (4 grams of icosapent ethyl per day) on top of statin therapy in patients with established cardiovascular disease or with diabetes and additional risk factors with concomitant high triglyceride levels and noted a highly significant 25% reduction in the primary endpoint. Thus, in patients who are not in the early post myocardial infarction setting, high dose marine omega-3s (4 grams per day) may be required to provide cardiovascular benefit when given on top of optimized medical therapy.

Introduction

Ever since the 1940s, marine omega-3s have been suggested to provide cardiovascular benefits. This idea began when Ehrstrom discovered that the Greenland Inuit had approximately one-third the atherosclerotic disease compared to the general population in Finland.[1] It was also documented in the 1970s that the Greenland Inuit had lower rates of myocardial infarction compared to Danish controls.[2] Considering that the Greenland Inuit's diet was rich in marine omega-3s (coming from whale and seal meat and blubber) it was only logical to assume that their diet may have something to do with their protection from heart disease. In 1978, Dyerberg et al. noted that Greenlanders had high blood levels of EPA and suggested that the high intake of marine omega-3s may protect them against thrombosis and atherosclerotic events.[2] Later on, several population studies also noted that those with higher intakes of marine omega-3s have a lower risk of cardiovascular disease. Our paper will review these population studies as well as clinical studies testing marine omega-3s for the prevention of cardiovascular disease.

Observational data

The Japanese have a long history of consuming a diet high in seafood. In fact, Japan is one of the highest consumers of fish and shellfish in the world,[3] with an omega-3 index

(eicosapentaenoic acid [EPA] + docosahexaenoic acid [DHA] in red blood cells) of around 10%.[4] Japan is also known for having a long life expectancy and lower risk of cardiovascular disease compared to Western populations, which correlates, at least partly, with a high intake of fish.[3, 5]

In the Adventist Health Study 2, a prospective cohort study encompassing over 73,000 participants, only pesco-vegetarian Seventh Day Adventists had a significant reduction in all-cause mortality and ischemic heart disease compared to controls.[6] Furthermore, a meta-analysis of 12 prospective cohort studies in 672,389 individuals found that compared to those who never consumed fish, those consuming approximately 2 oz. (60 grams) of fish per day had a significant 12% reduction in all-cause mortality.[7] Another meta-analysis of nine prospective cohort studies found that a higher intake of fish was associated with a lower risk of stroke.[8] Both lower intakes of fish (two to four times a week) and higher intakes ($\geq$ 5 times a week) were associated with a reduced risk of stroke (-13% and -31%, respectively).[8]

Older Clinical Trials

Patients with Hypercholesterolemia (with and without a history of heart disease)

JELIS

The Japan Eicosapentaenoic Acid Lipid Intervention Study (JELIS) trial tested 1.8 grams of EPA in 18,645 hypercholesterolemic patents who were also randomized to statin therapy. The addition of 1.8 grams of EPA on top of statin therapy lead to a significant 19% reduction in the primary endpoint, which was any major coronary event (including sudden cardiac death, fatal and non-fatal myocardial infarction, and other non-fatal events including unstable angina pectoris, angioplasty, stenting, or coronary artery bypass grafting) compared to statin therapy alone. This benefit was mainly driven by those with a history of coronary artery disease, whereby 1.8 grams of EPA lead to a significant 19% reduction in major coronary events. However, in those without a history of coronary artery disease the 18% reduction in major coronary events was non-significant.[9] Additionally, there was a significant 20% reduction in the incidence of recurrent stroke in the secondary prevention cohort.[10]

Patients with Stable Coronary Artery Disease

SCIMO

The Study on Prevention of Coronary Atherosclerosis by Intervention with Marine Omega-3 fatty acids (SCIMO) was a randomized, double-blind placebo-controlled trial performed in 223 patients with angiographically proven coronary artery disease.[11] The study randomized patients to either fish oil or placebo. Patients in the fish oil group were given 3.3 grams of EPA/DHA for the first three months and 1.65 grams EPA/DHA for the next 21 months. All capsules contained 4 mg of alpha-tocopherol as an antioxidant (the peroxide values were 0.5 in the placebo capsules and 0.6 in the fish oil capsules). Angiograms taken at baseline and two years later were evaluated for 80 of 112 patients in the placebo group and 82 of 111 in the fish oil group. Compared to placebo more patients in the fish oil group had mild plaque regression (7 vs. 14) and moderate regression (0 vs. 2), respectively. The authors stated, "…coronary segments in the fish oil group showed less progression and more regression than did coronary segments in the placebo group.". Additionally, there was a trend for fewer cardiovascular events in those receiving fish oil. The authors concluded, "…in our study, patients with coronary artery disease who consumed approximately 1.5 grams of omega-3 fatty acids per day for two years had less progression and more regression of coronary artery disease on coronary angiography than did comparable patients who ingested a placebo… In conclusion, in our study, dietary intake of w-3 fatty acids, approximately 1.5 g/d for two years, modestly mitigated the course of human coronary atherosclerosis, as assessed by angiography. Fewer cardiovascular events were noted. The dose and the preparation used were safe and well tolerated."[11]

Early Post Myocardial Infarction

DART

Advice to consume fatty fish (~ 2.5 grams of EPA/week or 300 grams of fatty fish every week) in the diet and reinfarction trial (DART) produced a significant 29% reduction in total mortality in the first two years in patients who experienced a first myocardial infarction (average time after myocardial infarction was 41 days).[12] Total number of myocardial infarctions were not significantly reduced with fatty fish. There was a non-significant reduction in ischemic heart disease events in those advised to consume fish versus those not advised (12.5% vs. 14.6%).[12] In a post-hoc analysis of DART, those who were supplemented with 3 grams of fish oil per day (Maxepa) also had a significant reduction in all-cause

mortality and ischemic heart disease mortality versus control.[13]

GISSI-P

The Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico (GISSI)-Prevention trial was a randomized trial in 11,324 patents given omega-3 polyunsaturated fatty acids early after a myocardial infarction (< 3 months). Supplementation with 1 gram of marine omega-3s caused a significant 20% decrease in all-cause mortality, 30% decrease in cardiovascular mortality and a 45% decrease in sudden cardiac death. Thus, when given early after a myocardial infarction, 1 gram of marine omega-3s was found to significantly reduce mortality and was well tolerated. In 2003, the European Society of Cardiology recommended that fish oil be part of standard patient treatment after a heart attack.[14]

GISSI-HF

The Gruppo Italiano per lo Studio della Sopravvivenza nella Insufficienza Cardiaca-Heart Failure (GISSI-HF) trials was a randomized placebo-controlled trial in 6,935 patients with chronic heart failure of New York Heart Association functional class II-IV. Those given 1 gram of EPA plus DHA for 3.9 years had a significant 8% reduction in death or cardiovascular hospitalization.[15] Moreover, mortality was significantly reduced by 9% and cardiovascular death was significantly reduced by 10%. The number needed to treat to prevent one death was 56 and the number needed to treat to prevent one death or hospitalization due to cardiovascular reasons was 44.

More Recent Clinical Trials

No History of Heart Disease

VITAL

VITAL was a randomized controlled trial in 25,871 patients over the age of 50 who had no prior history of cardiovascular disease. Participants were given 1 gram of fish oil (containing 460 mg of EPA and 380 mg of DHA).[16] During a median follow-up of 5.3 years there was a non-significant 8% reduction in the risk of major adverse cardiovascular events (a composite of myocardial infarction, stroke, or death from cardiovascular causes). However, 840 mg of EPA plus DHA produced a significant 28% reduction in myocardial infarction, 50% reduction in death from myocardial infarction, 22% reduction in percutaneous coronary revascularization and a 17% reduction in total coronary heart disease. In those consuming less than 1.5 fish meals per week there was a significant 19% reduction in the primary endpoint and 40% reduction in myocardial infarction. In the approximately 20% of the participants who were African there was a significant 36% reduction in all-cause mortality and a 77% reduction in myocardial infarction.[16]

Diabetics Without a History of Heart Disease

ASCEND

The ASCEND (A Study of Cardiovascular Events in Diabetes) study was a randomized trial in 15,480 diabetic patients without known atherosclerotic cardiovascular disease. Patients were given 1-gram of omega-3 fatty acids or matching placebo. During a mean follow-up of 7.4 years there was a non-significant 3% reduction in the primary endpoint of serious vascular events.[17] There was also no significant difference in the secondary endpoint of serious vascular events or revascularization. However, there was a significant 18% reduction in vascular death in those given 1-gram of omega-3 fatty acids. Thus, 1-gram of marine omega-3s in diabetic patients without a history of heart disease may lower the risk of vascular death.

Cardiovascular Disease or Diabetics with Hypertriglyceridemia and Other Risk Factors

REDUCE-IT

The Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial (REDUCE-IT) study was a multicenter, randomized, double-blind, placebo-controlled trial involving 8,179 patients with established cardiovascular disease or diabetes with hypertriglyceridemia and at least one additional risk factor who had been receiving statin therapy. Patients were randomized to either 4 grams of icosapent ethyl (2 grams twice daily with food) or placebo and were followed for 4.9 years.[18] Those given 4 grams of icosapent ethyl had a significant 25% reduction in the primary endpoint (composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina) with a number needed to treat of 21. Those given 4 grams of icosapent ethyl also had a significant 26% reduction in the key secondary

Table 1. Disease states that may benefit from marine omega-3 supplementation

Study	Patient population	Dose of omega-3	Benefit
JELIS	18,645 hypercholesterolemic patients on statin therapy	1.8 g EPA	Significant 19% reduction in the primary endpoint
DART	2,033 men who experienced a first myocardial infarction (average time post-MI was 41 days)	~ 2.5 grams of EPA/week or 300 grams of fatty fish every week	Significant 29% reduction in total mortality in the first 2 years
GISSI-P	11,324 patents early after a myocardial infarction (< 3 months).	1-gram of marine omega-3s	Significant 20% decrease in all-cause mortality, 30% decrease in cardiovascular mortality and a 45% decrease in sudden cardiac death.
GISSI-HF	6,935 patients with chronic heart failure	1-gram of marine omega-3s	Significant 8% reduction in death or cardiovascular hospitalization, 9% reduction in all-cause mortality and 10% reduction in cardiovascular death
VITAL	25,871 patients over the age of 50 who had no prior history of cardiovascular disease.	1-gram of marine omega-3s	Significant 28% reduction in myocardial infarction, 50% reduction in death from myocardial infarction, 22% reduction in percutaneous coronary revascularization and a 17% reduction in total coronary heart disease.
ASCEND	15,480 diabetic patients without known atherosclerotic cardiovascular disease	1-gram of marine omega-3s	Significant 18% reduction in vascular death
REDUCE-IT	8,179 patients with established cardiovascular disease or diabetes with hypertriglyceridemia and at least one additional risk factor who had been receiving statin therapy.	4-grams of icosapent ethyl	Significant 25% reduction in the primary endpoint (composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina) and a significant 26% reduction in the key secondary efficacy endpoint of major adverse cardiovascular events (composite of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke).

efficacy endpoint of major adverse cardiovascular events (composite of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) with a number needed to treat of 28. These benefits were noted on top of statin therapy (> 99% of participants were on statin therapy).[18]

Meta-Analyses of Randomized Controlled Trials and Cohort Studies

A Danish prospective cohort study (the Danish Diet, Cancer and Health cohort study) followed nearly 25,000 healthy subjects for almost eight years and found that an intake of omega-3 polyunsaturated fatty acids > 1.08 grams/day was associated with a 19% lower risk for acute coronary syndrome versus those eating 0.39 grams/day or less.[19] This suggests that the commonly recommended intake of only 250 mg/day of EPA and DHA (1-2 servings/week of fatty fish) in primary prevention may be insufficient.

A meta-analysis of 14 randomized controlled trials (RCTs) involving 32,656 patients found that omega-3 fatty acid supplements significantly decreased death from cardiac causes (-12%), sudden cardiac death (-14%), death from all causes (-8%) and myocardial infarction (-15%).[20] When RCTs with a long-term administration (at least one year) and higher dose (at least 1 gram/day) were included the benefits were even stronger on cardiac death (-32%), sudden death (-33%) and myocardial infarction (-25%).[21]

Two other meta-analyses of randomized controlled trials noted that dietary or supplemental omega-3 fatty acids decrease all-cause mortality (-16-20%), fatal myocardial infarction (-24%) and sudden death (-30%).[22,23] Furthermore, a systematic review of 11 randomized, placebo-controlled clinical trials noted that long-chain marine omega-3 supplements decrease all-cause mortality (-8%), non-fatal cardiovascular events

(-8%), sudden cardiac death (-13%), cardiovascular death (-13%) in those consuming an average dose of 1.8 grams/day for 2.2 years.[24]

Marine Omega-3s: Importance of Dose and Formulation

It is important when supplementing with marine omega-3s to use a quality supplement. Fish oil supplements should be molecularly distilled to remove mercury and filter out other environmental toxins such as persistent organic pollutants. Enteric-coated fish oil may also help reduce side effects such as belching and fishy aftertaste.

Summary

Studies providing approximately 1-2 grams of marine omega-3s in the secondary prevention setting have noted significant reductions in major coronary events and mortality. Additionally, providing 1-gram of marine omega-3s in those with chronic heart failure has been shown to significantly reduce mortality. Table 1 summarizes the disease states that may benefit from marine omega-3 supplementation. While there are some studies suggesting benefit of marine omega-3s in the primary prevention setting, larger longer-term trials are required to confirm these benefits.

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Disclosure

JJD is author of The Salt Fix, Superfuel and The Longevity Solution. JHO is an owner of a nutraceutical company which sells omega-3 supplements. **MM**

Childhood Obesity in the State of Missouri: A Review for Providers to Counsel and Treat Patients

by Usman Hasnie, MD, Matthew Lindquist, DO, Brooke Sweeney, MD, Sarah Hampl, MD & Betty M. Drees, MD

Pediatric obesity tracks into adulthood, and pediatric primary care providers are critical in its prevention and treatment in our society.





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Abstract

Childhood obesity is a common disease both nationally and in the state of Missouri. Obesity in childhood is often under-recognized and is difficult to treat. Screening, accurate diagnosis, and counseling is imperative to proper management. Common barriers to treatment include a lack of accurate identification and a lack of awareness of needed and available treatments of this disease in the pediatric setting. This review article highlights behavioral measures as well as pharmacologic and surgical therapies for obesity in children. This review is intended as guidance for providers to properly counsel and treat patients with this disease.

Background and Epidemiology

Childhood obesity is a global crisis, a rapidly growing national epidemic and the root of many serious and costly complications from which Missouri is not exempt. The need to address and manage it starting from prenatal care up through adolescence has become a top healthcare priority to enable future generations to lead healthy lives. In 2016, forty-one million children under age five were classified as overweight or obese and over three hundred forty million children and adolescents aged 5-19 years were classified as overweight or obese in the United States.[1] Over the last 30 years, the national prevalence of the disease of obesity has more than doubled for children and quadrupled for adolescents.[2] Current statistics for obesity in childhood across the nation are staggering. More than twelve million American children and adolescents (16.9%) are classified as obese and more than twenty-three million (31.8%) classified as overweight or obese.[2] On a national level 13.9% of 2-5-year olds have overweight or obesity as a diagnosis with rates in children of low-income families being disproportionally higher at 18.9 %.[3] Nearly 13% of Missouri's low-income 2-4-year olds have obesity and 34.3% of students in grades 9-12 have overweight or obesity.[4,5] Aside from the health complications, the epidemic is becoming a financial crisis, as well. In 2012, it was estimated that if current trends continue, by 2030, Missouri will spend thirteen billion dollars annually on obesity related health care, an increase of nearly 14%.[6] Low income, race, ethnicity, prematurity, large for gestational age, tobacco exposure, parents that are overweight or obese, and unhealthy lifestyle have all shown some correlation with increased incidence and prevalence of obesity over time. African American children have an odds ratio of developing obesity of



The four pillars of treatment are nutrition, activity, behavior, and advanced medical treatment as needed for Class 2 and Class 3 severe obesity.

2.7 compared to their Caucasian counterparts nationally. Preterm infants, particularly those born at more advanced gestational age, have higher risks, as well as those who had no or short duration breastfeeding.[7,8]

Screening

For children 2 years of age and older, BMI percentiles are the screening metrics to identify childhood overweight/obesity by age and gender. A BMI percentile between the 5th and the 84th percentile is considered normal weight, while a BMI percentile between the 85-94th percentile is overweight, and 95th percentile or higher is obesity. Severity of the disease of obesity can be further categorized into Class 1-3, an essential designation to assist with appropriate treatment by stage of the disease. The definitions of the stages of obesity are: Class 1 obesity (95th percentile to <120% of the 95th percentile), Class 2 severe obesity (120% to <140% of the 95th percentile or BMI 35.0 to <40.0 kg/m2), and Class 3 severe obesity (BMI ≥ 140% of the 95th percentile or BMI ≥ 40.0 kg/m2). These can be challenging to determine when most electronic medical record (EMR) programs use standard CDC and WHO growth charts. High-BMI growth charts can be incorporated into EMRs to help identify patients at higher risk and who may need earlier referral to a multi-disciplinary clinic. It is important to note the limitations of BMI in that it does not measure body fat directly nor does it account for lean muscle mass and varies by ethnicity. For example, in Asian or Hispanic populations, for each BMI level, adiposity is greater than that of Caucasians. However, due to its ease of measurement it is the recommended tool to use and research supports that BMI correlates with more direct measures of body fat.[3] As noted above, the CDC recommends using BMI to screen children ages 2-19 years.[9] The American Academy of Pediatrics recommends providers calculate and plot BMI percentiles annually in all children and adolescents and use change in BMI to identify excessive weight gain relative to linear growth.[10] Appropriate screening intervals for BMI have not been defined, even though height and weight- necessary for BMI calculation- are routinely measured at wellness check-ups. Health care providers should identify children at increased risk based on increasing BMI percentile and overweight as discussed above.

Treatment

Causes of obesity should then be evaluated; first, by age of onset. Though monogenetic causes of obesity are rare, very early onset obesity (i.e. before 4 years of age) should prompt consideration of causes such as melanocortin-4-receptor (MC4R) mutations, Proopiomelanocortin POMC deficiency, and leptin deficiency. Stunted or decreasing linear growth should trigger further evaluation for endocrine causes such as hypothyroid or Cushing syndrome. If dysmorphic features, cognitive delays, or hypotonia are also present then consider syndromes such as Prader-Willi, Laurence Moon, Beckwith-Wiedemann, or Alstrom. Further evaluation and management of pediatric overweight and obesity cases changes by stage and severity of disease per the 2015 AAP algorithm, based on expert committee recommendations released in 2007. Stage 1 or Prevention Plus is done in the Primary Care office and should be initiated when screening BMI percentile is 85-94%, focusing on behavior changes. Monthly follow-up for 3-6 months is recommended. Stage 2 or Structured Weight Management, is also typically provided in the PCP's office, and should be offered for Class 1 obesity with increased intensity seeing the patient every 2-4 weeks and using additional support such as from a dietitian, social worker, athletic trainer, or physical therapist. Stage 3, or Comprehensive Multi-disciplinary Intervention, follows in a subspecialty pediatric Weight Management Clinic and can offer further identification and diagnosis of psychological comorbidities, more intense and structured behavioral modifications, medication adjustment, and increased frequency of visits with the goal of 26 hours or more of contact over six months. Tertiary Care Intervention, or Stage 4, is recommended for patients with Class 1 obesity or class 2 severe obesity with complications or Class 3 severe obesity. Medications and surgery are often implemented at this stage, when appropriate, along with intensive diet and activity interventions.[11]

The four pillars of treatment are nutrition, activity, behavior, and advanced medical treatment as needed for Class 2 and Class 3 severe obesity.

The 2018 Physical Activity Guideline Advisory Committee released new evidence of relationships between physical activity and health outcomes in school aged youth. Strong evidence led to the conclusion that increased physical activity is associated with beneficial health outcomes in children including cardiorespiratory, muscular fitness, less age-related increase in body weight and adiposity, and higher bone mass and greater bone strength.[12] New to the evidence, though, were, 1) proven health benefits in replacing sedentary behavior with light-intensity activity, and 2) short episodes of moderate-to-vigorous activity of any duration which can be included in the daily total volume (previous guidelines included only 10 minutes or more). This may remove a barrier for patients and provide encouragement in those less able to perform longer bouts. Also, individual-level interventions are effective at increasing patients' volume of activity. The Physical Activity Guidelines for Americans issued by the US Department of Health and Human Services recommend that children and adolescents aged 6-17 years do 60 minutes or more of moderate to vigorous intensity aerobic physical activity and should include vigorous intensity physical activity at least 3 days a week. Muscle strengthening and bone strengthening physical activity should be part of the routine at least 3 days a week.[12]

The Physical Activity Guidelines for Americans also found that for BMI improvement a total of 26 or more contact hours with multiple components across interventions is needed.[13] The most cost-effective way to offer this intensity is through family based behavioral intervention in the group setting. Targeting both parents and child by providing information on healthy eating, encouraging use of stimulus control, goal-setting, self-monitoring, contingent rewards and supervised physical activity sessions are key to success. Multidisciplinary teams consisting of pediatric primary care providers, exercise physiologists, dietitians, psychologists, or other behavior specialists are needed to ensure successful implementation of these interventions. Behavioral interventions with a total of 52 contact hours or more, combining group and individual sessions, demonstrated greater weight loss and improvement in metabolic risk factors.[13] Effectiveness of interventions is based on adherence, which is a challenge for both children and families due to many factors including time constraints and transportation. Lower adherence leads to decreased overall benefit. MO Healthnet (Missouri Medicaid) has listened to stakeholders across MO and will be starting to offer a new benefit for children and adults with obesity based on this evidence. Details on the new treatment benefits are currently pending but should be available in 2020. These will likely include 26 hours of face-to-face family-based behavioral treatment (FBT) and 1.5 hours of medical nutrition therapy (MNT) over 6 months for children ages 5-19 with all classes of obesity. They may receive an additional 3.5 hours of treatment in the following 6 months if eligible and can receive a total 31 hours of behavioral and nutrition treatment over 12 months. They must be referred by a medical provider.

Primary care-based counseling about healthy nutrition changes should focus on consuming fewer foods, drinks, and snacks that are high in calories, fats, sugars and salt. Instead, replacements with fruits, vegetables, lean meats, poultry,

seafood, beans and soy products need to be encouraged. While whole grains are generally a healthy choice, most families should be encouraged to limit intake of starches. Water and/or fat-free or low-fat milk should be substituted for soda and other drinks containing added sugars such as flavored milk served at school. The use of zveero-calorie flavored drinks and powders is frequently requested and is an acceptable replacement. Portion control is important as is avoidance of fast food. Families should try to sit down together for meal times. It is also recommended that screen time during meals be limited.[14] Distractions such as TV during meals can prohibit awareness of satiety. Counseling all families on healthy lifestyles, while identifying and intervening early (before 2 years of age) when weight and weight for length are elevated or increasing, can save tremendous healthcare costs and complications.



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There are, of course, specific difficulties when it comes to healthy nutrition habits in children. Many kids will have breakfast at home only to eat more at the school-provided breakfast. Screening for and avoiding two breakfasts can be done in the primary care office. Food insecurity among the family is a frequent factor. Many parents encourage "finishing your plate" either due to their own upbringing or daily concerns about having enough food in the house. Encouraging parents to allow their children to self-regulate or to stop when feeling satiated is often helpful, especially at younger ages. Parents can be referred to the Ellyn Satter method. She promotes a division of responsibility of feeding consisting of parents choosing what, when, and where and the child choosing whether to eat and how much.[15]

When a child or adult has Class 2 or 3 severe obesity, intensive lifestyle modification is almost always insufficient to reach weight loss goals; therefore, advanced therapies including pharmacotherapy and/or weight loss surgery are recommended. At this stage of the disease of obesity, the body is in an energy-dysregulated state with adiposity and metabolic abnormalities driving unhealthy weight and habits. There are at least 15 hormones involved in appetite and satiety such as NPY, hypothalamic, Glucagon-like peptide 1 (GLP-1), ileal and colonic, ghrelin, gastric, leptin, and adipose-derived.[16] A decrease in calories can trigger an increase in ghrelin and subsequent increase in hunger for up to 12 months.[17] Often worsening this maladaptive physiology is on-going prescribing of weight-promoting medications.

Normal physiology is designed for keeping weight at a set point or to increase adipose deposition (during childhood, puberty, and pregnancy, for example) and we have no natural mechanism for sustained weight loss. Therefore, to achieve lasting improvement in weight status, we have to adjust the set point. Currently in adults we have more than 10 FDA approved medications and weight loss surgery to assist in changing this set point. Unfortunately, the current dearth of FDA-approved pediatric obesity medications leaves a relatively small group of off-label choices and a reluctant prescriber base. Orlistat is currently the only FDA approved prescription drug for the treatment of adolescents with obesity over the age of 12. However, a number of medications are weight-negative and have been approved for long-term use in pediatrics. Topiramate has been used for seizures and migraines, bupropion for depression, metformin for diabetes mellitus type 2, and lisdexamfetamine for ADHD and binge-eating. There is evidence of short-term efficacy with weight loss medication in addition to lifestyle modifications; however, long term results remain unclear. Studies are currently underway assessing the efficacy and safety of FDA-approved adult weight loss medications such as lorcaserin (Belviq), liraglutide (Saxenda), and phentermine-topiramate (Qsymia). Novel long-acting triple agonist GLP-1/GIP/glucagon therapies are currently being studied and have shown potent weight loss as well as improvement of liver fibrosis in non-alcoholic fatty liver disease.[18] Primarily due to insurance coverage, or lack thereof, our tertiary care

weight management clinic often prescribes topiramate, phentermine, and lisdexamfetamine. Phentermine is generic and financially feasible for most families despite lack of insurance coverage. Topiramate is often covered for migraine (seen with increased frequency and severity in patients with OB) prophylaxis.

For those with Class 2 and 3 severe obesity, metabolic/bariatric surgery (MBS), may be indicated. Indications include 1) Class 2 obesity (BMI >/= 35kg/m^2 or 120% of the 95th percentile) plus complications: insulin resistance, diabetes mellitus type 2, idiopathic intracranial hypertension, gastroesophageal reflux disease, Blount's disease, hyperlipidemia, hypertension, slipped capital femoral epiphysis, non-alcoholic fatty liver disease, depressed health-related quality of life, and obstructive sleep apnea[19] or 2) Class 3 obesity (BMI >/= 40kg/m2 or 140% of the 95th percentile (whichever is lower)). Though some providers have expressed concern about surgery due to age alone, the current contraindications for pediatric MBS include: medically correctable cause of obesity, ongoing substance abuse, a medical/psychiatric/psychosocial/cognitive condition that prevents adherence to postoperative diet and medication regimens, and current or planned pregnancy within 12-18 months of the procedure. Previously considered relative contraindications such as eating disorders that are being treated, cognitive disabilities or history of mental illness, immature bone growth, or low Tanner stage should no longer prevent treatment.

The surgical options are clearer yet. The vertical sleeve gastrectomy, which can be performed laparoscopically, is now the preferred surgical procedure for adults and children due to similar weight loss but lower complication rates than Roux-en-Y gastric bypass (RYGB). Due to high failure rates and high re-operation rates, laparoscopic adjustable gastric banding is no longer preferred and now makes up only 2.77% of total MBS (ASMBS).[20] RYGB remains an option, particularly for patients with concomitant GERD.

Conclusion

Pediatric obesity tracks into adulthood, and pediatric primary care providers are critical in its prevention and treatment in our society. They will need to be more adept at counseling all families on healthy lifestyles, preventing and identifying rapid weight gain early in childhood, intensifying treatment for the many children already with obesity, avoiding use of weight-promoting medications, and referring for intensive family-based lifestyle intervention, weight loss medications and surgery early. Current treatment models and policy need to focus on prevention as early childhood weight tracks into adolescence and adulthood.[21] The initial step in this process is to identify patients at risk, as the disease of obesity is treatment resistant especially at more advanced stages. Promotion of healthy weight is an essential focus for all children as the risk factors for being overweight and obese are ubiquitous.

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Disclosure

None reported.

MM

Low Dose CT for Lung Cancer Screening: The Background, the Guidelines, and a Tailored Approach to Patient Care

by Emily Tylski, DO & Mala Goyal, MD

Since the USPSTF guidelines were published in 2016, Low Dose CT for lung cancer screening has been a slowly growing trend. Many studies have demonstrated its utility in diagnosing more early-stage cancers than standard clinical practice and plain chest radiography.

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Abstract

Despite lung cancer's prevalence and high burden of mortality, a useful screening program has taken a long time to develop. Now, most of the associated national organizations recommend low dose CT screening in the appropriate population. However, since the USPSTF guidelines were published, implementation has been slow. This article outlines the current evidence and provides additional resources to help physicians tailor a screening program for their patients.

Introduction

Lung cancer is the second most prevalent cancer overall, and is the principal cause of cancer-related deaths in the United States.[1] Until the development of dyspnea from metastatic pleural effusions, hemoptysis and cough from invasion of the pulmonary vasculature and bronchial tree, or pain from bony metastasis, these cancers themselves do not tend to cause symptoms. Thus, two-thirds of patients are not diagnosed until they have Stage III or IV disease, at which time their 5-year survival is 16% and 4% respectively.[1]

Given this heavy burden of disease and high mortality, much effort has been put forth into early recognition of pulmonary nodules to aid in early diagnosis. Attempts to identify an effective screening test have been underway for decades. Simple chest radiography and sputum cytology have proven ineffective as a screening method.[2] Beginning in the 1990s, there was increasing interest in CT imaging as a screening modality. These studies initially established superiority over chest radiography, with one study demonstrating that 73% of CT-detected cancers were not visualized on screening chest x-ray.[3] Later studies reaffirmed a place for low-dose CT (LDCT) as a screening tool to aid in a more timely diagnosis for the growing number of patients falling victim to this growing epidemic.[2,4,5,6,7,8]

LDCT Screening

Establishing an effective screening program has not been easy. Many of the studies in the early 2000's were limited by small sample sizes. Over the last 10 years, several larger studies have been performed to analyze whether targeted CT screening programs would provide a mortality benefit. The Danish Lung Cancer Screening Trial (DLCST) compared 4,104 patients divided between an annual LDCT screening exam and no intervention. After five years, more cancers – primarily early

stage – were diagnosed in the LDCT group. There was no significant difference in the rate of cancer-related or all-cause mortality.[4] The Multi-centric Italian Lung Detection (MILD) trial randomized 4,099 patients amongst three groups – an annual and biannual LDCT group, as well as a control group. Over a five-year period, more lung cancers were diagnosed in the annual LDCT group, though there was no impact on lung cancer-related or overall mortality.[5] The Detection and Screening of Early Lung Cancer (DANTE) trial was a study of men aged 60-75 with a 20+ pack-year history. Each patient had baseline chest radiography and sputum cytology. Thereafter, patients were randomized to annual medical exam versus LDCT. Unfortunately, the study was underpowered to detect a mortality difference.[6] The U.K. Lung Screen (UKLS) trial randomized 4,055 patients between a CT arm and control arm. This study was also underpowered for detecting a mortality difference, but did result in more early-stage cancer diagnoses, and did support LDCT as a financially plausible screening tool for the diagnosis of lung cancer in the U.K.[7]

In 2011, the National Lung Screening Trial (NLST) research team published the largest trial to date with over 53,000 participants over 5 years.[8] Study participants were between the ages of 55 and 74 with a greater than 30 pack-year smoking history who continued to smoke or quit within the last fifteen years. They were randomized to be screened annually for 3 years with LDCT versus standard chest radiography.[8] In this study, there was a higher rate of both true positive and false positive tests in the CT arm, with a sensitivity of 93.8% and a specificity of 73.4%.[9] This detection led to a significant decrease in cancer-related mortality with a relative risk reduction of 20%, as well as an overall decrease in all-cause mortality by 6.7%.[8] Other important findings in this study included a relatively high rate of positive screening tests. Of the 25,309 patients in the CT arm, 27% had a positive screening CT, and 3.8% were ultimately diagnosed with cancer. For the majority, positive screens were followed with repeat imaging, but in 6% of patients with benign disease, invasive procedures were undertaken to obtain a diagnosis.[8] This was not significantly different from the standard radiography arm, in which 5% of patients with benign disease underwent invasive procedures. Fears exist as to the detrimental effects of anxiety, as well as unnecessary costs as a result of false positive screening exams.[10,11] Despite this, the NLST study has been monumental in bringing about the lung cancer screening (LCS) guidelines in the United States as we know them. The limitations of the study reflect the importance of shared decision making and clear identification of a high-risk cohort who would benefit most from screening.

Current Guidelines

Many national organizations have published guidelines for LCS (Table 1). They are, for the most part, in agreement. Any patient over the age of 55 with a 30-pack-year smoking history who continues to smoke, or has quit within the last 15 years and has no symptoms of lung cancer may be considered for LDCT-LCS.[12] For patients meeting these criteria, LCS is covered under Medicare.[13] Up for debate amongst these organizations is at what age this screening should stop (between 74-80 years of age – Medicare coverage up to age 77),[13] and the role other risk factors such as non-smoking-related exposures and family history of lung cancer should play in qualifying a patient for screening.[12,14,15,16,17] Most organizations also include a caveat that patients who have other comorbid conditions which would make them unable to tolerate surgical resection or other treatment should not be screened.[12,14,15,16] Additionally, given the relatively high false-positive rate, particularly on initial screening, as well as the potential for over-diagnosis (finding indolent cancers that are not life-limiting),[2] shared decision making is also emphasized as an important condition for enrollment.[12,13,14,15,16,17]

Critical exceptions to these guidelines include: patients who have symptoms suggestive of lung cancer, such as unintended weight loss or hemoptysis should have a full dose diagnostic CT chest,[14] and patients with signs or symptoms suggestive of infection should have their screening test postponed several weeks until the infection has been treated or resolved to minimize false positive exams.

Barriers to Lung Cancer Screening

There are a number of reasons why physicians are slow to refer their patients for lung cancer screening – unsurprisingly, time constraints play a major factor.[18,19,20] Shared decision making is key for quality patient-centered care. Unfortunately, studies have shown that providers as a whole are not participating in quality shared decision making discussions. In one study of providers enrolling patients for LCS, discussions were scored on a scale from 0 to 100, with 100 being a comprehensive discussion. The average score of all providers was 6, with the highest score being 17. Most discussions were less than one minute in length.[18] The time for shared decision making is noted as a barrier in many studies,[18,19,20] and few are aware of Medicare billing code G0296, which reimburses for time spent on shared decision making.[20] Of note, to be reimbursed, the physician must document a patient's eligibility, including pack-year smoking history , current smoking status including years since quitting, as well as provide clear documentation of the discussion of risks, benefits, ability and willingness to undergo treatment, smoking cessation education if

Table 1. General Recommendations:

- Start Screening: Age 55
- Smoking history: 30 + pack years. Current or former smoker within the last 15 years
- Asymptomatic for lung cancer
- General health status which would tolerate treatment if cancer were identified

U.S. Preventative Services Task Force	Stop Screening: Age 80[12]
Centers for Medicare and Medicaid Services	Stop Screening: Age 77[13]
American College of Chest Physicians	Stop Screening: Age 77[14] Should not be performed in those thought to be high risk but do not meet above criteria Could be considered, however, in those thought to be healthy enough to benefit.
National Comprehensive Cancer Network	Stop Screening: Age 74[15] Consider screening in patients >50 years of age with 20+ pack year history and additional risk factors that make the individual 'high risk' Consider screening those thought to be high risk are evaluated using the Tammemagi lung cancer risk calculator and receive a risk score >1.3% Risk factors include: radon exposure, occupational exposure, personal history of cancer or first degree relative with history of lung cancer, second hand smoke exposure, or personal history of COPD or pulmonary fibrosis.
American Association for Thoracic Surgery	Stop Screening: Age 79[16] Consider screening lung cancer survivors after 4 years of negative surveillance Consider screening in patients >50 years of age with 20 pack year history and other factors that increase risk of developing cancer to >5% in the next 5 years

applicable, and any decision aid utilized in guiding the choice to enroll.[13]

Apart from insufficient time with patients, a number of other barriers to LCS exist on the part of physicians. These include prior authorizations, failure of insurance coverage, and concern over financial burden or potential physical and emotional harm to patients who require additional workup.[10,11] Concern that a negative result will interfere with smoking cessation efforts is a reported concern as well.[10,12] As the guidelines note, screening is not meant to replace smoking cessation efforts.[12,14,15,17] The ultimate goal of lung cancer prevention via smoking cessation clearly supersedes that of early diagnosis.[12] Studies have not upheld the idea that an unremarkable LDCT hinders efforts to quit – in fact a trend towards higher rates of tobacco cessation have been reported.[17] Confidence in the utility of LDCT for lung cancer screening is also lacking, despite the data that shows the number needed to screen after 3 years is less than that of mammography, and sigmoidoscopy.[19] Unfortunately many physicians continue to order simple chest radiography for cancer screening.[11,19]

One of the other important limitations for widespread LDCT-LCS is geographic. According to the CDC, as of 2017, 28% of qualified patients did not live within a 30-minute drive of a screening center.[21] While this is a problem throughout the country, the majority of those patients were located in the northern Midwest. Missouri is a high mortality, medium access state. The surrounding states are all medium access as well, with Arkansas being the exception. Arkansas is part of a southeastern band of states with high lung cancer related mortality. However, Arkansas has disproportionately low screening access.[21]

More recent studies show some improvement in the numbers of physicians referring their patients for screening, though rates of enrollment in LDCT-LCS across the country remain suboptimal.[11,18,19,22] Patients themselves may be hesitant to enroll. Reasons for this are not consistent in studies. A study from France found that current smokers were more likely to desire screening if they were male, and had an intention to quit smoking.[23] Those with few or no comorbid conditions are also more likely to desire LCS, as well as those seeing their own primary care provider.[22,23]

This highlights the importance of the relationship between patients and their primary care physician, as well as the need for primary care providers to be the forerunners in promoting LCS for the appropriate population.[22] Radiation dose is occasionally a concern for patients and providers, but it is important to note that LDCT provides approximately a 1.4 mSv radiation dose, as opposed to 7mSv delivered by conventional chest CT.[24] For patients or physicians who desire more information on the benefits and risks associated with LCS, www.shouldiscreen.com is a useful resource created by the University of Michigan to help guide decision making.[25]

My Patient Has a Positive Screen – Now What?

The American College of Radiology has developed a standardized process for reading LDCT entitled LungRADS, similar to that which has been published for mammography.[26] Their website features a comprehensive table illustrating the various radiographic appearances of lung nodules, and the recommended follow up interval based on a nodule's malignant probability.[26] Based on these characteristics, a screening CT scan is given a category 0-4B: "0" meaning there is insufficient data for interpretation and comparison images are required, "1" being negative, and "4 A/B" categorized as suspicious and requiring short-term follow up with CT, PET/CT or biopsy (Figure 1).[26,27] For example, ground glass nodules, even those larger than 2cm, are often benign or represent indolent cancers, and are given a category 2 or 3 with a follow up interval of no sooner than 6-12 months.[26] Further, part-solid nodules are higher risk than completely solid nodules of the same size, and new small nodules are higher risk than their larger, stable counterparts. Higher risk nodules are of course prescribed closer follow up intervals.[26] Notably, a PET-CT is only recommended for nodules with an 8mm or larger solid component, due to the test's limited sensitivity for smaller nodules. Other categories, such as 4X, S and C are additional findings or modifiers which may guide further testing.[26]

Currently, guidelines support annual screening exams, with interval low-dose diagnostic scans in the event of a positive screen. Aside from scheduling ease, there is no clear basis for this recommendation, and studies are underway to scrutinize this practice.[28] A recent review article suggests that in patients with a negative initial screen and reassuring risk profile, a longer interval between screening exams (lying somewhere between 1 and 2 years) may be reasonable.[28] However, in order for a screening program to be successful, ease of application is key. A complex screening algorithm is unlikely to be optimally implemented and will thus not bring about the benefits that make a screening program worthwhile – i.e. those of early detection, early treatment and decreased mortality. As more patients are enrolled in LCS, we will hopefully be better able to identify this optimal timeline to minimize the financial burdens of screening, while maintaining its benefits.

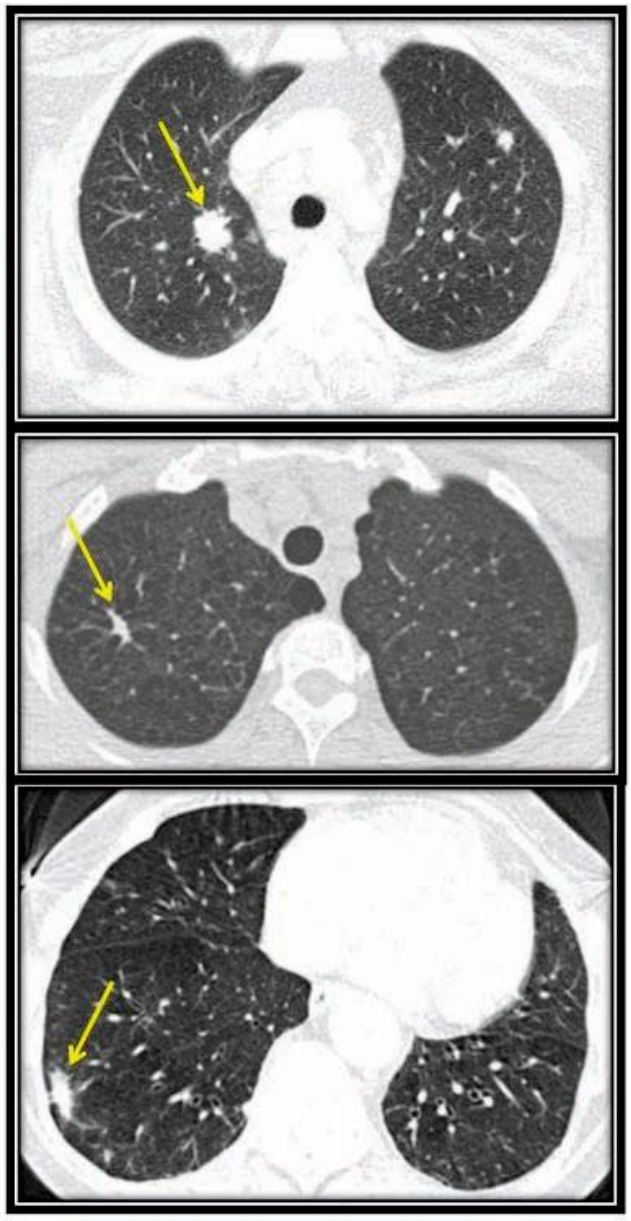


Figure 1. Suspicious spiculated pulmonary nodules – each >1cm which require further evaluation with follow-up CT versus PET-CT versus biopsy, depending on patient-specific and nodule-specific factors (symptoms, comorbid conditions, evolution of the nodule, presence of other nodules or adenopathy, etc.)

Going Forward – Minimizing Unnecessary Workups

A number of risk calculators have been developed to help physicians identify patients in whom an invasive workup

might be more appropriate. The Mayo Calculator was developed in the 1990's and identified a handful of variables which are independent predictors of lung cancer. These predictors include a patient's age, smoking status, history of cancer, as well as nodule-specific characteristics such as size, spiculation, and location (upper vs lower lobe).[29] The Brock calculator was developed in 2013 and incorporated additional factors including the presence of emphysema, radiographic qualities of the nodule, i.e. ground glass, solid or part solid, total number of nodules, and family history of lung cancer.[30] When compared, the Brock and Mayo calculators perform similarly, with an AUC of around 0.9 for each.[31,32] In 2015, the Bayesian Inference Malignancy Calculator (BIMC) was created, which took into account a nodule's volume doubling time[32] – a factor which has been shown to be a strong predictor of malignancy.[33] The BIMC also utilizes PET-CT data for further prognostication.[34] Though the BIMC has not been compared directly to the Brock model, the BIMC has been shown to be more predictive of risk than the Mayo calculator.[35] Although no studies have compared these predictive models together, any of them may be utilized to help guide decision making when developing a plan of care for patients with pulmonary nodules.

Genetic and serologic methods for noninvasive evaluation of pulmonary nodules have also been developed. EarlyCDT-lung test measures a panel of auto-antibodies found in patients with lung cancer.[36] In a validation study of the 7 antibody assay, the test was only 47% sensitive, but 90% specific. Whereas the majority of patients with a negative assay did not have a cancer diagnosis, 89.7% of those with a positive antibody assay also did not have a diagnosis of cancer. Of the 19 with a cancer diagnosis, only 9 had a positive test.[36] In a larger study of 1613 patients, sensitivity was similar at 41%, and again of the 35 patients with lung cancer, only 13 had a positive antibody test.[37]

Percepta is a genetics-based study using normal bronchial cells obtained at the time of bronchoscopy for suspected lung cancer.[38] Despite a normal macroscopic appearance, this test helps identify a pattern of abnormal gene expression in cells neighboring a malignant nodule. The specimen is stable for up to 20 days in refrigeration, and may be sent after bronchoscopy is ruled indeterminant.[39] In the initial validation study, the addition of genomic testing to bronchoscopy had a 97% sensitivity for detecting cancer.[38] Those with a low to intermediate probability of cancer had a negative predictive value of 100% and 91% respectively. It is important to note, however, that in those with a high pretest probability, the negative predictive value was only 38%.[38] Of those diagnosed with cancer despite initially indeterminant bronchoscopy, 87.4% had a positive genomics test. Just over half of those with benign disease, however, will also return positive.[38] When applied to clinical practice, Percepta decreases the rate of recommendation for invasive procedures in patients with low risk genetic profiles.[40] As with any test, it is important to identify the key cohort for implementation. Those patients with low risk for malignancy and high risk for invasive procedures might be best suited for genomic evaluation as a means to mitigate the risk of potentially unnecessary procedures.

Discussion

Since the USPSTF guidelines were published in 2016, LDCT for LCS has been a slowly growing trend. Many studies have demonstrated its utility in diagnosing more early-stage cancers than standard clinical practice and plain chest radiography.[2] Chest radiography has been proven ineffective as a lung cancer screening method and should no longer be utilized, although the prevalence of this remains surprisingly high.[11,19]

There are a number of caveats to the basic guidelines for LDCT screening (ages 55-77 with >30 pack year history who smoke or quit within the last 15 years), which all primary care and pulmonary physicians should be well acquainted with. Firstly, physicians must involve their patients in a detailed shared decision making process prior to enrolling them in a lung cancer screening program. Additionally, physicians should be mindful of the patients that they are referring. Those who would be unwilling or unable to tolerate treatment should not be enrolled. While the incidence of pulmonary nodules is high, particularly in the Midwest, the relative incidence of lung cancer is low, and it is important to discuss the risk of a false positive screening test with patients. In most cases, a repeat CT scan is all that is necessary to follow these abnormalities, though invasive procedures are sometimes required for confirmation. Thankfully, there are a number of tools available to help guide further workup, including risk calculators, antibody testing, and genomics, each with their own limitations. Of course, smoking cessation counseling is crucial, and pharmacologic therapy to assist patients in their efforts to stop smoking should be considered.

Although some of the smaller studies did not demonstrate a mortality benefit with LDCT, nearly all of them successfully demonstrated a higher rate of early-stage cancer diagnosis. Five-year survival for stage I and stage II disease is 55% and 35%, respectively.[1] If observed for a longer period of time, a mortality difference perhaps could have been identified in these smaller studies, as fewer patients were allowed to progress to late-stage disease. With

time and education, more physicians will become active in patient enrollment for LCS, and this mortality benefit found in trials may in fact be realized.

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Disclosure

None reported.

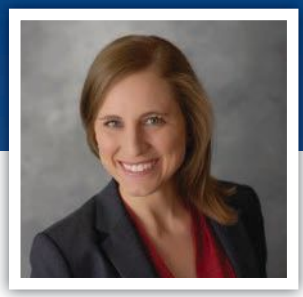
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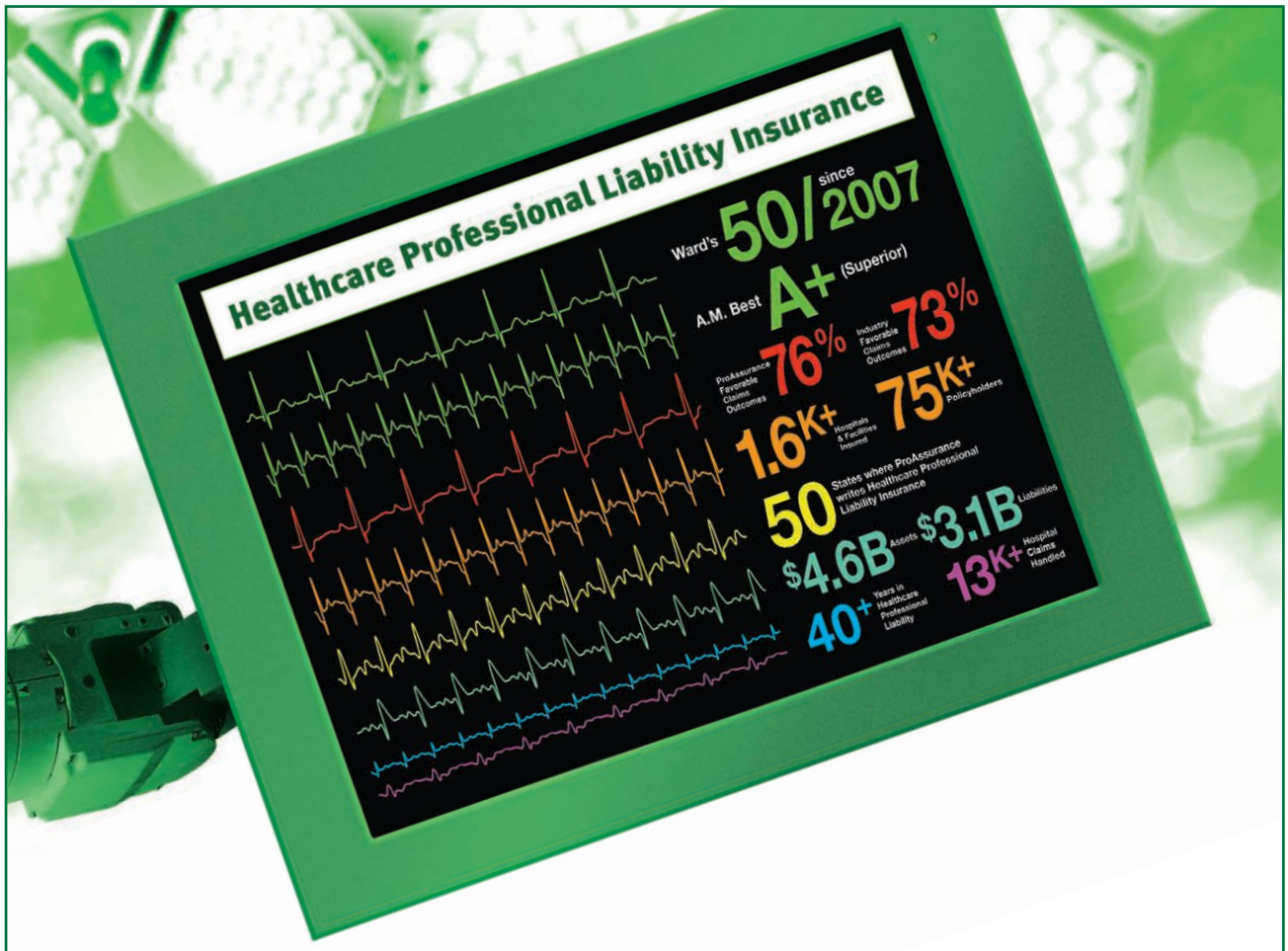
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