Missouri Medicine

The Journal of the Missouri State Medical Association www.msma.org November/December 2014



National Review

Why We Need GMO Crops in Agriculture

How MSMA Advocates for YOU

- *Tort Reform Gains Momentum*
- *Greet Your Physician Lawmakers*
- *2015 Legislative Preview*
- *Meet Local & National Champions*

Science of Medicine

- *Treating Geriatric Pain*
- *Improving Access to Care*
- *Psychological Effects of Dialysis*

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Missouri Medicine

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Missouri Medicine Celebrates 110 Years of Publishing in 2014



HOW MSMA ADVOCATES FOR YOU

EDITOR'S DESK
Physician Advocacy Begins With YOU!
by **John C. Hagan, III, MD** 456

GREET YOUR PHYSICIAN LAWMAKERS 457

2015 LEGISLATIVE PREVIEW
Big Push for Tort Reform This Legislative Session
by Jeff Howell, JD 458

WHITE COAT RALLY DAY 460
BE A PHYSICIAN OF THE DAY 460
GIVE TO MMPAC 460

PRESIDENT'S FORUM
MSMA Advocates Both For and To Our Physicians
by **Jeffrey G. Copeland, MD** 462

AMA REPORT
AMA Tackles Maintenance of Certification & Credentialing
by the Missouri Delegation to the AMA 464

AS I SEE IT
How One Physician Became the "Accidental Activist"
by **Ed Kraemer, MD** 467

The Intentional Activist
by **John B. Holds, MD** 470

The Art of Medicine
by **George M. Bohigian, MD** 472

PERSPECTIVE
Not Enough Primary-Care Doctors? Try Missouri's Prescription
by Arthur L. Caplan, PhD 474

Another Failed Government Program: Pay For Performance
by **Arthur Gale, MD** 476

MEDICAL-LEGAL
Product Liability Suits Involving Drug or Device Manufacturers and Physicians: The Learned Intermediary Doctrine and the Physician's Duty to Warn
by Jason Husgen, JD 478

Feature Series - Death/Near Death
Distressing Near-Death Experiences: The Basics
by Nancy Evans Bush, MA & Bruce Greyson, MD 486



SCIENCE OF MEDICINE NATIONAL REVIEW
Why We Need GMO Crops in Agriculture
by Melvin J. Oliver, PhD 492

ADDITIONAL SCIENTIFIC



PAIN MANAGEMENT
Pain Management Mini-Series Part IV
Pain Management in the Geriatric Population
by **Robert Borsheski, DO** & **Quinn L. Johnson, MD** 508

Improving Care Access for New Patients in an Outpatient Gastroenterology Clinic: A Novel Approach
by Michelle L. Matteson-Kome, PhD, Kristi T. Lopez, MD, Ashley D. Sliger, BS, Melisa J. Mathews & Matthew L. Bechtold, MD 512

Psychological Aspects of Dialysis: A Case-Based Discussion
by Walter F. Ricci, MD, **Harriet S. Langley, MD** & Kemal Sagduyu, MD 516

FROM YOUR ASSOCIATION
Correspondence 482
Missouri Medicine In the News 482
In Memoriam 484

MSMA member names in bold

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About *Missouri Medicine*

In publication since 1904, *Missouri Medicine*, a peer-reviewed, award-winning medical journal printed on acid-free paper, is indexed by MEDLINE, the National Library of Medicine, and is linked to PubMed Central, which is the U.S. National Institutes of Health digital archive of biomedical and life sciences journal literature. Missouri Medicine can be found on EBSCOhost databases, which provides researchers with the ability to search full-text articles, and are the most-used, premium online information resources for tens of thousands of institutions worldwide, representing millions of end-users. Missouri Medicine also provides featured content for www.medhelp.org, a top world health care website and the MedHelp.org e-newsletter, which has a half of a million subscribers.

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Physician Advocacy Begins With YOU!

by John C. Hagan, III, MD

Support Physician Advocacy: Join MSMA & Recruit Members

No matter your age, your geographic location, or your specialty within medicine, you need the advocacy of the Missouri State Medical Association (MSMA). This is true for self-employed physicians or hospital-employed physicians. In fact, a strong case can be made that MSMA advocacy is more important to hospital-employed physicians than self-employed physicians. The younger you are and the more years you have to practice the more important a strong MSMA is to you and your family.

You can run from the responsibilities of physician advocacy, but you cannot hide. Since the first legislative sessions following Missouri statehood in 1821, physicians have learned they stand above the legislative fray at their own peril. Each year bills are introduced to pay physicians less than reasonable amounts for their services; to open up the full and unrestricted practice of medicine and surgery to inadequately trained non-physicians including chiropractors, psychologists, nurses, optometrists, anesthetists, and naturopaths; and to reduce funding for medical education and research. In virtually all of the MSMA legislative positions the ultimate primary beneficiaries are our patients and the quality and availability of Missouri medicine.

As the tsunami of television and signboard advertising for litigant clients by trial lawyers attest, the tort kings and queens are reveling in their overturn of the 2005 Missouri Tort Reform Law. You are now feeling the effects of this in higher malpractice insurance premiums, more frequent filing of junk lawsuits, and awarding of eight and nine figure judgments. This has to stop! MSMA has put together a broad coalition of organizations adversely affected by the junk lawsuit industry. Tort reform can happen this session if we all get behind the MSMA-led effort.

MSMA membership dues are among the lowest in the country, and the effectiveness of MSMA advocacy for all Missouri physicians in the top five in the USA. Be sure your dues are paid. Help recruit new members from your practice and circle of physicians you interact with.

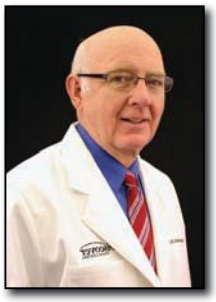
Meet with Your Personal Senator and Representative

Hopefully, you were active in your Senator's and Representative's election campaign. Your personal and financial support, while not buying votes, will earn you sincere consideration on bills of vital importance to the practitioners of Medicine. Contact your Senator and Representative now and ask for their support of tort reform in the 2015 Legislative Session. Regularly contact your legislators by phone, e-mail, mail, and fax; plan on coming to Jefferson City to spend a day (or half day) making personal lobbying visits. Throughout the legislative session the Capitol building is awash in lawyers and doctor wanna-bees and their lobbyists. That a physician would take the time to come to Jefferson City to advocate has an enormous impact on the legislators.

Read MSMA's weekly *Legislative Report* and be prepared to follow the action items that come up such as calls and personal visits about specific bills and hearings.

Physician Leadership: Set a Great Example

A special word to physicians in leadership at MSMA, county and specialty medical organizations and hospital medical staff officers: as leaders we must set the example and hold ourselves to a higher commitment of our time and money. It has long distressed me that every member of MSMA higher leadership and all members of Missouri Medical Political Action Committee (MMPAC) are not Super Diamond ($1,000/year) members. After the recent elections MMPAC needs to re-accumulate funds. If you are an officer or MMPAC member get out the check book and make a Super Diamond $1,000 donation for 2015, help recruit one or two new MSMA members, and make plans to come to Jefferson City to advocate for your profession. Go to www.msma.org/MMPAC. **MM**



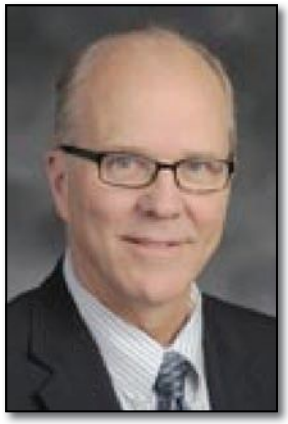
John C. Hagan, III, MD, FACS, is a Kansas City ophthalmologist and Missouri Medicine Editor since 2000. He is a multi-year Super Diamond Contributor to MMPAC.
Contact: jhagan@bizkc.rr.com



Greet Your Physician Legislators

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

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

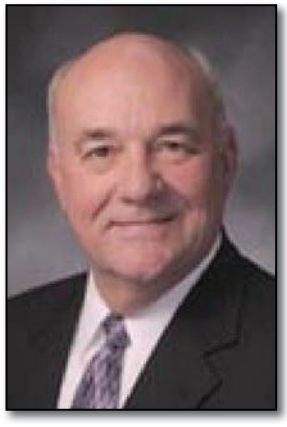


In addition to his legislative duties, Rep. Frederick is a practicing orthopedic surgeon in Rolla at the Phelps County Regional Medical Center, where is also chair of the Department of Surgery. He received his BS from St. Louis College of Pharmacy in 1976 and his DO from the Chicago College of Osteopathic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

Contact: keithjfrederick@gmail.com

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

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



Contact: jim.neely@house.mo.gov

Bob Onder, MD (R)
State Senate District 2
(St. Charles)



Bob Onder, MD, graduated from Washington University School of Medicine in 1987 and St. Louis University School of Law in 1994. He is a physician and small businessman who founded his private medical practice in 1992, specializing in allergy and asthma.

In 2006 he was elected State Representative, representing western St. Charles County. While in the legislature, he authored major legislation to cut taxes and fight illegal immigration. His immigration bill, HB 1549, was signed into law by Governor Matt Blunt in 2008.

Contact: rfonder@charter.net

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

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



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

Contact: rob@schaaf.com

MM



Big Push for Tort Reform This Legislative Session

by Jeff Howell, JD

Scan to Contact Lawmakers

Scan, look up lawmaker, and save to contacts.

Help out by coming to Jefferson City for our White Coat Day on February 24, 2015. The more physician visibility we have in the Capitol, the better.



Jeff Howell, JD, is MSMA's General Counsel and Director of Governmental Relations.
Contact: jhowell@msma.org

The 2015 legislative session will be upon us in no time. With the general election now behind us, the Republicans will control 117 of 163 seats in the House of Representatives and 25 of 34 seats in the Senate. In other words, they have a supermajority in both chambers, and a supermajority renders the Governor's veto pen less formidable.

Of the 197 seats in the 98th General Assembly, four will be held by physicians. Senator Rob Schaaf, MD, won re-election to the 34th district encompassing Buchanan and Platte counties. Bob Onder, MD, will be the new Senator representing St. Charles County's 2nd senatorial district. In the House of Representatives, Reps. Keith Frederick, DO, and Jim Neely, DO, won re-election representing districts in Rolla and Cameron, respectively. Missouri physicians are incredibly lucky to have four doctors in the legislature, protecting the practice of medicine from outside forces. Your MSMA lobby team looks forward to working with them this coming year.

In no particular order, here are some of the issues we anticipate working on/dealing with during the 2015 legislative session:

Tort Reform

Hopefully, the third time will be the charm. Back in 2012, the state Supreme Court overturned our successful $350,000 cap on noneconomic damages. The past two legislative sessions, MSMA has led a large coalition of organizations attempting to reinstate the cap. In both 2013 and 2014, our bill passed the House of Representatives only to get bogged down in the Senate. Opposition has been from Democrats and a few stalwart Republican attorneys. We hope this year will be different. During the summer, we have had courteous discussions with the trial attorneys in an effort to find common ground. Plus, with the Republican gains on election night, the veto option looks much less onerous. The Show-Me Tort Reform Coalition will hold its White Coat Rally on Tuesday, February 24, 2015. We certainly hope you can join us at the Capitol that day to lobby in favor of re-establishing the cap. Go ahead and save the date in your calendar, and look for more information on the rally in upcoming MSMA publications.

Nurse Scope of Practice

For the past few years, the nurse lobby has unsuccessfully lobbied for an expanded practice authority. Sometimes, they have asked for a complete end to physician collaboration in their desire for complete independent practice. Other times, they have asked for a lessening of what they consider overly burdensome restrictions on APRN practice. But make no mistake; in the end the nurses want to practice without any physician involvement. We've made efforts to compromise



with them in the past, but they seem to want all or nothing. We anticipate this issue to resurface yet again this year. In addition to the nurses themselves, CVS and Walgreens will be champing at the opportunity to allow APRNs to see patients in their pharmacies. So we foresee their involvement, as well as newcomer BJC HealthCare, who also sees nurses as a viable primary care option to physicians.

Board Opinions

A few years ago the state Supreme Court ruled, in part, that any opinion of general applicability issued by a state board was a rule, and needed to be properly promulgated under the law. That's a problem because promulgating rules can be a time consuming process. It certainly takes longer than the physician seeking the opinion desires. The ruling has hamstrung the Board of Healing Arts' ability to answer simple licensure questions and interpretive inquiries raised by physicians. Presently, the Board routinely answers physicians' questions with, "a state agency cannot make a statement of general applicability, including answering general questions or interpreting or clarifying statutes, without going through a formal rulemaking process." We think it's silly that the boards can't answer simple questions from their licensees. The potential legislation to fix this problem will allow the Board of Healing Arts - as well as the other professional boards - to offer non-binding opinions when licensees ask questions. Allowing this would definitely help physicians, and could potentially keep to public safe as well in certain circumstances.

Medicaid Expansion

This will be an interesting topic this coming year. With even more Republicans in Jefferson City in 2015 than in the prior General Assembly, it seems it will be difficult for anything remotely related to the Affordable Care Act (ACA) to pass. Just like 2013 and 2014, we predict a number of different bills that would give the state's MO HealthNet program a facelift. Some of those bills will propose full expansion under the ACA, and others will attempt to "fix" the program by offering to make things transparent or rein in fraud and wastefulness. As we've seen in the past, some of these ideas will benefit physicians and some will make it more difficult for you to practice medicine. We'll do our best to sort the wheat from the chaff, and if anything looks as though it might pass we'll do our best to make it beneficial to you and your patients, rather than the government and insurance companies.

Licensing Compact

Here's a new issue we anticipate for next year. The Federation of State Medical Boards is championing an interstate compact for physician licensure. Many other health professionals have similar licensing compacts. The compact would make it quicker and easier for qualified physicians to apply for licensure in multiple states. It would eliminate the state-specific nuances in licensure while ensuring states retain the ability to discipline independently when necessary. The FSMB indicates that only 6% of physicians hold licenses in multiple states, which hampers the ability of physicians to practice across states lines or on digital platforms. As with all legislation, much is determined once we get to read the actual bill language. If this issue pops up, we'll be prepared.

Summary

These are just a few of the things we'll see this year, but it doesn't come close to being an exhaustive list. We anticipate having our yearly discussions over the worthiness of state's motorcycle helmet law. We'll find ourselves advocating for stricter texting-while-operating laws and seat belt enforcement. The insurance companies will probably get an earful over narrow networks and prior authorization. Telemedicine will likely come up; as will the pharmaceutical industry and their numerous endeavors. We'll have to watch some public health groups who will attempt to offer solutions to their own issues for their select set of patients. We're the only state without a Prescription Drug Monitoring Program (PDMP), so that will be in play. Plus, the chiropractors, optometrists, midwives, etc., never seem to go away. And on and on and on…

Be sure to read MSMA's weekly *Legislative Report* during the 2015 session. It will keep you in the loop on all the above and then some. And don't forget to volunteer as the MSMA Physician of the Day at the Capitol. It's not difficult, and the legislators love seeing one their physicians from back home. Look for a sign-up sheet on the MSMA website soon. If you have any questions about our advocacy efforts on your behalf, feel free to give me a call anytime at 573-636-5151, or email jhowell@msma.org. **MM**



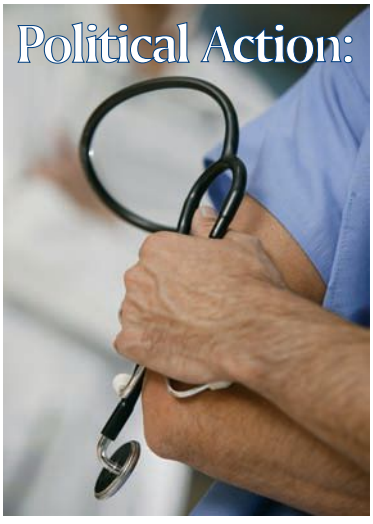


Volunteer to spend a day in the Capitol as MSMA's Physician of the Day in 2015!

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

If you are interested in serving in this worthwhile project, please contact MSMA's Kenny Jackson at 800-869-6762 or by e-mail at kjackson@msma.org.





Medicine's Muscle

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

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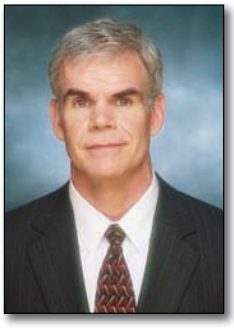
UNCOMPROMISING PROTECTION



MSMA Advocates Both For and To Our Physicians

by Jeffrey G. Copeland, MD

I believe advocacy is the most under-appreciated benefit of membership in our medical association.



Jeffrey G. Copeland, MD, MSMA member since 1988, is a plastic surgeon in St. Charles, Missouri, and President of the MSMA.
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In this edition of *Missouri Medicine*, the theme is advocacy. I thought it apropos to take a long view of what we mean by the term. Technically, the word means "pleading for, supporting or recommending; active espousal." It is used in the context of organized medicine as a political process initiated by an individual and/or group with the aim of influencing decisions within political, economic, and social systems and institutions.

This concept of asking for things in an organized, very purposeful way intrinsically leads to several questions. The questions include: who, what, to whom, and by whom. Our Missouri State Medical Association is focused on those things that fall under the purview of the practice of medicine, but a lot of nuances may arise within that structure.

Our "who" is the patients and physicians of Missouri.

Clarity of intent is also critical to well executed advocacy. This is our "what." That sounds simpler than it is in practical terms. To be successful, our message must be clear and concise.

Identifying the target audience of the message is obviously necessary, but that audience is not necessarily obvious. This is where our professional advocates come in. Sometimes it is not immediately apparent who has the critical influence over a matter. This might involve approaching the right group or person to diffuse objections so that actions can move forward. This is our "to whom."

Finally, one or more persons carry out the advocacy, so selecting those representatives plays a significant rôle in the likelihood of success. Also the support that those individuals receive is of critical importance. And to a real extent, we can all be involved in delivering our message. This is our "by whom."

I believe advocacy is the most under-appreciated benefit of membership in our medical association.

When looked at through the lens of public health, it is invaluable. Input into things that have an effect on the well-being of our population, like immunization or routine care of common health problems like diabetes or hypertension, is an example of this.

From the viewpoint of a physician, attention to those things which affect our daily practice lives, as in reduction of barriers (like attempts to redirect EMRs toward improving and simplifying patient care rather than collecting business information or making dealings with insurance companies less onerous)



are highly valuable and are appropriate subjects of advocacy.

MSMA also advocates for physicians with the State Board of Healing Arts, and is closely involved in the process of certifying bodies for continuing medical education activities. In this last area, we even get in our own way, as in the recent burdensome changes in certification (Maintenance of Certification and potentially Maintenance of Licensure) in some specialties.

We also work closely with the Missouri Physicians Health Program to assist impaired physicians and to advocate on their behalf as appropriate.

Then there is the whole realm of political advocacy, in which organized medicine strives to protect itself from threats from many quarters, including, but not limited to, scope-of-practice issues from many non-physician groups, increasing restrictions, diminishing reimbursement, meddlesome governmental oversight, unfunded mandates, and lack of meaningful protection from excessive awards in medical liability cases.

This is where it gets sticky. As we collectively seek to influence people in decision-making positions, it is important for us to develop a cohesive, consistent message that we can, as a group, support. After identifying an issue as clearly as possible, this requires discussion with open access and appropriate deliberation and finally a group decision to stand behind the results of the process. It has been my observation that many physicians either don't know how to be involved in the process or don't wish to put out the effort, either because they feel that it will be futile or too much work. As with most groups, there will be physicians who are interested in influencing the course of public health and medicine and who will show up for the meetings, make the calls, speak on behalf of their causes and, *de facto*, make decisions for the larger group. I don't have delusions that suddenly everyone will become active and involved in this important process, but those who chose not to ought not complain too loudly.

Then, as we seek to provide protection and advantage to our body, our advocates must look to different individuals and groups. Experience in the arena makes a great deal of difference here, and MSMA has excellent staff to identify the appropriate areas of contact and forward our various causes. Sometimes it is clear that there is a specific politician or faction who will either help or hinder as we pursue our goals. In that case, the approach may be clear, but sometimes bodies with whom we generally differ may be allies. That makes being fair and even-handed important, so those alliances are available when needed. An "it's just business" attitude is best here in order to minimize personal considerations. Then, hopefully, the more compelling argument (hopefully our patients' and ours) will carry weight without baggage. And, as the face of the physician population changes, it is necessary to be aware of and sensitive to many physicians' different frames of mind. We live in a time when a majority of physicians are employed and more will be. It appears that many employee-physicians depend on their employer to watch their back, but there can certainly be a conflict of interest when matters like overall reduced reimbursement must be divided (at which point most organizations with opt for their own interest) or contract re-negotiations come into play.

Our Association needs to advocate both for and to our physicians.

In the end, some consensus must be developed and carried forward. And as is a general rule with statistics, the larger the sample, the more truly representative of the whole population it is. Thus, the more physicians who are involved (read "active members" in this place) with setting our collective agendas, the more likely our advocates can do the best job for the most members.

That is all in the context of public advocacy. I would be remiss if I did not point out that we must also advocate on a personal, one-on-one basis with our patients. They are not naïve, but sometimes unaware of specific circumstances, and in my experience are interested to hear something about what is going on in the world of medicine, especially as it affects their access to good care. It is worth the time for us to formulate clear messages that are understandable to non-medical people and which give them a framework for consideration and action. That contact, as restrained as it is today because economically it frequently needs to be brief, is extremely valuable time. We can get information into our patients' hands and give them an easy path to contact decision-makers such as legislators and other members of the bureaucracy so they can make their opinions known. Do this. **MM**



AMA Tackles Maintenance of Certification & Credentialing

by the Missouri Delegation to the AMA & Compiled by Ted Groshong, MD

Complete information is available to all on the AMA website at ama-assn.org. Prior to each meeting of the House of Delegates, proposed actions of the House are available on our web site, and that any AMA member may contribute to the Online Member Forum.



Ted Groshong, MD, Columbia, MSMA member since 1976, is a pediatrician and a Missouri Delegate to the AMA.
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The 2014 Interim Meeting of the American Medical Association House of Delegates met in Dallas on November 8 through 11. As has been true for several years, members of the Missouri Delegation continued to be in leadership positions within the AMA and its House of Delegates (HOD). **Ed Cabbabe, MD**, St. Louis, served as the Chair of the Heart of America Caucus (Missouri, Arkansas, Oklahoma, and Kansas). **David Barbe, MD**, (Mountain Grove) continues to serve on the powerful Board of Trustees. **Jerry Kennett, MD**, serves on the Council on Legislation.

As might be expected, the uncontrolled epidemic in West Africa and the introduction of Ebola virus into the United States was an important issue addressed at the meeting. Captain Arjun Srinivasan from the CDC addressed the members and guests, giving us a rundown of current recommendations for control and treatment. Resolutions from the House of Delegates addressed the importance of advocating for public health policies for health workers returning from affected countries based on science and the advice of experts in infectious disease and public health, actively discourage policies which are not based on scientific evidence, such as enforced quarantine. At the same time, the AMA HOD wants to encourage American health care workers to care for those infected with this disease. It was stressed that it is essential that physicians take the lead in keeping the public informed about health threats.

There continues to be major concern among physicians regarding the increasing costs, both in time and money, for maintenance of certification (MOC). This concern is accentuated by the efforts by some political leaders to link MOC with maintenance of licensure. It was pointed out by representatives of the American Board of Medical Specialties and the Federation of State Medical Boards that these exams are not designed for licensure or for use in credentialing, either for health insurance companies or for hospital staff privileges. Nevertheless, there are efforts both in the political realm and among private insurers and health care systems to use those exams for credentialing. Additionally, increasing requirements being tacked on by the specialty boards have added to this burden. The AMA has been urged to take the lead in reducing those onerous demands, and in helping us to meet those challenges.

Among public health issues, the AMA will advocate for treating e-cigarettes the same as tobacco products, for restricting their availability to minors, and promote education to the public on the health



risks of these behaviors. The HOD urged that appropriate authorities update physicians frequently about new trends in recreational drug use. The House moved that medication cards be developed for patients.

After multiple efforts lasting several years, and with many revisions, the Council on Ethical and Judicial Affairs presented their report on physicians' exercise of conscience. One of the most sensitive of the CEJA efforts over the last few years, the revised report was accepted by the House. We physicians are expected by our patients to uphold high ethical standards, which include "fidelity to our patients, and respect for their self-determination." However, on occasion, the personal ethical standards of a physician may be in conflict with those of a patient. It is essential that we are able to act in a way that is consistent with our own conscience, but at the same time, meet the needs of our patients. This report is well thought out, and concise in its efforts to guide us when conflicts occur.

For many years, the Medical Student Section has introduced very thoughtful and meaningful resolutions to the House of Delegates. This year is no exception. Reflecting recent action by the American Public Health Association, the students introduced a resolution that judicial solitary confinement be strictly limited when applied to juveniles. They noted that children and adolescents placed in such confinement suffer in a manner similar to torture, experience increased mental illness, and increased physical harm. They recommended, and the House accepted, that solitary confinement be used only for extraordinary circumstances when it is necessary to protect the children themselves, the staff, or other detainees. When there is question of a mental health issue, it should be under the supervision of a physician.

Many who practice in Missouri have been suddenly dropped by insurance companies who are offering narrow network plans to employers and for Medicare. Not only have physicians been disadvantaged, but it has caused considerable disruption in the continuing care for patients when physicians are dropped with little advanced notice. Additionally, these narrow networks may provide inadequate access to specialized services. The AMA has been working on legislation to assure that adequate advance warning be given to physicians and patients. It is essential that criteria for dropping physicians be clearly identified in a timely manner, to allow us to meet those criteria, that changes to provider networks be provided to patients as well as physicians prior to enrollment, and that this information be widely disseminated. Patients must have adequate access to specialized services when those changes are made, and the House urged that appropriate state and federal (in the case of Medicare) authorities monitor plans to make sure this is accomplished, with quarterly reports of network adequacy.

One important provision of the ACA included a requirement that Medicaid payments to primary care physicians (Family Practice, Pediatrics, and Internal Medicine) be provided at Medicare rates. This provision is to cease December 31, 2014, unless re-authorized by Congress. The AMA is committed to advocating for continuation of those payments. We are also committed to including Obstetrics/Gynecology in this program. The best opportunity will be during this lame duck session. While the AMA government relations staff are optimistic that this will be accomplished, it is in no way certain. It is important for Primary Care physicians to speak with their congressional representatives to assure their support.

There were five hours of testimony regarding availability of TDaP for Medicare patients, Meaningful Use requirements, modernization of Tricare payment methods, access and equity for telemedicine services, and that out of pocket non-formulary prescription expenses be counted in calculations for Part D coverage gap.

Given the increasing number of physicians who are employed, the House supported a resolution to study its long-term significance on health care in the future. This includes identifying those factors leading to an increase in the proportion of physicians who are employed, its association with high physician turnover and the resulting effect on continuity of patient care, as well as its effect on physician/patient, and physician/hospital relationships.

Related to that, the House supported a second resolution which would explore employee associations and collective bargaining for physicians. While the AMA is certainly not advocating for unionization (though there were several delegates who are members of unions), the House felt it is a good time to return to an evaluation of these issues, given the proportional drop in independent practice which we are now experiencing.



House actions on legislative advocacy dealt with many issues and several stand out in their significance. All Delegates were concerned with the increasing cost of generic drugs. In addition there is an effort by pharmaceutical companies to force switching to a more expensive drug by changing their distribution channels. These issues were referred to the Board of Trustees for decision and action. The AMA will also work with CMS to eliminate Medicare's prohibition on drug price negotiation and will work to improve the parity of drug cost reimbursements between different categories of providers.

ICD-10 is still of concern. The AMA will work to try to have the government or insurers to cover the cost of switching to the new system.

Preauthorization is worsening. Requests for the preauthorization of many diagnostic tests will only delay their use in urgent settings. The AMA will work with insurance companies to eliminate unnecessary requests.

A resolution to have the AMA educate the media and legislators on the health effects of the chronic use of cannabis was referred to the Board of Trustees. The post-hospital surveys for pain relief border on the absurd. The practitioner is at the whim of the patient in deciding whether their pain was adequately relieved. There are many other factors entering into this equation. This was also referred to the Board of Trustees.

As with all the actions of the House of Delegates, complete information is available to all on the AMA website (ama-assn.org). We also want to remind all AMA members of MSMA, that prior to each meeting of the House, proposed actions of the House will be available on our web site, and that any member may contribute to the Online Member Forum, where the testimony of each AMA member is equivalent in influence to that of Delegates who are testifying at the reference committees. **MM**





How One Physician Became the "Accidental Activist"

by Ed Kraemer, MD

It was very gratifying to have played some part in improving the health of an entire community, well beyond my ability to do so in my day-to-day practice.

As practicing physicians, the majority of patient care that we provide takes place in hospitals, in office exam rooms, or via phone and email communications. We deliver this care in a traditional one-on-one fashion, affecting the health of one patient at a time.

Additionally, there are myriad opportunities (and needs) for each of us to expand our medical sphere of influence beyond this 1:1 paradigm, allowing us to impact the health of larger populations of people. These opportunities may be as simple as writing a health-related article for your local newspaper. Or you may choose a more complex and time-consuming venture such as getting involved in a local or state health initiative or perhaps serving on a health advisory board of some type.

If you are reluctant to add yet another layer of complexity to your already jam-packed calendar, please allow me to share my own testimonial in this regard. I have had the privilege of being involved in two major health-related initiatives in Lee's Summit, which have had ripple effects throughout the Kansas City region and more broadly in the state of Missouri. These two initiatives are the Smoke-Free Workplace initiative and the Livable Streets initiative.



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My personal foray into the world of physician activism began not as an act of pure altruism, but rather as a reluctant agreement to attend just one meeting. You see, in the fall of 2005, my friend and fellow family physician, Steve Salanski, MD, MSMA member since 1993, was planning to meet with a group of citizens to address the health concerns of secondhand smoke exposure in workplaces in our city of Lee's Summit. Their hope was to convince the City Council to pass a law requiring all public places, including bars and restaurants, to become smoke-free. (Such laws, while fairly commonplace now, were rare in Missouri at that time.)

Although Dr. Salanski seemed convinced that I should be a major player in this worthwhile effort, I myself was not so sure. While I initially told Steve that I was simply too busy, the whole truth went much deeper. The fact was that I was terrified at the thought of becoming involved in a high profile, potentially controversial public initiative of any type. My personal modus operandi was to avoid conflict at all cost. Public scrutiny and conflict played out in City Hall and in the media were simply way beyond my comfort zone.

"On the other hand, what harm could come from showing up for just one meeting?"

Well, the next thing I knew, I had become co-chair (along with Steve) of Clean Air Lee's Summit! That one meeting quickly evolved into a major public health initiative, complete with a massive education campaign including personal presentations to community groups all over town. We appeared in front of a wary City Council armed with the Surgeon General's 700-page report on The Health Consequences of Involuntary Exposure to Tobacco Smoke.[1] In spite of the objective evidence in the Surgeon General's report, the Council failed to pass our proposed ordinance, which was based on a national model. In response, our group spearheaded a citizens' petition effort, forcing the City Council to either pass the ordinance or place it on the ballot for local voters to decide for themselves.

ADVOCACY - AS I SEE IT



Ultimately, a hybrid solution was reached, incorporating partial Council action and a resounding 71% YES vote from the electorate. The end result, known as the Clean Indoor Air Act of 2006, was a comprehensive law requiring virtually all public places in Lee's Summit, including all restaurants and bars, to be smoke-free. (Our neighbors in Independence, led by Donald Potts, MD, MSMA member since 1977, among others, passed a similar law at the same time.)

It was very gratifying to have played some part in improving the health of an entire community, well beyond my ability to do so in my day-to-day practice. Even more gratifying was watching as community after community around the KC Metro area followed the lead of Lee's Summit and Independence and passed their own smoke free workplace laws. Since that time, many other communities across the state of Missouri have followed suit.

Multiple studies of communities in the United States have shown that these types of laws result in improved public health, with more people quitting smoking and fewer people (smokers and non-smokers alike) being hospitalized for acute myocardial infarction.[2,3] This was really exciting stuff!

Below, Dr. Kraemer bicycling on "Livable Streets." The photo illustrates his commute to (work) Truman Medical Center-Lakewood, only two miles, all in Lee's Summit except for the last half block, which is technically in Kansas City, but the "street has a nice paved shoulder for cycling."



"So…that's how I evolved from a reluctant attendee of just one meeting into what I like to call…an Accidental Activist!"

Not long after the passage of the Clean Indoor Air Act, I was appointed by the Mayor to serve on the Health Education Advisory Board of the City of Lee's Summit. Serving on such a board is one more example by which a physician can expand their sphere of influence. (Dr. Salanski and I serve as co-chairs of the board to this day.)

My next plunge into public health activism was not so accidental. As a bicyclist and a proponent of active lifestyles to improve my patients' health, I am constantly recommending that people do more bicycling and walking. But early in 2008, I began to openly question just how safe it was to do these things, especially in certain areas of our community.

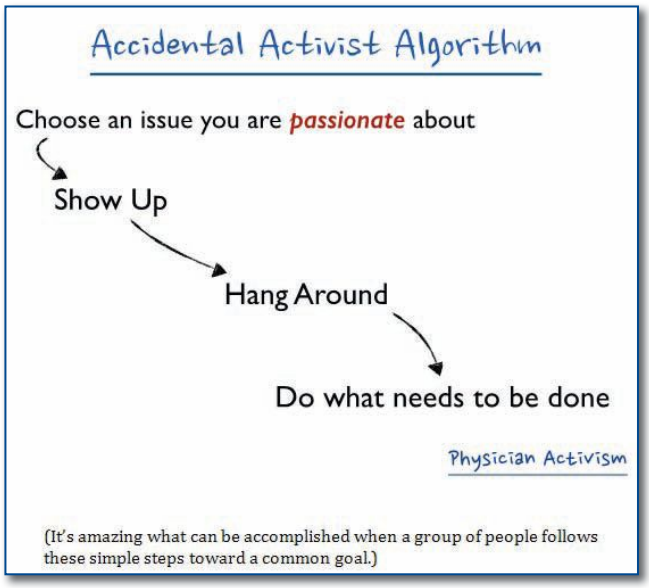
So, along with Lee's Summit's city manager and city traffic engineer, I attended a Bicycle Friendly Community rally and workshop in Shawnee, Kansas. After the meeting, the three of us began to envision Lee's Summit as a nationally recognized Bicycle Friendly Community. How could we achieve that vision? Beyond bicycling, we also started to envision a city that was safer and more accessible for people trying to walk, for people taking transit, and for people with disabilities.

It turned out that our expanded vision was not so original after all. In fact, it already had a name: Complete Streets. There was even a National Complete Streets Coalition and a website, www.completestreets.org. The basic concept is that: our streets belong to everybody. We should build them that way. This includes not only people in cars, but also people walking, riding bicycles, taking transit, and people of all ages and abilities. The big question was, how do we convince the Mayor and City Council of the need to transform this vision into reality for our own city?

The answer to this question is long and involved, with the process spanning several years and continuing well into the future. Milestones in the process have included:

- Education of citizens, city staff and elected officials about what we came to call the Livable Streets concept, including the effect of the built environment on personal activity level and subsequently on public health.[4,5,6,7]
- Endorsement of the Livable Streets concept by a local Citizens' Strategic Planning group and multiple community groups.





- Adoption of a Livable Streets Policy by the City Council in 2010.
- Creation of an ongoing Livable Streets Advisory Board in 2011, to assist the city in implementing the policy and to continue with local education efforts.
- National designation as a Walk Friendly Community in 2011.
- National designation as a Bicycle Friendly Community in 2012.

As with the Smoke Free Workplace initiative, Lee's Summit's Livable Streets initiative spawned passage of similar policies in other communities in the Kansas City region and contributed to momentum relative to this issue across the state of Missouri. (In 2012, the state of Missouri adopted its own Complete Streets Resolution, a culmination of years of work by multiple organizations and elected officials from across the state.)

So, there you have two examples of physicians and other concerned citizens working together to improve the health of their community and our state.

I encourage each of you as physicians to expand your own medical sphere of influence in some way. You'll need to pick your own passion. A few ideas include:

- Writing articles for your local newspaper or writing a health-related blog.
- Participating in or leading local or state health-related initiatives.
- Serving on a local or state health-related board/commission/committee.
- Serving on a committee or as an officer for MSMA, or specialty organization.
- Advocating for health-related issues to your local and state elected officials.[8,9] (e.g. statewide Smoke Free Workplace law, Livable Streets policy in your community, tort reform, Medicaid transformation, etc.)

OK, physician colleagues…so that is my official advice to you. Unofficially, however, you may want to consider the following: The next time anybody invites you to attend just one meeting, take my personal advice and just say, "No!" Otherwise, you might become the next "Accidental Activist!"

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MM



The Intentional Activist: John B. Holds, MD

No matter what your specialty there is a non-physician organization that will be in Jefferson City lobbying the 2015 Missouri Legislature to allow them to inappropriately practice medicine and surgery.

I became a member of MSMA and my state ophthalmology society, the Missouri Society of Eye Physicians and Surgeons (MOSEPS), shortly after I moved to Missouri in 1990. At first it seemed like a good way to meet other physicians and ophthalmologists at regional meetings. I became interested in the issues that are regulated at the state level, such as licensure, scope of practice, and tort reform. Knowing that all politics are local, I got involved with state legislative issues through MSMA, MOSEPS and our St. Louis Metropolitan Medical Society.

Watching the practice of Medicine evolve in Missouri over the past 24 years has been interesting and informative. Every year has offered fascinating legislative fireworks. MSMA, MMPAC, and the American Academy of Ophthalmology Surgical Scope Fund (on which I now serve) have all been absolutely key in promoting good legislative policies in Missouri. Attempts by optometry to expand their scope of practice into surgery are always on the back-burner. No matter what your specialty there is a non-physician organization that will be in Jefferson City lobbying the 2015 Missouri Legislature to allow them to inappropriately practice medicine and surgery.

The lessons I have learned over those years are important to all physicians. Participation in organized medicine through membership in Missouri State Medical Association is an absolute essential. Pay your dues; contribute to MMPAC, and help recruit new MSMA members.

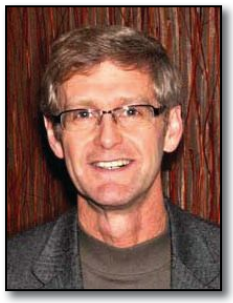
All physicians must become involved in the political process by developing close relationships with their own state legislators and foster influential relationships with state-wide key legislators. Be sure your State Senator and State Representative know you personally and that you contact them often.



John B. Holds, MD, (left) and Gregory Kwasny, MD, (right) present a OphthPAC contribution to US Representative Ann Wagner (St. Louis).

Ultimately this means spending some of your time and money developing these relationships; traveling to the state capitol at least once per session (sometimes on short notice to testify in a committee hearing) and making campaign contributions. This strategy might be called "Bucks on the Ground (during elections) and Boots on the Ground (during legislative session)." Read the MSMA *Legislative Report* weekly and follow the "action items" appearing there.

You are never too old, too young, too busy, or too cash-strapped to contribute to your profession by membership and active participation in MSMA and the legislative process. **MM**



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The Art of Medicine

by George M. Bohigian, MD

The highest level of the practice of Medicine includes rendering the most up to date scientific therapeutics using the timeless artistry of compassionate human to human interaction.

Armand Trousseau stated Medicine is both an art and a science.[1]

Science gets its due from physicians; artful medicine, highly valued by patients since antiquity, is often neglected. What physicians may not realize is that implementation of the art of medicine will enhance the effectiveness of scientific medicine. I will review some time-honored, easily implemented strategies that will increase patient satisfaction, trust, compliance and reduce the risk of malpractice claims.

Establishing a Human-To-Human Connection

In artful medicine the powers of touch and listening cannot be over-emphasized. What patient could doubt their physician's humanity and concern after hearing, "I will see you through this, I will not abandon you, I am sorry this happened to you." Shaking a hand, or reassuring pat on a shoulder makes a connection and meaningful progression toward the act of healing.[2] Touching a patient must be in the appropriate context of the exam. Just listening to the patient is therapeutic.[3] These caring rituals are transformative; they are at the heart of the patient-physician relationship. In general patients believe physicians are well-trained and capable. Their assessment of physicians is often based on intangibles such as perceived care, concern and listening skills. This traditionally has been called "bedside manner." A physician with average medical and surgical skills that projects compassion and concern may have a better reputation than a superlative clinician or surgeon that projects a haughty, non-caring, non-listening persona.

Another powerful tool in the art of medicine and communication is eye contact. One increasing dilemma spawned by electronic health records is looking at the monitor as though it were the most important thing in the exam room.

Positioning of the patient, the computer and the physician is important. The physician and staff must look away from the monitor and frequently make eye contact and acknowledge the primacy of the patient not their electronic health record. The conundrum is to create a thorough EHR and a mutually satisfactory patient encounter.

Other important skills to develop are: a look of benevolence, an empathetic attitude, appropriate tone of voice, conveying a high degree of professional competence, being informative, instructive and enlisting the patient as "co-therapist" in their disease treatment plan.

Placebo Effect

The 'placebo effect' is profound and poorly understood. The word "placebo" comes from the Latin for "I shall please." Studies have shown that about 30% of the time, the use of placebos is effective.[4] Scientifically, the purpose of a placebo is to serve as an inactive control for randomized clinical studies. However, placebos are not completely inactive.[5] It has been demonstrated by neuroscientists using functional MRI that a placebo can produce anesthesia in the pain centers of the brain.[6] Words, symbols, and meaningful rituals are active in shaping the



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In artful medicine the powers of touch and listening cannot be over-emphasized. What patient could doubt their physician's humanity and concern after hearing, "I will see you through this, I will not abandon you, I am sorry this happened to you."

patient's brain. The mind can fool the body - a secret healers and charlatans have known for millennia. Shamans, witch doctors, priests, and medicine men have used placebos with rituals to heal. The ethical use of placebos is outlined in the World Medical Associations Declaration Helsinki.[7]

Alternative Medicine

Rudyard Kipling said, "The East is east and the West is west and never the twain shall meet."[8] However, today we are incorporating healing therapies from both oriental and occidental worlds. Some alternative medicines, now called Complementary Alternative Medicine (CAM), have been shown scientifically effective.

Acupuncture from Chinese medicine has been a useful adjunct for fifty medical conditions, including stress.[9] The National Institute for Health is endorsing acupuncture as a potential treatment for migraines, menstrual cramps and addiction.[10]

Eastern medicine has taken a more holistic approach. In China, the early stages of medicine and magic were indistinguishable. The harmony of nature - Yin and Yang - a balance. Disease is the result of an imbalance of Yin and Yang. Many medical centers and schools are now adding CAM as part of their curriculum for medical students.

Theology

The history of medicine is interlinked with theology. Faith and superstition are twins.[1] Humans have always prayed for help and healing. If their prayers are answered, an offering is given - an "ex-voto," or a gift in gratitude for fulfillment of the pray-a just as in ancient times. The power of prayer is controversial. A well-constructed scientific controlled investigation The Coronary Bypass Study did not show any difference between the controls and the patients who were prayed for.[11] Physicians must always respect the faith traditions and beliefs of their patients.

Rituals Then and Now

In the past, the "patient" (from the Latin "to suffer") made a pilgrimage to a temple of healing or a shrine to ask for guidance and relief from illness. Today, patients go to a medical center or hospital looking for help. The modern MRI has atavistic rituals. Patients enter the inner sanctum of the shrine - the MRI room. They wear special garments while hearing the incantations of the whirling sounds of the MRI. When the ceremony (procedure) is ended, the priest in the white robes doesn't look at the entrails of an animal to divine the future, but a doctor holds up an image of the patient's inner self to guide the path to healing.

Conclusion

The highest level of the practice of medicine includes rendering the most up to date scientific therapeutics using the timeless artistry of compassionate human to human interaction.

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MM



Not Enough Primary-Care Doctors? Try Missouri's Prescription

by Arthur L. Caplan, PhD

Everyone agrees that the United States does not have enough primary-care physicians. There are huge swaths of the nation, especially rural and inner-city areas, that lack any primary-care physicians. The Department of Health and Human Services estimates that the shortage is at least 16,000 doctors.

Various strategies have been pushed to solve the problem, such as creating medical schools that emphasize educating primary-care providers, increasing the number of residencies for medical school graduates, and expanding the number and authority of non-physician providers of primary care to include nurse practitioners, physician assistants, psychologists and pharmacists.

But these are all long-term changes to a problem that is only going to become more dire. A growing aging population will need more primary medical care. The Affordable Care Act, with its laudable emphasis on primary care and prevention, is likely to increase the demand for primary-care doctors as insurance coverage is extended to more Americans. Some primary-care doctors, already overwhelmed by patient demand and paperwork, are becoming less accessible by creating smaller, boutique cash-only practices or are simply retiring.

So what to do? One exceedingly controversial idea has just become law in Missouri.

Missouri will allow medical school graduates to work as "assistant physicians" treating patients in underserved rural areas, even though they have not been trained in a residency program. In the U.S., at least one year of residency after medical school is usually required to practice medicine independently. Most medical school graduates spend at least three years in residency before starting to practice on their own. Under the new law, an assistant physician must have passed the first two sections of the national licensing exam for doctors but not the final one. If they want to become full-fledged physicians, they will still have to pass the last test and do a one-year residency.

These assistant physicians - not to be confused with physicians' assistants, who are not medical school graduates - must work in person with a collaborating physician for 30 days and could prescribe most medications. They then may treat patients on their own if they practice within a 50-mile radius of that supervising doctor. They also must be approved by the state Board of Healing Arts, which issues medical licenses.

The Missouri State Medical Association, which represents the state's 6,500 physicians, helped draft the legislation. It argued the law was needed to address a severe shortage of health care professionals in the state. At least one-fifth of Missouri's residents lack adequate access to a doctor.

There are many national medical groups who oppose the idea. Letting someone practice without a residency in the view of critics is to dangerously weaken professional competency.

So who will these new doctors be? Some will be graduates of medical schools who failed to get into a residency program - a growing problem as more medical schools open but more residencies do not. Even some highly competitive students do not get a residency in their chosen specialty. This year, among students who are more than one year out of medical school, and thus probably in their second try at getting a residency, only 48% succeeded.



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Others will have failed or gotten low scores on Step 1 or Step 2 of the U.S. Medical Licensing Examination on the first try, even if they passed or did better on subsequent attempts. Some will have gone to non-U.S. medical schools.

It's a bit of a leap to say that those who choose the assistant physician route in Missouri all failed at getting a residency. A few medical school grads will choose to be an assistant physician rather than enter residency. That being said, the most competitive U.S.- and non-U.S.-trained students are going to go the residency route.

So the bottom line is that assistant physicians are not likely to be the cream of the U.S. medical school crop. But that crop is not yielding many primary-care providers, given the level of debt new graduates face and the lower salaries primary care pays. And new residency slots are not going to open any time soon.

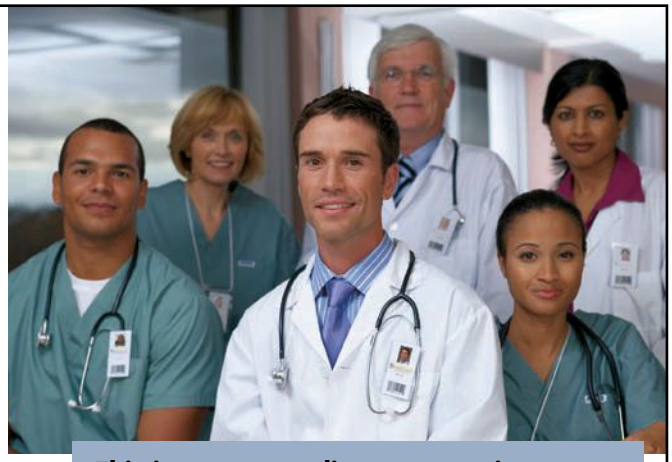
The real question is, can someone who successfully got through four years of medical school, including a lot of clinical time, who is supervised and certified by another doctor for a month and by the state board but who is probably not near the top of their class, deliver high-quality primary care to people who currently have nothing?

I think we don't know. But I think it is very likely that most can. And Missouri, and other states like Michigan that are considering following its lead, are right to give assistant physicians a chance. Fairly good primary care is a lot better than no care at all.

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Another Failed Government Program: Pay For Performance

by Arthur Gale, MD

All of the major objective independent studies to date in England and the United States have shown that pay for performance does not improve the quality or efficiency of patient care. Preliminary studies also indicate that it does not reduce costs.

Pay for performance is a health insurance program wherein financial incentives are made available to physicians and hospitals in return for achieving "better" outcomes. Under this system providers of health care services are rewarded financially for achieving certain goals or performance measures for quality and efficiency. This model represents a fundamental change in how doctors are compensated from fee for service payment. Although some more recent programs have attempted to analyze cost savings, as well as quality, the main focus to date of pay for performance has been improvement in the quality of medical care.[1]

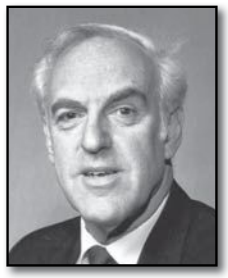
Two recent reports from England, where pay for performance has existed for ten years, cast doubt on the assumption that pay for performance improves quality. Both reports appeared in recent issues of the *New England Journal of Medicine*.[2, 3]

One large study analyzed the 30-day in-hospital mortality for three medical diagnoses among 1,825,518 hospital admissions to 24 hospitals. Mortality for these conditions was compared to 137 hospitals not in the pay for performance program. The authors of the study concluded that although short-term relative reductions in mortality were achieved, there was no long-term reduction in mortality in the hospitals using pay for performance compared to the control hospitals not using pay for performance.[2]

The second article attempts to assess the effects of pay for performance quality measures on physicians treating patients in their offices. Most physicians used electronic health records and had to meet specific goals using metrics just as is done in the United States today. After analyzing more than 20 systemic studies over a ten \-year period the authors conclude that the pay for performance program has many problems and will have to be "reined in."[3]

They list five lessons to be learned from the United Kingdom experience with pay for performance:

1. Pay for performance is not a "magic bullet" and needs to be combined with other quality improvement initiatives.
2. Financial incentives may increase the risk of unintended consequences such as gaming or "cherry picking" healthier patients and avoiding sicker poorer patients. Financial incentives must be aligned with professional values.
3. Pay for performance administrators need to recognize that large parts of clinical practice cannot currently be measured.
4. There are substantial problems with linking patient experience scores (rating of doctors by patients) directly to physicians' pay and this unpopular indicator was dropped in 2011.
5. Attaching 25% of income to pay for performance, which increased revenue for individual physicians (by as much as $40,000) resulted in doctors 'focusing on limited areas of patients' problems. Reduction of pay for performance's role in physician income was enacted and was welcomed by physicians.



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To summarize, this study shows that pay for performance as it directly affects clinicians in the United Kingdom is at best a work in progress if not an outright failure.

In the U.S. there have also been studies of pay for performance. The largest such study using Medicare data compared outcomes between 252 participating and 3,363 control hospitals between 2003 and 2009. The authors compared 30-day mortality among more than six million patients who had acute myocardial infarction, congestive heart failure, pneumonia, or who underwent coronary bypass grafting. They concluded: "We found no evidence that in the largest hospital-based pay for performance program that led to a decrease in 30-day mortality."[4] Other studies have shown similar results.

Studies of pay for performance have been undertaken in low income minority populations. Hospitals that care for these patients performed worse on both quality and cost metrics. There are fears that pay for performance could exacerbate racial and ethnic health disparities if providers avoid patients that are likely to lower their performance scores.

Despite the absence of clinical benefit, policy makers continue to promote pay for performance. Some investigators have challenged the basic concept that quality measures as determined by experts can improve the quality of care. They point out how the metrics used to define quality care can change. One example they cite was the recommendation for tight control of blood sugars in ICUs. This recommendation was later contradicted by new data. They also point out how experts in a particular field can disagree on optimum treatment of patients. Their conclusion is that "Medicine is an imperfect science… Information evolves and changes… Flexibility is appropriate… A good doctor exercises sound clinical judgment by consulting expert guidelines and assessing ongoing research, but then decides what quality care is for the individual patient. And what is best sometimes deviates from the norms."[5]

In another article titled "Rise of the Medical Expertocracy" the same investigators elaborate on this point by challenging governmental panels of experts who offer "sweeping recommendations on clinical care." They note that in most of the 20th century a form of paternalism existed where the physician dictated what was to be done and the patient complied. This has been replaced by a new form of paternalism "based on the assumption that Americans are not receiving quality care. A new lucrative industry has grown up to generate ever more medical metrics, to give report cards to doctors and hospitals, and to base payments on compliance with 'best practices'. Yet beyond safety protocols, there is scant evidence that such measures improve health."[6]

Despite the lack of evidence that pay for performance improves quality it has become popular among policy makers and private and public payers including Medicaid and Medicare. It is included in the Affordable Care Act. A number of physician organizations have expressed concern about the validity of quality indicators, patient and physician autonomy and privacy, and increased administrative burden. These organizations include the American Academy of Family Physicians, American College of Physicians, American Geriatric Society, American Academy of Neurology, and the Endocrine Society. The American Medical Association has developed guidelines for pay for performance.[7]

All of the major objective independent studies to date in England and the United States have shown that pay for performance does not improve the quality or efficiency of patient care. Preliminary studies also indicate that it does not reduce costs. It is simply an added costly burden that physicians and hospitals have to cope with. The government, including all of its policy makers and experts, must now review the data, accept the facts and cut back on their cherished but failed pay for performance programs.

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Product Liability Suits Involving Drug or Device Manufacturers and Physicians: The Learned Intermediary Doctrine and the Physician's Duty to Warn

by Jason Husgen, JD

Common-sense measures are essential for physicians to meet their legal duty to patients when patient treatment involves prescription drugs or medical devices.



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The information contained in this article should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and readers are encouraged to consult their own attorney regarding specific legal questions.

Introduction

Robert Larkin became paraplegic after a 1964 car accident.[1] Due to his paraplegia, Larkin suffered significant musculoskeletal pain. Larkin was treated by the same internist beginning in 1988. Over the years, the physician prescribed a variety of nonsteriodal anti-inflammatory drugs to treat Larkin's pain.

In July 1998, Larkin visited his physician, complaining of a head cold and exhibiting symptoms of blisters in his mouth and on his arms and legs. The physician prescribed separate medications to treat Larkin's apparent sinus infection and his blistering.

Larkin's condition did not improve. In late August 1998, Larkin again visited his physician. He complained of sinusitis and shoulder pain. For the sinusitis, Larkin's physician gave him a six-pill sample of Zithromax, an antibiotic manufactured by Pfizer, Inc. For the shoulder pain, Larkin's physician changed his anti-inflammatory medication to Daypro, a drug manufactured by G.D. Searle & Co.

Over the next few months, Larkin began to develop fluid-filled blisters over a large portion of his body. When the blisters drained, Larkin's skin sloughed off. Larkin's physician diagnosed him with toxic epidermal necrolysis ("TEN"), and its milder form known as Stevens-Johnson syndrome. TEN is a severe and sometimes life-threatening condition, which is often drug-induced. More than 100 drugs - including Zithromax and Daypro - have been implicated in TEN cases.

Prior to his TEN diagnosis, Larkin had been able to move about with crutches. After his TEN diagnosis, and several



weeks in a hospital burn unit to treat and eventually reduce his direct TEN symptoms, Larkin exhibited substantially decreased stamina and became wheelchair-bound.

In late 1999, Larkin sued Pfizer and Searle for his injuries, alleging that Zithromax and Daypro were defective and unreasonably dangerous products, thereby causing his injuries. Pfizer and Searle successfully insulated themselves from liability, however. The manufacturers argued that Larkin's doctor knew that TEN was a risk associated with both Zithromax and Daypro, and that he failed to warn Larkin of this risk because he believed that the risk was insignificant. After years of litigation, Larkin was unable to recover damages from the manufacturers. Multiple courts sided with the manufacturers' argument, concluding that the buck stopped with the physician.[2]

The Role of the Learned Intermediary Doctrine in Drug or Device Product Liability Suits

The argument made by Pfizer and Searle in the Larkin case - known as the "learned intermediary" doctrine - is very common in cases involving injuries allegedly caused by a prescription drug or medical device. In a typical case, an injured patient files suit against all parties in the "chain of distribution" of the drug or device, from the manufacturer down to the physician. But, because the ultimate treatment decision is made by the physician in the course of the doctor-patient relationship, the manufacturer of a drug or device is routinely able to avoid liability by "blaming the physician."

In this regard, a manufacturer generally contends that, so long as the manufacturer transferred the drug or device to the treating physician with adequate accompanying information (including warnings about any risks), subsequent treatment decisions made by the physician break the line of causation between the manufacturer and the patient. An injured patient, unable to demonstrate causation, is then unlikely to prevail on a claim that his injuries resulted from the manufacturer's conduct. An injured patient's claim against his physician arising from the same injury, however, often survives. This places great pressure on physicians to reach settlements with patients in such suits.[3]

The learned intermediary doctrine is settled law in an overwhelming majority of states, including Missouri.[4] It limits a drug or device manufacturer's duty to warn of its product's risks to treating physicians, who then serve as "learned intermediaries," assuming the duty to pass those warnings on to patients.

Three basic and related rationales have, historically, supported the learned intermediary rule. First, the treating physician is in a superior position to impart warnings to patients, and to exercise her independent medical discretion in determining whether a treatment is appropriate for a particular patient.[5] Second, manufacturers lack effective means to communicate directly with each patient.[6] Thirdly, imposing a duty to warn on the manufacturer would unduly interfere with the doctor-patient relationship.[7] Further, as a corollary, some courts have expressed concern that, since the typical manufacturer's warning may list scores of potential side effects regardless their probability, lay consumers might overreact to a manufacturer's warning and forego critical treatment.[8]

In short, with few exceptions, a manufacturer relieves its duty to warn patients by providing adequate warnings to treating physicians, whether or not those physicians adhere to the warnings and communicate them to their patients.



The Learned Intermediary Doctrine and the Pressures and Consequences of Physician Settlements in Product Liability Suits

Because the physician is often the last defendant standing in drug or device "chain of distribution" suits, the eventual pressure on a physician to settle with an injured plaintiff is, again, strong. And a separate rule, known as the "settlor-barred" doctrine, commonly prevents a physician from, later, seeking contribution from the manufacturer to offset her losses.[9]

A Missouri "chain of distribution" suit illustrates this rule well.[10] In 1978, a physician at Cardinal Glennon Hospital in St. Louis administered Orimune, an oral polio vaccine, to three-month old Danny Callahan. Callahan appeared to be in good health following the vaccination, until approximately one month later, when he was diagnosed with an unrelated perirectal abscess. Following protracted treatment of the abscess, Callahan contracted polio, which permanently paralyzed his legs and left arm. A jury concluded that the hospital had been negligent in treating Callahan's abscess, and that this negligence suppressed Callahan's immune system, rendering him susceptible to the live polio virus in the vaccine.

The doctor settled with Callahan prior to trial for $290,000. The doctor then sued the manufacturer and distributor of Orimune - American Cyanamid Company and Hesselberg Drug Company, respectively - seeking contribution from them to offset his $290,000 settlement. The Missouri Supreme Court concluded that the "settlor-barred" doctrine, which prevents a settling defendant from recovering from a third party unless he has relieved the third party of liability to an injured plaintiff, prohibited the doctor's contribution claims against American Cyanamid and Hesselberg. The court explained that, by settling with Callahan, the doctor "discharged only his liability … and protected himself from contribution claims of other defendants." But, equally, settling with Callahan barred the doctor "from seeking contribution from American Cyanamid or Hesselber."[11]

A clear consequence of this settlement bar is that the pressure on physicians to settle in drug or device suits is paired with an element of finality. Settlement will almost always prevent a physician from, subsequently, seeking contribution from a drug or device manufacturer. This is true regardless the merits of a physician's claim, because the physician speaks only for her own conduct, not a manufacturer's.

How Physicians Can Better Protect Themselves From Liability in Drug or Device Product Liability Suits: Satisfying the Duty to Warn

In light of the shifting of accountability from manufacturers to physicians in drug or device product liability suits, as well as the resulting pressure on physicians to settle and the finality of settlement, it is critical for physicians to safeguard themselves by meeting their duty to warn patients of the risks and side effects associated with a prescription drug or medical device.

Although no legal outcome is certain, there are sensible steps that physicians should take in an effort to satisfy their duty to warn patients:

- Stay informed of FDA drug and device recalls and FDA-approved drug and device labeling requirements.
- Keep abreast of drug and devices manufacturers' product disclosures and warnings. Also, date and archive manufacturers' disclosures and warnings for recordkeeping purposes.
- Determine if additional information regarding a drug or device is available, including studies suggesting risks or dangers that the FDA has yet to act on.
- Require patients to provide a list of all prescription and over-the-counter drugs being taken. Relatedly, inform patients of potential drug-food and drug-drug interactions.

- Advise patients of other treatment options available and the medical rationale for the one being used.
- Document all disclosures and warnings made to patients.
- Instruct patients to read drug labels.
- Provide patients with simplified drug or device instructions (e.g., dosing instructions) in writing.
- Obtain written informed consent from patients when prescribing a drug or using a medical device for an off-label purpose.
- Seek legal or risk management guidance when uncertainties arise.

The law is well settled that physicians have a primary duty to warn patients about the risks and complications associated with prescription drugs and medical devices. While legal arguments have been made - by both injured patients and physicians themselves - that manufacturers should be responsible for this duty to warn, courts continue to hold physicians accountable. Common-sense measures, like those set forth above, are essential for physicians to meet their legal duty to patients when patient treatment involves prescription drugs or medical devices.

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CORRESPONDENCE

Medical Libraries Lose Their Librarians

I enjoyed reading about the trends in Academic Health Science Libraries in the September/October 2014 issue of *Missouri Medicine*. For those of us on the front lines practicing clinical medicine, the changes in the medical library are not all for the better. The trend now in community hospitals is to discharge their medical librarians, where they are seen as an unnecessary financial burden. The administration released ours where I practice and I have been waiting over a year for the hospital administration to come up with a plan to retain assistance in searching the literature. Obviously, this is not a high priority for medical administration at the community level.

Medical librarians have been a tremendous help to me both to research unusual disease processes in a given patient and in collecting literature prior to onset of a clinical study. Just because you are a physician does not mean that you can effectively or efficiently search the world's online holdings to collect clinically-relevant information. Our journals support this observation in many letters to the editor when an article is published which omits a relevant reference. The missed articles are not necessarily old, as the authors of the missed publications are often still alive and publishing.

And probably the most disturbing thought herein is that this is likely to be our trend for the future as no fix for the problem is on the horizon.

William L. White, MD
MSMA Member since 1995
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Editor's Note

This increasing tendency is disturbing. North Kansas City Hospital has eliminated their medical librarian also. I have found the medical librarian a great resource for both patient care and research.

Thank You to Non-Editorial Board Reviewers

Missouri Medicine would like to publicly thank non-Editorial Board experts who have done peer-review of submitted manuscripts in 2014: **Doug Bogart, MD**, **Jim Blaine, MD**, Brady Deaton, PhD, **John Doane, MD**, **Lenard Politte, MD**, **John Taylor, MD**, Randy Sprague, MD, Dragan Svrakic, MD, and Jane McHowat, PhD.

Missouri Medicine announces a new addition to its Contributing Editor and Editorial Boards. Members are selected on the basis of exceptional professional accomplishments and expertise in their specialty.



Jeffrey G. Copeland, MD, FACS, MSMA member since 1988, currently the MSMA President and a Plastic Surgeon from St. Charles, has accepted the position of Contributing Editor.



Donald K. Allcorn, MD, of Lincoln, has been an MSMA member since 1980. His family was recently honored by the American Legion with a three-star Blue Star Banner and certificates for the military service of Air Force Capt. Nicholas C. Scalzitti, Navy Lt. Jacob Crabb, and Air Force Combat Controller and Staff Sgt. Jesse Wedemeyer.



Jason Anast, MD, is helping Carroll County Memorial Hospital bring the addition of urology services to its outpatient clinic this month. MSMA is pleased to call this young physician a member since 2013.



A 50-year member of MSMA, **Andres Apostol, MD,** of Monett, has been honored by the Missouri Senate with a framed resolution recognizing his career in medicine.

Rachelle Bridges, MD, became an MSMA member in 2010 and has joined Ozarks Community Hospital at their new location in Sparta.

New MSMA Member **Humam Farah, MD,** of Palmyra, attended the American Thoracic Society's Leadership Summit in Orlando, Fla.

Congratulations to Springfield-based Caduceus - The Doctor's Band for celebrating its 25th anniversary this year playing jazz and swing ensemble for charity. MSMA member physicians of the band include **Drs. Rod Geter**, since 1982; **Frank Corry**, since 1977; **Ben Lampert**, since 1985; and **Charlie Ash**, since 1977.

Metropolitan Medical Society of Greater Kansas City Immediate Past President **John Gianino, MD**, had the distinct honor of presenting a Lifetime Achievement Award to **Charles Van Way, III, MD**, during their Annual Meeting on October 8. Dr. Van Way has been a Contributing Editor to *Missouri Medicine* since 2007 and an MSMA member since 1989.

MSMA is very proud of one of our newest members, **Stacy Harms, MD,** who is preparing for a three-year medical mission to rural Zimbabwe, Africa.

Two MSMA members from Hannibal Clinics participated in the MU School of Medicine Summer Intern Program. **Trish Hirner, MD**, member since 1999, worked with Nick Arnold from New London; and **Gina Pontius, MD**, member since 2011, worked with Alan Keller from Palmyra.



George Hruza, MD, MSMA Treasurer and member since 1989, was inaugurated as President of the American Society for Dermatologic Surgery, in San Diego on November 7, 2014. He represents an organization of almost 6,000 dermatologists specializing in dermatologic surgery.



Congratulations to **Dr. Robert W. Jones'** Eye Center for being highlighted as the West Plains Chamber of Commerce Business of the Week! Your membership support since 1991 is very much appreciated.



An MSMA member since 1980, **Jerry Kennett, MD,** of Columbia, is resuming to a full-time cardiology practice schedule in January.



MSMA commends **Debra Koivunen, MD,** MSMA member since 1990, for serving as the new medical director of Ellis Fischel Cancer Center's breast clinic and cancer screening clinic.

Benjamin Lampert, MD, MSMA member since 1985 from Springfield, has been elected to serve as president of the Missouri Board of Healing Arts, and **Jeffrey Carter, MD,** member since 2002 from St. Louis, is the newly-elected secretary of BOHA. MSMA is proud of these members, as well as other BOHA Board Members, including **James DiRenna, DO**, MSMA member since 1996 from Gladstone; **Bradley Freeman, MD**, MSMA member since 1999 from St. Louis; and **David Poggemeier, MD**, MSMA member since 1993 from St. Charles.

New MSMA Member **Liana Makarian, MD,** of West Plains, was among the panelists who spoke in October when Ozarks Medical Center hosted cancer treatment experts to discuss prevention, diagnosis and treatment to 50 women during a Ladies First Dinner.



Erik Meidl, MD, MSMA member since 1996 from Hannibal, recently earned his recertification from the American Board of Internal Medicine. Dr. Meidl also attended the 12th Annual Cardiology Update at the University of Missouri.



Drs. Ben Till (left) and **Kirby Turner** (right) of Kneibert Clinic in Poplar Bluff were recently honored for 50 years of medical practice at the University of Missouri's homecoming during the 57th Annual Physician Alumni Weekend. Both have been members of MSMA since 1977.

MSMA wants to wish **Hope Tinker, MD**, all the best as she moves her practice to Fitzgibbon Hospital in Marshall, where the clinic's name is now Fitzgibbon Family Health. Dr. Tinker joined MSMA last year. **MM**

In Memoriam

- Lafe W. Bauer, MD, 94, Little Rock, AR, Anesthesiology, March 14, 2014
- John J. Corzine, MD, 64, St. Joseph, MO, Anesthesiology, June 21, 2014
- James R. Criscione Jr. MD, Arnold, MO, Emergency Medicine, September 14, 2014
- Birkle Eck, MD, 97, St. Louis, MO, Internal Medicine, September 17, 2014
- Louis A. Gilula, MD, 71, St. Louis, MO, Radiology, July 2, 2014
- Theodore J. Glenn, MD, 86, San Antonio, TX, Psychiatry, February 25, 2014
- Cornelius E. Hogan, MD, 83, St. Louis, MO, Internal Medicine, June 6, 2014
- R. Eugene Holemon, MD, 81, St. Louis, MO, Psychiatry, May 30, 2014
- Roland C. Kappesser, MD, 89, Utica, MO, Anesthesiology, November 10, 2014
- William E. Lafferty, MD, 60, Kansas City, MO, Allergy, May 5, 2014
- James P. McGonigle, MD, 74, Longboat Key, FL, Ophthalmology, June, 2014
- Franklin L. Mitchell, MD, 84, Columbia, MO, General Surgery, November 14, 2014
- Karl D. Nolph, MD, 77, Columbia, MO, Nephrology, June 16, 2014
- Mark D. Ost, MD, 82, Pineville, MO, Pathology, February 10, 2014
- Chris L. Palcheff, MD, 91, Springfield, MO, Pediatrics, July 12, 2014
- Carol A. Robinson, MD, 57, St. Louis, MO, Pediatrics, April 22, 2014
- Russell D. Shelden, 92, Kansas City, MO, Anesthesiology, June 20, 2014

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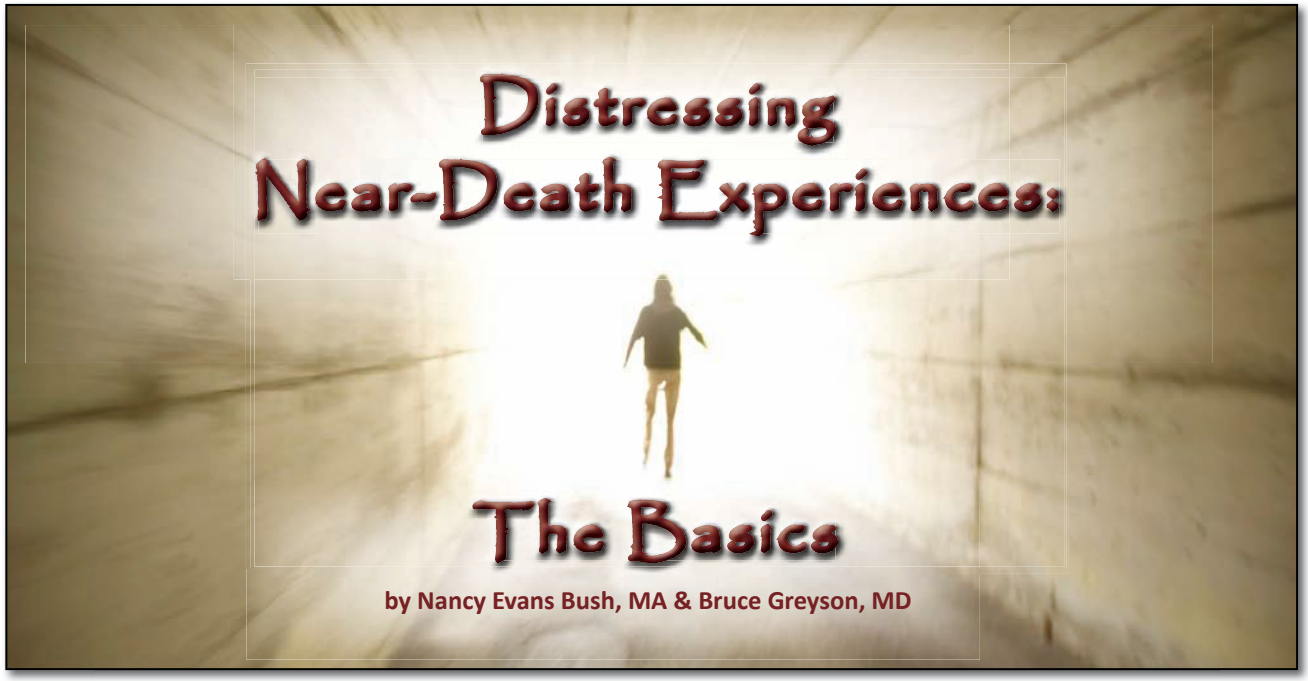
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From the following who most graciously made donations
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Distressing NDEs occur under the same wide range of circumstances and feature most of the same elements as pleasant NDEs. What differs is the emotional tone, which ranges from fear through terror to, in some cases, guilt or despair.

The great majority of near-death experiences (NDEs) reported publicly over the past four decades have been described as pleasant, even glorious. Almost unnoticed in the euphoria about them has been the sobering fact that not all NDEs are so affirming. Some are deeply disturbing.

Few people are forthcoming about such an event; they hide; they disappear when asked for information; if inpatient, they are likely to withdraw; they are under great stress. What do their physicians need to know to deal with these experiences?




Nancy Evans Bush, MA, (left) is President Emerita, International Association for Near-Death Studies. Bruce Greyson, MD, is the Chester F. Carlson Professor of Psychiatry & Neurobehavioral Sciences and Director, Division of Perceptual Studies, University of Virginia School of Medicine.
Contact: nanbush5@gmail.com

Varieties of Distressing Near-Death Experiences

We have documented three types of distressing NDE: inverse, void, and hellish.[1] The brief descriptions below illustrate the types. All examples are from the authors' files unless otherwise indicated.

Inverse NDE

In some NDEs, features usually reported in other NDEs as pleasurable are perceived as hostile or threatening. A man thrown from his horse found himself floating at treetop height, watching emergency medical technicians working over a his body. "No! No! This isn't right!" He screamed, "Put me back!" but they did not hear him. Next he was shooting through darkness toward a bright light, flashing past shadowy people who seemed to be deceased family members waiting. He was panic-stricken by the bizarre scenario and his inability to affect what was happening.

A woman in childbirth felt her spirit separate from her body and fly into space at tremendous speed, then saw a small ball of light rushing toward her: "It became bigger

and bigger as it came toward me. I realized that we were on a collision course, and it terrified me. I saw the blinding white light come right to me and engulf me."

A woman collapsed from hyperthermia and began re-experiencing her entire life: "I was filled with such sadness and experienced a great deal of depression."

The Void NDE

An NDE of the "void" is an ontological encounter with a perceived vast emptiness, often a devastating scenario of aloneness, isolation, sometimes annihilation. A woman in childbirth found herself abruptly flying over the hospital and into deep, empty space. A group of circular entities informed her she never existed, that she had been allowed to imagine her life but it was a joke; she was not real. She argued with facts about her life and descriptions of Earth. "No," they said, "none of that had ever been real; this is all there was." She was left alone in space.[2, pp. 1-5]

Another woman in childbirth felt herself floating on water, but at a certain point, "It was no longer a peaceful feeling; it had become pure hell. I had become a light out in the heavens, and I was screaming, but no sound was going forth. It was worse than any nightmare. I was spinning around, and I realized that this was eternity; this was what forever was going to be. . . . I felt the aloneness, the emptiness of space, the vastness of the universe, except for me, a mere ball of light, screaming."

A woman who attempted suicide felt herself sucked into a void: "I was being drawn into this dark abyss, or tunnel, or void. . . . I was not aware of my body as I know it. . . . I was terrified. I felt terror. I had expected nothingness; I expected the big sleep; I expected oblivion; and I found now that I was going to another plane . . . and it frightened me. I wanted nothingness, but this force was pulling me somewhere I didn't want to go, but I never got beyond the fog."

A man who was attacked by a hitchhiker felt himself rise out of his body: "I suddenly was surrounded by total blackness, floating in nothing but black space, with no up, no down, left, or right. . . . What seemed like an eternity went by. I fully lived it in this misery. I was only allowed to think and reflect."

Hellish NDE

Overtly hellish experiences may be the least common type of distressing NDE. A man in heart failure felt himself falling into the depths of the Earth. At the bottom was a set of high, rusty gates, which he perceived as the gates of hell. Panic-stricken, he managed to scramble back up to daylight.

A woman was being escorted through a frighteningly desolate landscape and saw a group of wandering spirits. They looked lost and in pain, but her guide indicated she was not allowed to help them.

An atheistic university professor with an intestinal rupture experienced being maliciously pinched, then torn apart by malevolent beings.[3]

A woman who hemorrhaged from a ruptured Fallopian tube reported an NDE involving "horrific beings with gray gelatinous appendages grasping and clawing at me. The sounds of their guttural moaning and the indescribable stench still remain 41 years later. There was no benign Being of Light, no life video, nothing beautiful or pleasant."

A woman who attempted suicide felt her body sliding downward in a cold, dark, watery environment: "When I reached the bottom, it resembled the entrance to a cave, with what looked like webs hanging. . . . I heard cries, wails, moans, and the gnashing of teeth. I saw these beings that resembled humans, with the shape of a head and body, but they were ugly and grotesque. . . . They were frightening and sounded like they were tormented, in agony."

Three Types of Response

These NDEs are traumatic in their realness, their rupturing the sense of worldly reality, and the power of the questions they raise. Three common responses cut across all experience types: the turnaround, reductionism, and the long haul.[2]

1. The Turnaround: "I needed that"

A classic response to profound spiritual experience is conversion, not necessarily changing one's religion but in the original sense of the Latin convertere meaning "to turn around." The terrifying NDE is interpreted as a warning about unwise or wrong behaviors, and to turn one's life around: "I was being shown that I had to shape up or ship out, one or the other. In other words, 'get your act together,' and I did just that."[4, p. 46]

Movement toward a dogmatic religious community is common in this group. Clinical social worker Kimberly Clark Sharp observed, "All the people I know who have had negative experiences have become Bible-based Christians. . . . They might express it in various sects. But they all feel that they have come back from an awful situation and have a second chance."[5, p. 85]

No evidence supports the conventional assumption that "good" people get pleasant NDEs and "bad" people have distressing ones. Saints have reported extremely disturbing NDEs, while felons and suicide attempters have encountered bliss.

Fear may remain a powerful influence, but a strict theology may offer a way out. The atheistic professor above who experienced being maliciously pinched, then torn apart by malevolent beings left his university and attended seminary.[3] Others also reported newfound devotion, "I've stopped drugs, moved back to Florida, and now I'm in Bible college. I used to have a casual attitude toward death, but now I actually fear it more. So yes, it was a warning. I was permitted another chance to change my behavior on earth. . . . I've taken my fear of death and given it to the scriptures."[4, p. 43] Since then, I have dedicated my life to the most high God Jehovah, and spend 60 hours a month speaking and teaching about the Creator of Heaven and earth and all living creatures. I'm not worried now about when I die, because now I know that God has promised us something far more."

2. Reductionism: "It was only . . ."

As a response to a distressing experience, reductionism has been described as the "defense [that] allows one to repudiate the meaning of an event which does not fit into a safe category" and to "treat the event as if it did not matter."[6, p. 35]

A woman whose anaphylactic reaction precipitated an NDE with both loving and frightening elements concluded, "There are actual rational explanations for what I experienced. . . . The brain, under stress, releases natural opiates that stop pain and fear. . . . Lack of oxygen disrupts the normal activity of the visual cortex. . . . Too much neural activity in the dying brain causes stripes of activity. . . . Our eyes, even closed, interpret those stripes of activity as . . . the sensation of moving forward in a tunnel. . . . There are more brain cells concentrated in the middle of the cortex than on the edges so as we get closer to death, the brain interprets all those dense cells with their crazy activity as a bright light in the middle of our visual field. It's all very scientific."[7, p. 95]

Her conclusion is that, based on the scientific evidence, the experience had no ontological meaning. Any lingering anxieties will go unaddressed.

A woman who had a terrifying experience during childbirth likewise dismissed the reality of the experience: "Perhaps it was the effect of the ether and not an NDE." A woman attacked by a lion dismissed the memory of her NDE as hallucinatory: "I often wonder if, in the shock of the attack, my mind played tricks on me, and that I may have just been unconscious and my brain deprived of oxygen."

A man who for many years had spoken publicly about his radiant NDE had a second experience, in which he felt attacked by gigantic, sinister, threatening geometric forms, leaving him with a deep-seated pessimism and terror of dying. Learning that drug-induced hallucinations include geometric forms, he concluded that his second NDE was "only a drug reaction." This may be an appropriate conclusion clinically, but the experience remains. Reductionism provides a temporary buffer to mask questions and anxieties, but does nothing to resolve them.

3. The Long Haul: "What did I do?"

Other experiencers have difficulty comprehending or integrating terrifying NDEs. These people, years later, still struggle with the existential implications of the NDE, "I had an experience which has remained with me for 29 years. . . . It has left a horror in my mind and I have never spoken about it until now." And, "After all these years, the nightmare remains vivid in my mind." "For some reason, [31 years later] all the memories are back and vivid. . . .It's like living it all over again, and I don't want to. I thought I had it all resolved and in its place, but I'm having a really bad time trying to put it away this time.

Also, "For the next 50 years, I would try to repress the memory of the black, threatening experience, because it felt so real it continued to be frightening, no matter how old I got." And, "I've been married for 33 years and I do

not even discuss the experience with my husband. . . . Yet it is as clear to me today as it was when it happened." Additionally, "I just buried the whole thing as deeply as possible, got very busy in civic affairs, politics. . . . It seems pretty clear to me now, though the specifics aren't in place, that there's some core issue that still needs dealing with."

"I see this vision as flashbacks constantly. I cannot get this out of my head. . . . I still see it in my mind from my own eyes. It has been two years, yet I have never talked about it. My husband does not even know. . . . I want to put this behind me, but am unable."

This group is often articulate people haunted by the existential dimension of their NDE, searching for a cognitively and emotionally grounding explanation. They find a literal reading of the event intellectually unacceptable, but reductionist explanations only assign a cause without addressing meaning. They struggle to make sense of the distressing NDE without destroying them (and their trust in the workings of the world) in the process.

More than others, these experiencers enter psychotherapy, some for many years, though without data, this may indicate nothing other than openness and financial means. Too often physicians prescribe medications to mask questioning and dismiss the NDE as fanciful or pathological; therapists will not address the matter or leave the client feeling blamed or romanticize spirituality and cannot deal with its dark side; and clergy have no idea what to say or reject the experience outright.

The religious element of their NDE is often an absence:

"I was filled with a sense of absolute terror and of being past the help of anyone, even God."

"I looked around me. Consciously searching for . . . God or some other angelic creature, but I was alone."

"I expected the Lord to be there, but He wasn't. . . I called on God and He wasn't there. That's what scared me."[4, p. 53]

Overwhelmingly, their questions include some variant of "What did I do to deserve this?" or "What are the rules, if the rules I lived by don't work?" Not for a long time, if ever, do they lose their fear of death." The man above attacked by a hitchhiker still struggled with the aftermath, "I've pondered if I was in that hell, will I go back on my death? Was I sent there for something perhaps I'll do in the future, or something I did in the past? . . . I don't believe in a hell, but it was such a strong experience, there is always that underlying uncertainty and trouble and fear."

Posttraumatic Growth

The psychological literature on posttraumatic growth did not exist in the early years of our study of distressing NDEs, so that aspect of response remains underreported. As a growing number of studies make clear, even the most devastating life event, "like the grit that creates the oyster, is often what propels people to become more true to themselves, take on new challenges, and view life from a wider perspective."[8, p. 7] This is a promising and as yet underdeveloped approach for clinicians working with those who report struggling after a distressing NDE.[9]

Seven Things to Know about Distressing Near-Death Experiences

1. Distressing NDEs occur under the same wide range of circumstances and feature most of the same elements as pleasant NDEs. What differs is the emotional tone, which ranges from fear through terror to, in some cases, guilt or despair. The reports typically lack two elements common in pleasant NDEs: a positive emotional tone and loss of the fear of death.

2. A notorious reluctance to report a distressing NDE may lead to long-lasting trauma for individuals as well as limiting the data on occurrence. A literature review covering thirty years of research concludes that as many as one in five NDEs may be predominantly distressing.[10]

3. The etiology of all such events remains unknown. Despite decades of clinical studies, none so far adequately explains either the cause or function of NDEs. Further, NDEs cross so many clinical circumstances and demographic bases, there is no way to predict who will have what type of NDE. No evidence supports the conventional assumption that "good" people get pleasant NDEs and "bad" people have distressing ones. Saints have reported extremely disturbing NDEs,[11, pp. 63-75] while felons and suicide attempters have encountered bliss.[12, pp. 41-44]

4. Pleasant NDEs tend to convey universal messages of compassion that cross religious and philosophical systems. Distressing NDEs typically have less focused messages but follow the ancient shamanic pattern of suffering/death/resurrection, which in less metaphoric terms can be read as an invitation to self-examination, disarrangement of core beliefs, and rebuilding. In practical terms, a common interpretation of a distressing NDE is that it is a message to turn one's life around.

5. The description of any NDE is shaped by the experiencer's pre-existing mental categories and

The great majority of near-death experiences (NDEs) reported publicly over the past four decades have been described as pleasant, even glorious. Almost unnoticed in the euphoria about them has been the sobering fact that not all NDEs are so affirming. Some are deeply disturbing.

vocabulary. As example, although the archetype of a benevolent guide is common in NDEs, individuals typically identify the presence according to their own cultural vocabulary. Any report identifying an archetypal individual by name is a perception that may or may not be factually true but cannot be confirmed as such. Understandably, it is facts like these which religious groups and materialists alike may find troubling. Secular Westerners often believe an NDE indicates a psychotic episode.

6. The primary effect of many NDEs is a powerful and enduring awareness that the physical world is not the full extent of reality. Because this perception runs so deeply counter to Western materialism, and conversely because its implications affect some dogmatic theological teachings, the new conviction commonly overturns experiencers' personal life and social relationships abruptly and permanently.

7. A major challenge for physicians and other scientists dealing with reports of near-death experience is to manage this intrusion of non-materialist religious and philosophical language and understandings into the hard data of clinical thinking. Curiously, it is at the extremes of religious fundamentalism and material scientism that one finds literalism an issue. For fundamentalists, the accounts are believed to be literally, physically actual; for convinced materialists, they must be dismissed as lunacy because a literal, physical actuality is impossible and no alternative concept is acceptable.

Raymond Moody, in the article introducing this series, observed, "The best practice for physicians is to stick strictly to clinical and research concerns."[13, p. 371] The post-NDE convictions of patients and their family members with whom physicians must interact are likely to make that a difficult suggestion to follow. Non-judgmental listening may be the most workable alternative.

Summary

Like the better-publicized pleasurable NDEs, distressing near-death experiences are both fascinating and frustrating as altered states of consciousness. Because of the deeply rooted concept of hell in Western culture and its Christian association with eternal physical torment, they pose serious challenges to the individuals who must shape their lives around such a profoundly durable event, and to their families, friends, and physicians. In the absence of clear-cut clinical data and universal cultural views, physicians are advised that neutrality of opinion and careful listening are likely to constitute best professional practice for addressing these difficult near-death experiences.

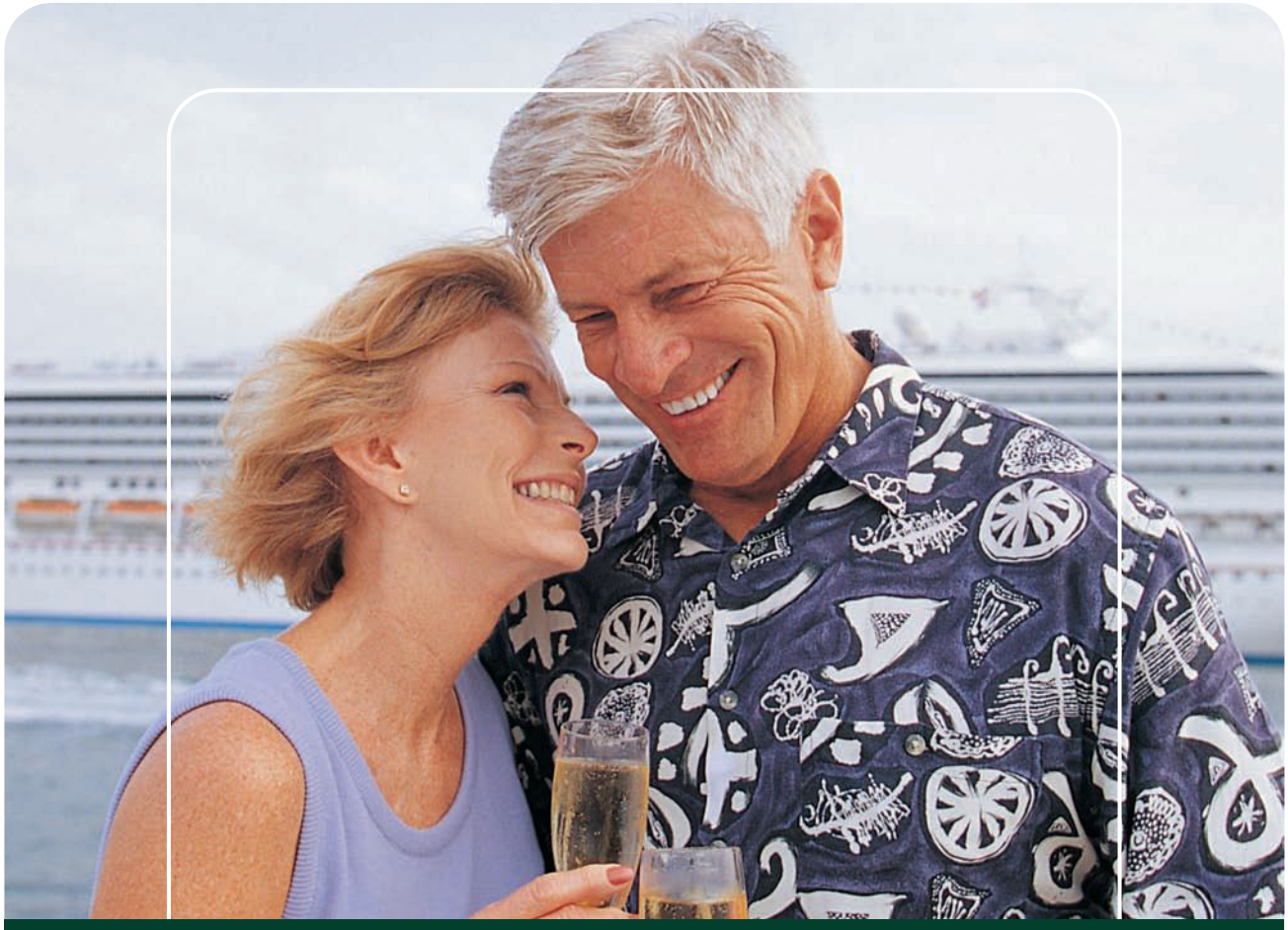
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Disclosure

None reported.

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Why We Need GMO Crops in Agriculture

by Melvin J. Oliver, PhD



The future is very promising for GM technologies to meet the future global needs for food feed and fiber in a sustainable and responsible way.

Abstract

Within 35 years (2049) the global population will reach an estimated nine billion people. This presents a massive challenge to agriculture: how do we feed all of these people with nutritious food in a sustainable way?

Presently the yields of most major crops are stagnating while the demand for food, both grain and animal protein, is growing. To meet the challenge of improving yields requires a constant commitment to generating a steady supply of improved cultivars and lines for all major crops. Conventional breeding cannot keep pace with what is required; to meet the targets biotechnology and the production of genetically-modified (GM) crops is filling the gap. However, there are still concerns as to the safety of GM crops for human consumption and the environment. In this review I explore the need for GM crops, the way they are produced, and their impact and safety.

The future is very promising for GM technologies to meet the future global needs for food feed and fiber in a sustainable and responsible way. GM crops are only one part of the solution. To meet the targeted yields, nutritional quality, and sustainable production, we need all of the tools at our disposal including conventional and organic food production systems.



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Introduction

In August of 2013 anti-GMO (Genetically-Modified Organisms) activists destroyed the Philippine Department of Agriculture's field trials of Golden Rice, a rice variety genetically-modified to deliver high levels of β-carotene in the seed (See Figure 1). Within the scientific community there was a rapid and unprecedented condemnation of this action, led by a widely signed petition and a strongly worded letter to science in support of GMOs by a cadre of highly respected and prominent scientists.[1] This outrage and widespread condemnation by the scientific community had not been forthcoming following the many similar destructive acts perpetrated on research fields involving GMOs. However, the primary reason for such a vigorous response was that "Golden Rice" (http://www.goldenrice.org/) was a community supported effort to meet a critical humanitarian need. β-carotene is a precursor of vitamin A, an essential component of rhodopsin the fundamental light absorbing pigment in the human eye. A chronic deficiency of vitamin A in the diet leads to blindness and a compromised immune system. It is an all too common affliction in the world's poverty stricken and malnourished, claiming the sight of half a million children a year and the lives of almost half of them. According to a recent study[2] vitamin A supplements reduce the mortality rate in children aged six months to five years by 24% and deliver a large reduction in poor vision and blindness. Golden Rice was envisioned as a non-commercial venture to deliver a cheap and effective (easy to distribute and deliver) dietary source of vitamin A for areas of the world where rice is the staple and often the main source of nutrition. Golden Rice, developed by the research teams of Ingo Potrykus and Peter Beyer, has taken 25 years to reach the point where field trials can be undertaken. Nearly all scientific and regulatory hurdles have been successfully navigated. This effort took an unmatched partnership between public and private sectors to fund and required private concerns to agree to release the intellectual property rights free of charge for the many patented components involved in the gene constructs.

Why was the reaction to the Golden Rice incident limited to the scientific community? The answer to that question is a complex one, but at its root is a lack of understanding of both Genetically-Modified Organisms (GMOs) as they pertain to crops and the food supply and the depth of the problem that agriculture faces over the next two decades and beyond. I have deliberately focused on agriculture and plants in the preceding sentence because GMOs have been fully accepted in the medical arena. Recombinant proteins are widely used to develop effective treatments of a variety of diseases and ailments and there has been no effort to ban them or to vilify the practice of producing them. The prime example of this is the use of genetically-modified bacteria to produce human insulin[3] widely used in the treatment of diabetes. Biopharmaceuticals, the products obtained from the use of GMOs, were well established in the 1980s[4] and have since been fully accepted. Their benefits and risks are well understood. GM crops have not experienced this widespread acceptance and remain controversial for many people and advocacy groups.[5]

Figure 1

Golden Rice (far right, yellow color) was envisioned as a non-commercial venture to deliver a cheap and effective (easy to distribute and deliver) dietary source of vitamin A for areas of the world where rice is the staple. *Source: Wikipedia*



The Need for GMOs

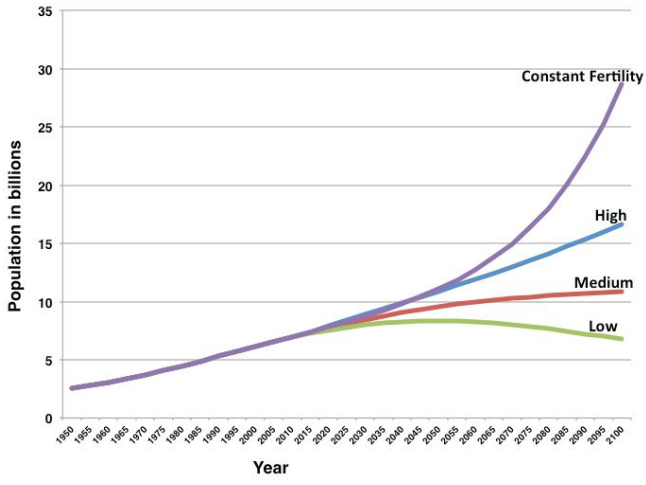
Before I discuss GM crops, how they are produced, what GM crops are currently grown and will be available in the future, I think it is important to understand why there is such a commitment to developing them.

At the time of writing, the global human population is approximately 7.15 billion according to the U.S. Census Bureau population clock (http://www.census.gov/popclock/). The United Nations predicts, depending upon which growth model is used, that by 2030 (only 16 years from now) the global human population will be between 8.9 (high) to 7.9 (low) billion, and by 2050 somewhere between 10.9 and 8.3 billion (See Figure 2). The majority of the population growth will occur in what are now designated as developing countries (http://www.landcommodities.com/farmland-supply-and-investment-fundamentals/). The U.N. Food and Agricultural Organization (FAO) reported that in 2012 a total of 868 million people were suffering from hunger and malnutrition, just over two-thirds of which (563 million) live in Asia and the Pacific and a quarter (234 million) in Sub-Saharan Africa.[6] Although these figures have declined from the 1,000 million people level recorded in 1990, there is still a long way to go. Consider that the death toll from hunger and malnutrition, a curable condition, is greater than "for AIDS, malaria and TB combined" (http://www.wfp.org/stories/what-need-know-about-hunger-2012). This is a complex issue with many socioeconomic and political ramifications. A major factor that drives any realistic solution is the need to match the rate of increase in global demand with rate of increase in yields of staple crops (primarily grains), feed, and livestock (including fish). Tilman et. al[7] concluded that to provide sufficient food to cope with the increase in the global population, agricultural production would have to double by 2050. Even the more conservative FAO estimates that agricultural production must increase by at least 60% globally (77% in the developing economies) in the same time frame.[6] In practical terms, if we focus on just the major global crops: maize, wheat, rice, and soybean (66% of calories in the "global" diet) this would require an annual increase in yield of 2.4%.[8] On a global level the current rates of increase for these four crops are 1.6% for maize, 0.9% for wheat, 1% for rice, and 1.3% for soybean which is significantly less that what is required.[8] On a regional level there are areas of the world that will double agricultural yields by 2050, primarily in regions where population growth is somewhat stable. There are large portions of the world that will not be able to come close to such a goal even for one of the four major crops. Historical analyses of yield data from over 13,500 political units across the globe reveal areas where current yield gains have stagnated or declined under the current agricultural production systems.[9, 10] To reverse these trends and to achieve the necessary yield gains on a yearly basis is a daunting task. It will require both an ongoing improvement in the genetics of our major crops (and livestock) and how we manage our cropping and animal production systems. These improvements will have to be tailored to regional and local needs and environments as well as ensure that the agricultural systems we put in place are sustainable. Such a task will require all of the tools we have at our disposal and the development of new ones.

Figure 2

Predictions of future global population growth.

Source: Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2012 Revision, http://esa.un.org/unpd/wpp/index.htm



The problems we face are compounded by several complicating factors foremost of which is the finite amount of arable land that we have available for agriculture. The FAO baseline scenario predicts that by 2050 there will be approximately 0.18 hectares of arable land available for food production for each person on the planet, down from the current 0.242 hectare value.[11] The consensus of opinion, formulated from this FAO study is that the global yield increases required to meet future demands must be obtained from the same area of land that is currently under cultivation. Without the ability to farm more acreage yield increases must come from genetic improvement or greater agricultural inputs (fertilizer, water, and pest/weed management). The baseline scenario does not take into account additional demands on the land for biofuel feedstock production or possible alterations in land use driven by urbanization, desertification, salinization, and soil degradation. Also the increase in demand for animal protein in the diet alters land use from crops to pasture as prosperity comes to developing economies. All of these factors have the potential to further reduce the amount of



arable land available for food production. Putative global climate change scenarios and water resource problems further complicate the task of maintaining arable lands for agriculture. These factors also add specific challenges to crop improvement through genetics and improved cropping systems as they directly affect crop yields rather than simply limit farmable acreage.[12]

To meet the challenge of improving crop yields each season requires a constant commitment to generating a conveyor belt of improved cultivars and lines for all of the major crops. Such a commitment has been in place since organized breeding programs were established in the 18th century even though genetic principles were not yet understood (pre-Mendel). Conventional breeding programs were able to sustain and advance yields for the staple grain crops to keep up with the demand for food in the developed countries of Europe and North America. In the late 1950s and early 1960s large areas of Asia were facing widespread famine. Fortuitously, in the 1940s a very insightful plant breeder, Norman Borlaug, had seen the danger of such a catastrophe occurring in Mexico and had initiated a breeding program for high-yielding and disease resistant wheats. His success in doing so, coupled with the development of new mechanized agricultural technologies and cropping systems, resulted in the aversion of famine in Mexico and allowed the country to becoming a net exporter of wheat by the early 1960s.[13] Borlaug, through his tireless advocacy and the foresight of Asian governments, was able to translate his success with wheat to the development of a high-yielding disease resistant rice cultivar, IR8, which was quickly adopted. Mass famine was averted and Borlaug was credited with saving a billion lives by his breeding and advocacy efforts. He was awarded the Nobel Peace Prize in 1970. It is clear that we are currently facing a similar crisis to the one that Borlaug saw coming in the 1940s. It is also clear that conventional breeding, as practiced in the 20th century, will not be the entire solution this time around.

Conventional breeding relies on the introduction of new traits/genes into existing cultivars or commercial lines by sexual crosses i.e. crossing of one parental line with a second parental line that is expressing the desired trait (disease resistance, drought tolerance etc). Such a cross results in progeny that have inherited a complete set of genes from both parents so that although they have inherited the desired trait they have inherited a multitude of others, some of which may not be desirable and may reduce yield (a phenomenon called yield drag). To reduce yield drag breeders select progeny that best express the desired trait and cross it back to one of the parent plants in order to dilute out the negative traits inherited in the first cross (backcross). Through several iterations of this backcrossing scheme breeders eventually end up with a high yielding line that carries the desired trait. To achieve this requires many generations and several years (10 to 15years for wheat depending on the starting material) before lines can be tested in an agronomic setting or, as in the case for corn, used as a parental line in the production of commercial hybrids. Conventional breeding is also limited

to what genetic variation is available in the gene pool of the crop or in a close relative that is sexually compatible. The search for genetic variation (gene variants) that can impact yield and productivity becomes more and more difficult and the incremental increases in yield become smaller and smaller with time. Yield is a complex phenotype and is the sum of the activity of a multitude of genes and rarely lends itself to rapid yield gains. Norman Borlaug's lines dramatically altered crop yields not only by increasing the number of seeds per plants but also by adapting the plants to mechanized and high density cropping systems. Modern conventional breeding programs use varieties that are well adapted to modern production agriculture and thus yield gains based solely on plant performance are not as dramatic as those witnessed in the "Green Revolution" (http://en.wikipedia.org/wiki/Green_Revolution).

Modern breeding programs are also focused on nutritional and compositional qualities of the final product, whether it be grain, bean, fruit, or vegetative outputs. Variation can be increased using mutagenesis (chemical or radiation) but this is not selective and introduces many genetic changes into the crop and extends the breeding timeline. Currently our efforts fall short of the desired target yield increase rates (2.4% per year) if food production is to keep pace with the growing population. Modern breeding efforts are starting to be driven by molecular and genomics driven technologies, such as marker assisted breeding and genotyping-by-sequencing. These promise to dramatically reduce breeding timelines and fuel the rapid discovery of here-to-with untapped genetic variation. Thus although there are limitations, conventional breeding has a major role to play.

If we are to succeed in doubling global agricultural production for both crop and animal food commodities we need to be able to reduce the production timelines for both plant and animal breeding programs and to introduce new sources of genetic variation that improve yield potential, nutrition, and lower yield losses from disease and environmental factors such as changing climate and soil depletion. This is where biotechnology and the development of Genetically-Modified Organisms comes into its own and along with conventional breeding, molecular and genomic assisted crop/livestock improvement and novel genetic modification technologies, may be the vital tools that gets us to the critical goal of sustainable global food security. GMO technologies offer more rapid crop improvement, novel genetic strategies for crop improvement, and the ability to use genes from all sources regardless of origin from within the tree of life.

For the remainder of this review I will be concentrating the narrative on GM crops rather than the more universal use of the term GMO. For information regarding GM farm animals and fish I refer the reader to the recent review by Forabosco et al.[14]

What Are GMOs?

The term Genetically-Modified Organism is amorphous and somewhat imprecise. All of our crops and livestock are GMOs in that their genetics have been manipulated and designed by man over the last 10,000 years or more. This has occurred to such an extent that most barely resemble their wild progenitors. The majority could not compete or survive long outside of an agricultural setting. The FAO and the European Commission define a GMO, and the products thereof, as being plants or animals that are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Although this is a closer description of what is meant in the general usage of the term GMO, it would also encompass several crops that have long been accepted as conventional, e.g., Triticale. Triticale is a grain crop commonly used in bread and pasta that was developed to offer a more nutritious food source (higher protein and low gluten). It is totally "man-made." It was first developed in the laboratory in 1884 by crossing wheat with rye to form a sterile hybrid which would not survive in nature. To produce the crop, fertility had to be restored, and this was achieved by chromosome doubling to form a stable polyploid plant with two copies of each of the parental genomes (rye and wheat).[15] This was achieved in the late 1930s using *in vitro* culture technology and treatment of embryos with the chemical colchicine, which interferes with the normal process of cell division (mitosis) to generate polyploid cells. Clearly, this is a crop that would fit the FAO definition of a GMO but it is not designated as such. Perhaps a better definition would be a modification to The Cartagena Protocol[16] definition for "living modified organisms," which would then read, "Genetic Modified Organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

I would suggest something new and less obtuse such as Biotechnologically Modified Organism (BMO) but for the sake of convention I will stick to the use of GMO as defined in the aforementioned modified Cartagena Protocol definition.



How Do We Produce GM Crops?

To transfer genes into a crop plant to generate a GMO, (a transgenic plant) generally requires a two-step process:

1. Successful delivery of the gene into a plant cell(s), called transformation, and
2. The regeneration of a transgenic plant, primarily in tissue culture, from the transformed cell(s).

The transferred gene, termed a transgene, is usually engineered to control when and in what tissue it is expressed so that the maximum benefit can be realized. Gene delivery into plant cells is generally achieved in one of two ways: either direct transfer of "naked" DNA or indirectly using a bacterial vehicle, the "natural genetic engineer," *Agrobacterium tumefaciens*. Efficient regeneration protocols have been developed for almost all crop species but they will not be discussed here.

The direct delivery of DNA into plant cells leading to transformation has been achieved in several ways, electroporation into protoplasts (plant cells minus the rigid cell wall), microinjection, chloroplast transformation, silicon-carbide slivers (coated in DNA), mesophorus silica nanoparticles, and microparticle bombardment.[17] By far the most common and widely used technique for direct DNA transfer is particle bombardment. Microparticle bombardment, also known as biolistics or the "gene gun", was first developed by Sanford in the late 1980s[18] using pressurized helium to fire gold or tungsten microparticles (diameter between .5 and 1.0 μm) coated with the engineered gene of interest as naked DNA into the plant tissue at high velocities. The pressure used to project the microparticles varied depending upon the target tissues but could go up as high as 2,200 psi: the higher the velocity of the particles, the deeper the penetration into the target tissue. The primary targeted tissues were embryonic tissues from the seed or meristems. The engineered gene was delivered as a high copy number plasmid (a circle of DNA capable of replicating in a bacterial host during the engineering process) and once in the cell was capable of integrating into the plant genome, often in multiple copies. Although the equipment has become more sophisticated and the microprojectiles have changed with time, microparticle bombardment still operates on the same principles as the original Sanford "gene gun". Microparticle bombardment has been successfully used to produce transgenic plants in a wide-range of crops including all of the cereals, some tuber crops, and trees. It has the advantage over other methods in that it can be used to transfer large DNA fragments and has even been used to transfer whole chromosomes and multiple independently engineered genes at the same time.[19]

Although micropartical bombardment has been successful, its use is greatly surpassed by the use of *Agrobacterim tumefaciens* in the commercial realm. *A. tumefaciens* is a soil bacterium that infects plants, generally where stem and roots meet (known as the crown in gardening terms), and alters the genome of the plant by inserting genes that cause cell proliferation. The cell proliferation forms a mass of cells (a gall or tumour) within which the bacteria live. Not only does *A. tumefaciens* "instruct" the plant to form a gall (crown-gall disease), it also provides the cells with genetic information to make opines, modified amino acids that the bacteria use as a nutrient source. It accomplishes this natural genetic engineering via a large tumour-inducing plasmid (Ti plasmid) that contains a section of DNA known as T-DNA (for transfer DNA). The T-DNA is flanked by two small (25 base pairs) direct repeats, known as the right (RB) and left border (LB) sequences, that act as insertion signals for the T-DNA transfer into the plant genome. The T-DNA contains genes that encode enzymes that synthesize plant hormones, auxin and cytokinin, that cause cell proliferation and tumour formation along with the genes that encode the enzymes for opine metabolism. The rest of the Ti plasmid, along with the bacterial chromosome, contains the virulence genes that control the ability of the bacteria to infect the plant tissue and to transfer the T-DNA into the nucleus of the target plant cell. A complete description of the mechanism by which *A. tumefaciens* infects plant tissues, transfers the T-DNA into the cell, and incorporates it into the plant genome can be found in Barampuram and Zhang.[17]

The exploitation of *A. tumefaciens* as a possible means to insert a novel gene in to plants was first recognized in the late 1970s, [20] but the real explosion in the field occurred in the early 1980s with the advent of binary vectors. Binary vectors separated the T-DNA region onto a separate smaller plasmid away from the rest of the Ti plasmid, which remains as a separate vector within the *Agrobacterium* cell. The smaller binary vector was engineered so that it could replicate in both *A. tumefaciens* and *E. coli*, which greatly facilitated the construction and insertion of the target genes of interest between the RB and LB of the T-DNA.[17] Replacement of the T-DNA with engineered genes capable of expression in plant cells, "disarmed" the binary vector so that the infection and transfer of DNA to the plant by the bacteria no longer resulted in cell proliferation and opine biosynthesis.

Little has changed in this part of the process since these early days and we still use only a limited number

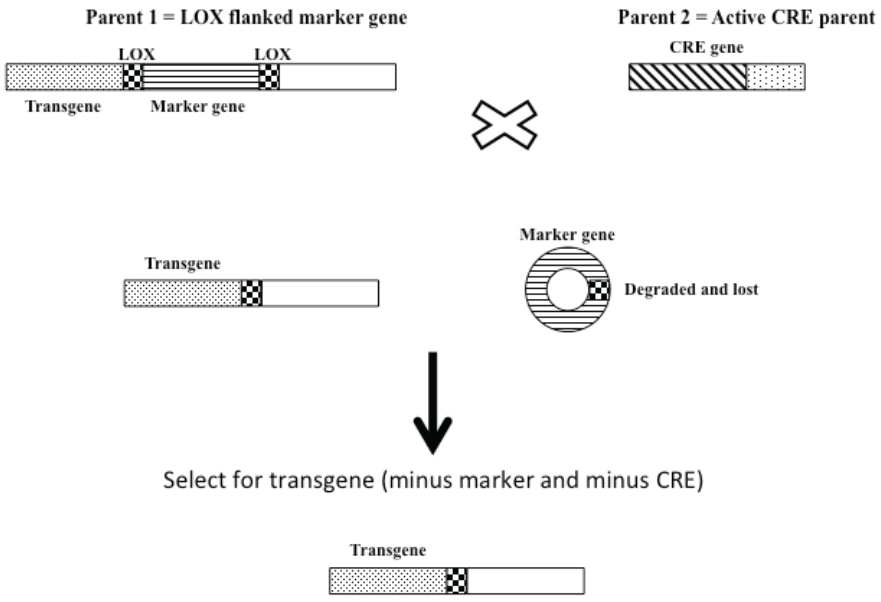


Figure 3
The CRE-LOX system for removal of antibiotic marker genes from GM plants. Each block represents the strands of the genomic DNA of the plant. The checkered boxes represent the recognition sites (LOX) for the CRE recombinase.

of binary vector systems, more focus has been placed on increasing the efficiency of the transformation and new ways of introducing *Agrobacteria* to plant tissues. For the former the most successful development has been the introduction of explant wounding techniques that deliver *A. tumefaciens* deep into a wound site to promote closer contact of the bacteria to transformable plant cells. The "dip-wounding" technique for soybeans where explants are wounded with a blade covered in *A. tumefaciens* prior to placing them in a suspension of *A. tumefaciens* for cocultivation in tissue culture, increased transformation efficiency ten-fold.[17] The most promising of the latter efforts has been the development of methods that target the delivery of *A. tumefaciens* to transform developing ovules *in situ*, as a means of avoiding the need for regeneration of whole transgenic plants in tissue culture. Such an approach, known as the floral-dip method, has long been used to transform the model plant *Arabidopsis thaliana* for research purposes. More recently variations on this established method have been used to transform wheat, pakchoi and rape/canola by vacuum infiltration of flower buds, sorghum, corn, cotton, and wheat by application of *A. tumefaciens* directly to the pistil.[21]

In generating transgenic plants (GMOs) the binary vector systems contained selectable markers, genes whose products allowed for the selection of transformed cells of the target tissue, and the tissues that were regenerated from them, away from non-transformed cells/tissues. These selectable marker genes were located along side the gene of interest within the T-DNA. The most commonly used selectable marker genes are those that infer antibiotic resistance or herbicide tolerance.[17] The inclusion of these selectable marker genes within the transferred DNA was considered to pose an unacceptable added environmental risk[22, 23] and their elimination became a commercial priority.

There are a multitude of techniques, or in development, that have been mobilized in this effort.[23] The most effective and successful of these has been the use of site-specific recombinases. Site-specific recombinases are enzymes, common in bacterial and some eukaryotes such as yeast, which catalyze recombination of DNA between two enzyme specific recognition sites (short inverted repeat sequences). The two most common site-specific recombinases in use are the CRE-*LOX* and the FLP-*FRT* systems (the first triplet of letters designates the enzyme and the second triplet the recognition sites). The recombination activity that these enzymes catalyze is guided by the orientation of the recognitions sites, if they are oriented in tandem (in the same direction) the DNA between the two sites is excised, and if in opposite directions (facing each other) the DNA is inverted. The strategy for using these recombinases in producing marker-free GM crops (See Figure 3), in this example using CRE-*LOX*, involves:

1. engineering *LOX* sites (in tandem) either side of the marker gene within the binary vector gene construct;
2. expression of the CRE recombinase enzymes in the transgenic plant or tissue after selection; and
3. segregation of the marker free transgenic plants from the progeny for development of the GM crop.



These and other technologies to remove the antibiotic marker genes have been deployed even though there is no evidence that such genes pose a risk to either animals, including us, or microbial communities within the soil. The amount of DNA encoding the antibiotic gene that is ingested by an animal or us is an extremely small component (approximately 0.00005%) of the 0.1 to 1g of DNA a day consumed in a normal diet[24, 25] and is subject to degradation by the same digestive processes as all DNA. The perceived risk for ingested antibiotic maker genes is that they might be incorporated either into the DNA of the animal ingesting the DNA or by microbes in the gut thus rendering them antibiotic-resistant. DNA is generally cleaved into very small fragments during digestion (and food processing) making it even less likely that a whole gene remains intact. This is true for all ingested DNA and so the likelihood that any gene is incorporated into the genome of the animal or the microbes in the gut is highly unlikely.[26] It is also well documented that the antibiotic resistance marker genes pose no health risk to humans or livestock, and that they are naturally present in environment and in gut flora,[27] so should such an unlikely gene transfer event into the genome of a gut microbe occur it would be of little consequence. To date there is no evidence that DNA absorbed through the intestines following ingestion can be integrated into the germ line of either humans or livestock.

Impact and Safety of GM Crops

It has been thirty years since the first genetically engineered plants were generated, and it has been eighteen years since the first introduction of a transgenic crop into U.S. agriculture. Since their emergence the acreage planted with GM crops has steadily increased such that in 2013, 433 million acres (175.2 hectares) of land were dedicated to their production, 56% of which were grown in developing countries.[28] As of 2013, a total more than four billion acres of GMA crops have been grown in 27 countries world-wide, primarily in corn, soybean and cotton, although new crops are being introduced at an increasing rate. The economic benefits of the deployment of these crops have been substantial. Mannion and Morse[29] report that on a global level, from 1996 to 2006, GM crops increased farm income by $40.7 billion, occurring in both developed (47%) and developing agricultures (53%). In the following six years (as of 2012) the global increase in farm income from GM crops had almost tripled that of the previous 10 years to reach $116 billion.[28, 30] Both studies estimate that 42% of this economic gain is derived from the increased yield associated with lower weed and pest damage as well as superior genetics. The remaining 58% accrued from a decrease in production costs (decreased herbicide and pesticide costs and a reduction in tillage). These figures indicate that the underlying agronomic benefits derived from GM crops are equally impressive: with a global yield increase of 377 million tons from 1996 to 2012. In 2012 the increase in yield attributed to GM crops for the U.S. was 47 million tons.[28, 30] Brooks and Barfoot[30] estimate that to attain an equal yield increase to that delivered by GM crops between 1996 and 2012, an additional 303 million acres (123 million hectares) of conventional crops would have been required. As James[28] postulates that to attain this extra land industrial nations would have to use marginal lands that are generally characterized by poor soils (requiring substantial inputs such as fertilizer and irrigation) and developing countries would primarily target tropical forests. Certainly such an added conversion of land to agricultural purposes would have serious ecological and environmental impacts regardless of what part of the world it is acquired.

It is well documented that the use of biotechnology is having an impact on the alleviation of poverty and to hunger in those developing countries, especially China and India (if one can still classify these two as developing), where development and deployment of GM crops has been adopted.[28, 29, 31] Economic gains are being translated into improving agriculture-based economies and higher and more stable yields are alleviating some of the concerns about food security.

GM crop production is a vital tool in the "agricultural toolbox" and along with advances in the development of the new genomics based genetic technologies that improve conventional crop production it may be realistic to expect to meet the aforementioned lofty goals. Organic crop production technologies, although generally delivering lower yields than conventional crops,[32] have an important role in yield improvement and stability efforts in areas where these technologies are optimal. To abandon any one of these efforts would be unwise and potentially catastrophic, especially without sound scientific reason, as agricultural production systems are complex and changing, more so now than ever before, as global climate change alters the "farming landscape."

There are those that are adamantly opposed to the adoption of GM technologies in agriculture (though not in medicine) as a means of increasing yields and improving nutrition, and thus removing this key tool from the toolbox. The reasons for this opposition are



complex and multifaceted, but from what is articulated and communicated by those who oppose GMOs, they are based on the perception that such crops pose an unacceptable risk to both human health and the environment. Such sentiment exists even though there have been no adverse health or environmental affects from the almost four billion acres of GMO crops grown since their introduction in 1996. Several National Research Council committees and European Commissions (as well as joint commissions) have concluded that with the extensive scientific inquiry into the safety issues surrounding the adoption of GM crops, genetic engineering using biotechnology is no different from conventional breeding in terms of unintended consequences to the environment or animal and human health.[33] The European Commission funded more 50 research programs from 2001-2010 to address concerns regarding the use of GM crops to reach this same determination.[34] Nicolia et al.[24] constructed a database of 1,783 scientific original research papers, reviews, relevant opinion articles, and reports published between 2002 and October of 2010 on GMO safety issues, and reviewed the contents to generate a comprehensive overview of the accumulated knowledge. The overall conclusion of this mammoth undertaking was that "the scientific research conducted so far has not detected any significant hazards directly connected with the use of GM crops.

At the present time, two types of GM crops dominate GMO crop plantings:[30]

1. herbicide-tolerant crops, primarily glyphosate (Roundup™) resistant, that express enzymes that are unaffected by the herbicide and thus bypass the native susceptible protein (5-enolpyruvoyl-shikimate-3-phosphate synthetase (EPSPS) in the case of glyphosate) or enzymes that degrade the herbicide; and
2. insect-resistant crops, almost exclusively crops expressing the insecticidal crystal proteins (CRY) produced by *Bacillus thuringiensis* (Bt) a soil bacterium.

In both cases, the aim was to improve yields by limiting losses due to competition from weeds and damage from insect pests, reduce input costs for the farmer by better crop management, and to reduce both herbicide (by reducing the need for multiple sprayings) and insecticide use. As much of the debate as to the safety and impact of GMOs is focused on these two classifications, a detailed look at the adoption of these technologies and associated outcomes will serve to highlight some of the issues that fuel the ongoing debate.



Herbicide Tolerance

Herbicide-tolerant GM crops have been widely adopted in the U.S., such that >90% of corn, soybeans, and cotton are GM and herbicide-tolerant[28] and as other countries adopt GM technologies, the amount of acreage planted with herbicide-tolerant GM crops will continue to grow. In Canada 98% of the canola crop is GM. The perceived issues with herbicide-tolerant crops relate to the development of herbicide-resistant weeds (so called "superweeds"), transgene transfer (gene flow) to wild relatives or non-GMO crops close by, and environmental/ecological concerns that relate to biodiversity and chemical usage. All of these issues actually predate the adoption of GM crops. Herbicide resistant weeds have long been an issue for countries that rely on herbicides for weed control.[35] Gene transfer is not a unique property of GM crops and is equally an issue with herbicide tolerance (or any other trait) that is developed through conventional breeding methods.[36] Herbicide use, as is true for agriculture in general, has environmental and ecological consequences even for crops derived by conventional breeding programs. These considerations should be taken into account in any risk assessment for GMO crops.

Gene flow between closely related plant species (wild or cultivated) is a natural phenomenon that has been difficult to document and study but is known to occur in both directions.[37] It is somewhat ironic that the transgenes inserted into GM crops are ideal markers for documenting and studying this process.[38] The transfer of a transgene from a GMO crop to a wild relative depends on several factors: the reproductive strategy of the crop (open or self-pollination), the proximity of sexually compatible wild relatives, and the fertility/fecundity and fitness of the resultant hybrid. The fertility/fecundity and fitness of the hybrid is the controlling factor in establishing the presence of the transgene in the population of the wild relative of the GMO crop. To date, even with the large acreage of GM crops, this has only been observed in a small number of cases and only in the U.S. and Canada.[37] The glyphosate tolerance transgene from GM grasses grown in a field trial in Oregon escaped and has been incorporated into native creeping bentgrass populations[39] and the establishment of GM canola (rapeseed in the U.S.) along trucking routes in North Dakota has led to transgene transfer into non-GMO "feral" canola in these locations.[38] As far as can be determined there is no evidence that the establishment of the herbicide tolerance gene in these populations has had a detrimental effect and mitigation strategies have been identified.[40]

Transgene flow from a GMO crop into a neighbouring field of an identical non-GMO crop is a problem for organic farming where registration as a non-GMO crop relies upon the lack of a transgene. This is also true for conventional farming operations that wish to take advantage of the non-GMO market. There are strategies to prevent this from occurring but as of yet they have not been deployed.[41, 42, 43] Prevention of this occurrence remains a crop management problem. Coexistence strategies for many crops have been investigated and deployment is driven not only by a scientific or social compulsion but also by economic feasibility factors.[24] These strategies include separation by a distance that negates pollen flow from one crop to another, harvesting practices that reduce residual seed accumulation, and transportation and other post-harvest containment practices. All of these present an economic challenge for producers where coexistence is desired.

Although herbicide tolerance in weeds resulting from transgene flow from a crop is rare and limited to a small number of crops and related weeds (and does not occur when the crop and weed are sexually incompatible), the development of herbicide tolerant weeds in agricultural settings is becoming a problem. The widespread adoption of glyphosate resistant GM crops in the U.S. and the reliance of upon the use a single herbicide for weed control established a strong selection pressure for weeds that have natural herbicide tolerance genes. This would occur whether or not the herbicide tolerance in the crop is GM or conventionally bred: as documented for the toxic herbicide atrazine for which GM derived resistance has not been employed.[44] The over reliance on a single herbicide as the main strategy for weed control will eventually limit the usefulness of both the herbicide and the tolerant GM crop.[45] There is a broad consensus in the agricultural scientific community that over reliance on a lone herbicide strategy is not sustainable. The problems associated with the evolution of herbicide tolerance in weeds can be mitigated or solved if GM herbicide tolerance is part of a broader integrated weed management program that incorporates crop rotation, herbicide tolerance gene-stacking technologies and field management technologies.[29, 44-47]

The adoption of GM herbicide tolerant crops does alter the biodiversity of plant populations (weeds) in agricultural ecosystems and some of the insects and other organisms that rely upon them but this is related to weed management and herbicide use not the GM crop. Alterations in biodiversity also occur in conventional agriculture where weed management strategies are employed.[48] Nevertheless there is great deal of evidence that the adoption of GM

herbicide tolerant crops has had a beneficial impact on the environment. The conversion of natural habitat and ecosystems to urban development and agriculture is clearly the most detrimental aspect of human activity as it relates to environmental impact and loss of biodiversity. As yields increase with the adoption of GM crops, as discussed previously, the need to dedicate land for agriculture decreases. Apart from the reduced conversion of land to agricultural use the emergence of GM herbicide tolerant crops has accelerated and enabled the adoption of conservative tillage (no-till and reduced-till) practices.[30, 45, 48] Such practices enhance soil quality, reduce water run-off, conserves nutrients, increases water infiltration, and contributes to a reduction in greenhouse gases.



The GM herbicide tolerant crops have also been developed to enable the use of less toxic and more environmentally-friendly chemicals. Glyphosate and glufosinate (another GM targeted herbicide resistance), for example are both Class III herbicides (EPA), which are only slightly toxic and have low persistence in the soil and environment, averaging approximately 40 days. These herbicides have replaced herbicides either more toxic or that are known to contaminate and persist in groundwater.[33] In Argentina, glyphosate replaced several Class II herbicides (significantly toxic) by over 83% deployed on herbicide tolerant soybeans.[48] Thus the impact of targeting less toxic herbicides is a reduction in human exposure and a positive impact on environmental and human health.

With the global increase in acreage of GM herbicide tolerant crops there has been some concern that overall herbicide use would increase and thus the possible environmental impact would negate the value of planting GM crops and ultimately render them a detriment. Initially, at least for the U.S., the overall quantity of herbicide deployed in the environment was reduced but by 2010, when USDA stopped collecting usage data, the amount of herbicide used was approaching pre-GM levels. However, the quantity of herbicide used in an agricultural endeavour is not a satisfactory indicator of environmental impact as the new herbicides substituted for older more toxic chemicals. Kovach et al. [49] developed a metric entitled the Environmental Impact Quotient (EIQ) that utilizes toxicity and exposure data for each herbicide, pesticide, or fungicides to derive a single value that is effectively the average risk/impact of the farm worker, consumer, and ecological components of the agricultural production system. Brooke and Barfoot[30] describe a field EIQ that is derived by multiplying the EIQ for a herbicide (or a pesticide or fungicide) by the amount of the active ingredient applied per hectare and thus conventional herbicide (or pesticide or fungicide) usage can be directly compared usage in a GM crop production field. They point out that the EIQ is a useful, but not comprehensive indicator, for environmental impact but it is more informative than simply recording and comparing the quantity of a chemical used. Using the available data Brookes and Barfoot[30] report that both the amount of active ingredient used and the environmental load (EIQ) has been significantly reduced for all of the major GM crops (maize, soybean, and cotton) in all of the GM adopting countries between 1997 and 2012.

Insect Resistance

Insect-resistant GM crops have also been widely adopted in the U.S., over 90% of corn, soybeans, and cotton are GM for insect resistance,[28] and like herbicide-



tolerant GM crops the insect-resistant GM crops are rapidly growing in acreage globally. As mentioned above the primary transgene used in the production of insect resistant GM crops is one that allows the synthesis of a CRY protein toxin from the bacteria *Bacillus thurengensis* (Bt). This toxin is relatively specific to key agronomic caterpillar and beetle pests that feed on the crop plants, affecting the gut cells of the insect and preventing digestion. The CRY toxins are specific to their target insects and are innocuous to vertebrates, including humans, and have no impact on the plant. They are also biodegradable and thus do not persist in the environment.[50, 51] This made them ideal targets for GM technology to combat insect pests and the damage and the resultant yield reductions they cause. The recognition that these proteins were useful pesticides predated GMOs. Sprayable formulations, of both the crystal proteins and bacteria preparations (a microbial pest control agent [MCPA]), have long been used in agriculture.[51] It is one of the few pesticidal treatments available to an organic farmer. It is widely used today, making up over 90% of the MCPA market (http://www.bt.ucsd.edu/organic_farming.html).

The use of the same pesticide in GM crops that has long been used in organic and conventional agriculture took advantage of the wealth of EPA and FDA testing data for this toxin. This allowed government agencies worldwide to conclude that Bt GM crops are as safe for both human and animal consumption as well as the environment as conventional/organic crops that have been sprayed with the CRY protein or bacterial preparations.[33] In fact, because the Bt GM crop only delivers the CRY toxin to those insects that eat the crop, whether directly or in crop residue, it was considered less likely to cause environmental issues than spraying or dusting plants with the toxin or bacterial preparations. Nevertheless, as with herbicide-tolerant GM crops, concerns remain and for Bt GM crops these relate to the development of Bt-resistant insects, transgene transfer (gene flow) to wild relatives or non-GMO crops close by and environmental/ecological concerns that relate to biodiversity.

The concern for Bt GM crops in regards to gene flow is that unlike herbicide tolerant GM plants the transfer of insect-resistance to wild relatives theoretically could offer a selective advantage to the recipient from increased seed production as a result of reduced loss of vegetative tissue from herbivory. The transfer of insect resistance from a crop to a wild sexually compatible relative is not dependent

on the transgene but would occur in conventional insect resistant crops, as discussed previously. After almost twenty years of cultivation there have not been any negative effects of gene transfer from a Bt GM crop to a wild relative.[29, 45] In a review of the literature of gene flow, Chandler and Dunwell[37] uncovered reports of Bt gene transfer between Bt-canola (*Brassica napus*) and a related wild species *Brassica rapa* that indicated that plants that have the Bt gene are less fit than those that do not in the absence of the herbivorous insects but survived better than the non-Bt plants under heavy infestations. Other studies using similar populations did not see an increase in fitness in the hybrids. Snow et al.[52] crossed Bt-sunflowers with a weedy relative and demonstrated that the GM hybrids and offspring produced more seed than the non-GM siblings but as this was in a controlled experimental system, and it was not clear if fitness would be enhanced in an agricultural setting. The transfer of the Bt transgene from a GMO crop into a neighbouring field of the non-GM crop counterpart is, as described for herbicide tolerant GM crops, a specific concern for organic farming and requires specific management strategies to negate its occurrence.

As with all insecticides, insect populations that are resistant to the pesticide arise, and Bt crystal proteins are no exception. Long before Bt-GM crops emerged on the scene, the diamondback moth (or cabbage moth), an important pest of cruciferous crops developed resistance to Bt preparations repeatedly applied to fields of conventional crops.[53] Although the Bt toxin is only contained within the tissues of a Bt-GM crop and not applied as a spray in the field, it is not surprising that resistance to Bt-GM crops has emerged in the target insects; most recently in western corn root worm.[54] The strategy to combat the development of resistance to Bt in the targeted pests has been to establish Bt-GM crop free refuges, either within or adjacent to the Bt-GM crop. The refuge strategy works on the theory that if there is a large population of susceptible target insects close to the Bt-GM crop then the rare insect that survives feeding on the crop will, in all likelihood, mate with a susceptible insect that is feeding on the non-GM plants nearby. As most resistance genes tend to be recessive the hybrid offspring of such a mating would be susceptible to the Bt in the GM crop and would die. This has delayed the evolution of Bt-resistant pests.[33] This is not a perfect system and Bt-resistant insects have evolved. In some cases this has arisen because the level of Bt in the GM plants is not sufficient to kill the hybrid insects or because of the significant costs associated with establishing and maintaining refuges some producers fail to provide them at all or limit the size. Strategies to ensure that refuges are established and maintained are being implemented, including increasing the dose of CRY protein that the plant delivers, economic incentives, and "refuge in the bag" (adding non-GM seed to the bag of Bt-GM seed to ensure refuge establishment) may help further delay widespread resistance. Recently GM crops containing "stacked" Bt genes, more than one CRY protein gene, have been developed in the hope of eliminating or slowing insect resistance. New emerging technologies that utilize more than one mode of action (Bt plus another insecticide) as well as maintaining sufficiently large refuge areas may also help prevent or severely delay the development if pest resistance.

The deployment of Bt-GM crops has resulted in a significant decrease in the use of chemical pesticides in all countries where they have been adopted, along with the reduction in environmental impact and associated human exposure.[29-31] The reductions are both in quantities of active ingredient and the overall field EIQs for each major crop. In the U.S. the use of Bt-GM maize reduced the amount of pesticide used on corn to target corn borers and root-worms by 80% and the field EIQ load by 54%. Since 1966 the overall decrease in pesticide use on corn was 45% with a reduction of 38% for the field IEQ load. Where data is available, the reductions in total pesticide use and EIQ in all countries that have adopted Bt-maize cultivation. Similar figures are also available for Bt-cotton and other crops.[30] The beneficial economic, environmental, and human health effects resulting from a reduction in pesticide use (and reduced need for toxic pesticide alternatives) can be directly attributed to the ability of GM technologies to contain the pesticide within the plant that is targeted by specific insects (or other invertebrate pests) and to deliver the pesticide only to those pests that ingest the tissues of the plant. The reduction in the need to expose the environment and workers to chemical sprays is clearly a positive outcome of the deployment of GM crops.

The widespread use of broad-spectrum pesticides to combat agricultural pests has significant and negative effects on biodiversity at all levels in the agricultural ecosystem, from mammals to soil microbes and is well documented.[55, 56] This is not the case for Bt-GM crops, where the consensus is that the effects on biodiversity have been positive. The debate on the possible impact of Bt-GM crops on biodiversity was fueled by early reports that laboratory-feeding experiments using Bt-pollen indicated that Bt-GM corn posed a serious threat to the conservation of monarch butterflies in the U.S. These reports spawned a series of field-based ecological impact studies that



concluded that commercial large-scale cultivation of Bt-maize did not pose a significant threat to monarch populations and that the lab-based studies were flawed.[57] This initial flurry of environmental impact assessments of Bt-GM crops on biodiversity of both beneficial organisms (non-targeted) and the targeted pests has continued and the data collected is substantial.[48] The analysis of the literature and data leads to the following conclusions:

1. The deployment of Bt-GM crops has had little or no effect on the biodiversity of soil organisms. There are some reports of changes in soil organisms, primarily soil microbes but these changes are indistinguishable or can be explained by the effect of temperature, soil type, or other unrelated parameters.
2. No significant adverse effects of Bt-GM crops on the non-target organisms or beneficials have been detected in the field.
3. Controlled lab or greenhouse studies only observe an effect of Bt-GM crops on the natural predators or parasites of the targeted pest if they are fed (or use as a host) an insect which is damaged by feeding on Bt-GM plants but not dead and that in the field these effects are not observed.
4. In some areas where Bt-GM crops predominate the landscape, the populations of the targeted pests decline to levels that benefit nearby farms that grow non-GM crops of a reduction in the level and frequency of insecticide deployment.

In a more recent study of the impact of Bt-GM crops, using data collected between 1990 and 2010 at 36 sites across northern China, Lu et al.[58] demonstrated that with the adoption of Bt-cotton and the resulting decrease in insecticide use there was a major reduction in the target insect, the cotton bollworm, and an increase in abundance of several generalist predators (ladybugs, spiders, and lacewings). With the increase in the generalist predators they also saw a decrease in the cotton aphid populations that damage the plants but are not controlled by the Bt toxin. As reported by others they conclude that the impact on beneficial predators (generalists) provides a measure of biocontrol of plant pests that affect neighboring crops that are not necessarily GM.

Substantial Equivalence

A major paradigm in the risk assessment of GM crops, particularly for human consumption, is the concept of "substantial equivalence" which is based on the idea that a GM crop is directly comparable (within normal levels of variation) to its non-GM counterpart to ensure that there are no unintended hazards associated with the insertion of the transgene. The GM and non-GM plants are compared with regard to their agronomic and morphological characteristics prior to an in depth compositional analysis. The compositional comparisons encompass "those components in a particular food that may have a substantial impact in the overall diet"[59] present in the food/feed products that are derived from the GM crop. The analysis can include macro- and micronutrients, anti-nutrients, secondary metabolites, and toxins. The non-GM crop that is used as a point of comparison is presumed to be safe, as it will have had a history of successful and safe use as food or feed. Any difference in the composition of the GM crop must fall within the normal range of variability for the non-GM counterpart for it to be considered safe. If the differences fall outside the normal range then the GM crop must be further assessed for its safety. All of the GM crops adopted so far have been fully tested for substantial equivalence, and all have been graded as equivalent to their non-GM counterpart, and thus, safe.[60] The approaches to assess equivalence are constantly improving and there is a movement towards non-targeted approaches including "omics" based analyses (genomics, proteomics, metabolomics, etc.). In a recent review, Ricroch et al.[61] concluded that GM crop plants more closely resemble the parental line from which they were generated than do their conventional bred (or mutagenized) counterparts. The "omics" analyses would support the conclusion that the insertion of a transgene into a plant to generate a GM crop is neither inherently risky and nor does it present novel or greater sources of risk than conventional breeding. The use of "omics" in the normal testing for substantial equivalence is not yet part of a standard approach.[24]

GM crops are more rigorously tested for safety than any conventionally bred crop (which are not tested), even though the genetic changes that are made in the production of GM crops are precisely assessed and minimal, and none have yet failed to pass this intense scrutiny, including golden rice.

On the Horizon

The focus of the discussion so far has been on the first generation of GM crops that are primarily targeted to two agronomic traits. At the present time the only other agricultural crop grown commercially is the GM papaya,

the first GM tree crop, with resistance to the devastating papaya ringspot virus that threatened to wipeout the papaya industry in Hawaii.[62] This was the pioneering public institution driven (Cornell University, USDA-ARS) development of a GM crop, with cooperation from private industry, to combat a national crisis. The safety of GM papaya can be attested to by the fact that they have been approved for direct consumption in Japan, a difficult consumer market to penetrate with a GM product. However, with recent advances and the prior establishment of "transgenic pipelines" we are beginning to see other important traits being addressed using GM technologies. These next generation GM crops involve more than just the major crops such as corn, soybeans, and cotton, and have utilized genes from sources other than microbes, including genes that are derived from plant sources that can enable new trait development in our commercial crops. The farthest advanced is the new drought-tolerance technology that uses a bacterial gene (a protein that stabilizes RNA structure) that is in its first year of commercialization in the U.S., and under a public-private partnership in development for deployment in Africa. Those that are still in the pipelines for commercialization address such traits as: pest and disease resistance, photosynthetic efficiency, salinity, nutrient efficiency (nitrogen and phosphorus uptake), nitrogen fixation, modifications for biofuel production, and biofortification. The latter trait, biofortification, is where golden rice is leading the way and other nutrient deficiencies that significantly impact human health, such as vitamin A, iron, and zinc deficiencies, are all in the GM pipeline (see reference 45 for a comprehensive look at new technologies).

Each trait will undergo the rigorous testing that is demanded of commercial or public entities, so that any environmental or health safety issues are addressed and accounted for before release.

The Future of GM Technologies

The future is very promising for GM technologies to enhance our efforts to meet the future global needs for food, feed and fiber in a sustainable and responsible way. Conventional breeding methods, especially with the advent of genome level technologies, that are designed to both generate and exploit genetic variation in order to isolate effective alleles (variants) of genes that generate yield increases, disease resistance, pest resistance etc., also clearly play a role in this effort. Organic farming practices also have a place at the global table[63] where such practices make sense. Agriculture is a diverse endeavor ,and if we are to be successful we need to embrace that diversity.

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Disclosure

None reported. **MM**



PAIN MANAGEMENT

Pain Management in the Geriatric Population

by Robert Borsheski, DO & Quinn L. Johnson, MD

Although pain becomes increasingly prevalent with age, it is not a normal part of the aging process. Pain introduces a serious compromise to the quality of life of geriatric patients and limits independence or ends it altogether.





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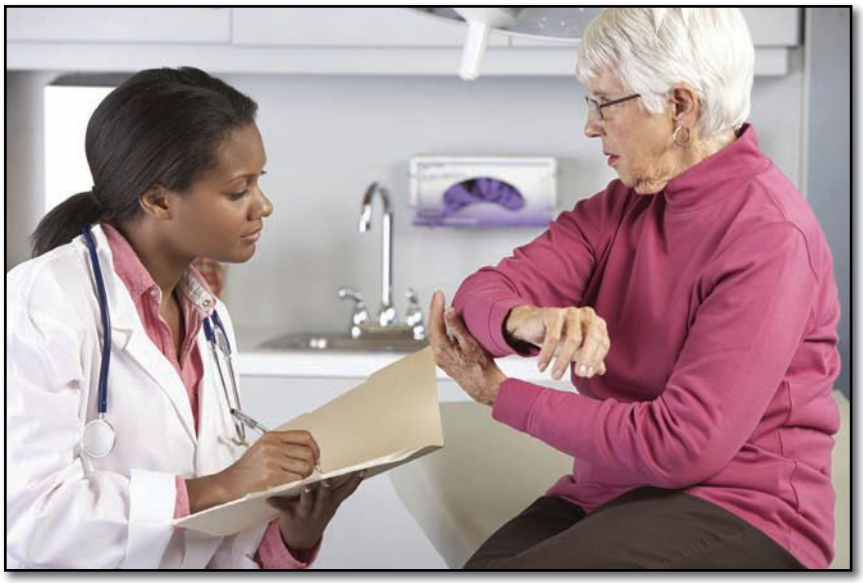
Abstract

Pain is a highly prevalent and clinically important problem in the elderly. Unfortunately, due to difficulties in assessing pain in geriatric patients, the complexities of multiple comorbidities, and the high prevalence of polypharmacy, many practitioners are reluctant to treat pain aggressively in this unique patient population. Safe and effective treatment therefore, requires a working knowledge of the physiologic changes associated with aging, the challenges of accurately assessing pain, the unique effects of common therapeutic agents upon the elderly as well as the importance of adjunctive therapies. The following review is intended to provide the practitioner with practical knowledge for safer and more effective treatment of pain.

Introduction

Appropriate management of chronic and acute pain in the geriatric population creates several unique challenges, as it is an increasingly common and often undertreated condition. In patients over 60-years old, the prevalence of pain was more than two times that reported for patients under 60-years old.[1] Other studies have indicated that 60% of independent and 80% of long-term care geriatric patients report substantial daily pain[2] clearly making it one of the most common symptoms reported by elderly patients.[3] Inadequate treatment of pain is associated with adverse outcomes including depression, anxiety, sleep disturbances and mood changes.[4] Appropriate recognition and treatment of pain becomes important, because in developed countries, the fastest growing portions of the population are individuals who are greater than 75 years of age.[5] This group is increasingly active with expectations of having a functional lifestyle with increased quality of life.[3] Appropriate pain management is essential in achieving these expectations.

Pain is often undertreated in the geriatric population for a number of reasons. First, many practitioners and patients hold the misconception that pain is an expected and natural consequence of aging.[1] Second, many elderly patients have physical impairments, such as visual or hearing loss, or cognitive impairment which include confusion, memory loss, or dementia that interfere with clear communication.[3] Third, concerns of either the practitioner or patient regarding the side effects of opioids, including respiratory depression, addiction[6] and falls, often create a barrier to indicated therapies. Fourth, because of the multitude of medications typically used by the elderly in treating a variety of other medical conditions, there is concern about drug-drug interactions and



Some non-pharmacological treatment options include physical therapy, osteopathic manipulation, massage therapy, TENS units, acupuncture, biofeedback, cognitive behavioral therapy and psychotherapy.

polypharmacy.[5] Finally, the patient often underreports pain because of the fear that it may represent impending death, loss of autonomy or require further treatment or testing.[1] Fortunately, health care providers can better understand the unique aspects of pain control in the geriatric population and greatly improve quality of life.

Geriatric Physiology and Pharmacology

The appropriate pain management regimen starts with a clear understanding of the physiological changes associated with aging and their effect on pharmacology. Aging affects the absorption, distribution, metabolism and clearance of medications.[4] Advanced age is associated with increased body fat and a reduction in total body water.[3] These changes increase the volume of distribution for a lipophilic and decrease it for a hydrophilic medication, thus altering the medication's onset and effective dose. Protein binding is also frequently altered in the geriatric population, resulting in increased bioavailability in some medications.[6]

Both hepatic and renal function are decreased in the elderly resulting in a decrease in the ability to metabolize and eliminate medications,[3] placing the patient at increased risk of toxic side effects of pain medications.[4] Hepatic function decreases by 1% per year after the age of 50,[3] hepatic mass and blood flow are reduced and the cytochrome P450 metabolic pathway is less effective with increasing age.[6] While the ability to metabolize drugs is generally decreased with age, the clinical result with regard to metabolic function remains highly individualized.[6] Renal function decreases with age starting at age 30 with a decrease in glomerular filtration rate of 10 ml/min per decade.[7] Due to the loss of muscle mass with age, the patient's creatinine will also decrease[3] resulting in a "normal" blood chemistry value this may mask the fact that the patient has some renal impairment. Unfortunately, many medications are eliminated by the kidneys and renal impairment can lead to a prolonged half-life.[3] Of particular concern is the potential accumulation of pharmacologically active metabolites that also rely on renal elimination.

Central and peripheral nervous system changes are also associated with increasing age. While the amount of perceived pain is the same for both older and younger patients, the overall opioid requirements to control that pain is decreased with age.[4] Neural transmission is altered along Aδ and C type pain carrying fibers[1] due to a decrease in density of both of myelinated and unmyelinated fibers.[3] Despite these changes, there is little evidence that the process of nociception is altered due to age.[5] By appreciating these differences, with careful monitoring and the slow adjustment to a single medication, geriatric patients can be effectively and safely treated with many pain medications despite a narrower therapeutic window.

Categorization and Assessment of Pain

Most of the chronic pain experienced in the elderly can be broadly categorized as cancer related pain and non-cancer pain. Cancer pain carries with it many unique aspects and is beyond the scope of this review. The most common etiologies for non-cancer pain in the elderly are arthritis (osteoarthritis and rheumatoid) and postherpetic neuralgia (PHN).[3] Assessment of pain is essential in order to effectively recognize and treat pain. Self-reporting of pain is considered to be the most accurate way to measure the presence of pain and its intensity.[1] In circumstances where communication is impaired because of sensory, motor or cognitive dysfunction, pain tools and scales have been shown to be an effective means of measuring pain[1] so long as they are explained clearly and used consistently.

Opioids

The use of opioids for treatment in the elderly has increased within the past few years due to adverse gastrointestinal and cardiovascular complications

associated with NSAIDS.[8] The World Health Organization has advocated the use of opioids as part of three-step ladder in treating pain starting with simple analgesics like acetaminophen, and if pain is uncontrolled adding weak opioids (for example codeine) and finally if needed strong opioids, such as morphine.[5] Opioids are recognized to greatly aid non-cancer chronic pain as well, but tend to be underutilized in the elderly population.[3] A commonly held misconception is that avoiding opiates or using very low doses will help prevent the development of delirium in the elderly. One study showed that undertreating pain actually resulted in increasing rates of delirium in geriatric patients.[9] Opioids can and should be used for geriatric patients but often require initially reduced doses (usually 50% less) when compared to younger patients.[5] Multiple studies have demonstrated that opiate requirements decline with age,[6] and that slow and incremental titration of the opioid is typically required to find the optimal level of drug administration. Clearly defined end goals need to be established prior to initiating treatment.[4]

Opioids act by binding presynaptic opioid receptors, which prevents release of the neurotransmitter substance P via membrane hyperpolarization, thereby preventing impulse propagation. Three subtypes of opioid receptors are found in varying locations: μ, κ and δ. Stimulation of differing receptors accounts for the varying clinical effects of opioids. Opioids useful in the treatment of pain are almost exclusively receptor agonists. Stimulation of the μ receptor produces analgesia, euphoria, miosis, bradycardia, hypothermia, respiratory depression, physical dependence, constipation and urinary retention. The κ and δ receptors also cause analgesia and a mixture of the unwanted effects listed above, plus dysphoria, sedation and diuresis. Opioids do not have a ceiling effect like acetaminophen and NSAIDS. Thus, if enough agonist is administered, analgesia will occur, though untoward effects may occur first and prevent further administration. The individual response to any given dose is highly variable and must be carefully tailored, particularly in the elderly and opioid naïve. Through receptor up-regulation, tolerance to opioids develops after repeated doses, meaning higher doses will be required to achieve the same efficacy. This occurs for both analgesic properties as well as most adverse effects save two, miosis and constipation, which will persist for the duration of opioid therapy.

With regard to the incidence of the adverse effects listed above, the most commonly reported among patients treated with opioids are constipation, nausea, dizziness and somnolence, all occurring in 21-30% of patients regardless of age.[12] Patients greater than 65 years of age are more likely to report constipation, fatigue and anorexia when compared to a younger cohort.[12] These findings highlight the importance of concomitant use of stool softeners and anti-nausea medications.

A recent meta-analysis suggests that analgesic efficacy is independent of age and provide significant pain reductions in older ($\geq$65) and younger ($<$65) patients alike. Significant treatment effects in favor of opioid therapy for patients aged 65 and older were also reported for physical functioning, sleep and quality of life.[12]

Though abuse and misuse of opioids are certainly a growing problem in the United States, practitioners must be careful not to extrapolate those findings uniformly to all populations. Patients older than 60 are far less likely to exhibit behaviors most consistent with opioid abuse or misuse such as seeking prescriptions from multiple providers, forging prescriptions and claims of lost or stolen prescriptions.[12]

Acetaminophen and NSAIDS

Acetaminophen represents front line therapy for treatment of pain in the geriatric population. Acetaminophen is thought to selectively inhibit prostaglandin in the central nervous system.[10] Although it is an effective antipyretic, it is devoid of anti-inflammatory effect. Unlike opioids, it does have a ceiling effect, meaning increasing doses will not yield increasing efficacy. Even in elderly patients, if the daily dose of acetaminophen is limited to 4 grams there is no evidence of liver failure or hepatic dysfunction.[4] It is important for patients to examine all over the counter medications since many common formulations contain acetaminophen.

Since inflammation plays an important role in the nociceptive pathway, non-steroidal anti-inflammatory drugs (NSAIDS) are an important part of the multimodal approach to analgesia. Pain itself can also reciprocally fuel the inflammatory state, so-called neurogenic inflammation. Neurogenic inflammation can produce the same physiologic effects as direct tissue injury. When tissues are disrupted, some of the phospholipid bilayer of the membrane is converted to arachadonic acid. The cyclooxygenase enzyme then converts arachadonic acid into prostaglandin, necessary for transduction of noxious stimuli to the nociceptor as well as neurosensitization of painful stimuli and subsequent hyperalgesia. The cyclooxygenase enzyme has two isoforms, COX-1 and COX-2, with very different physiologic effects. Aspirin and most NSAIDS nonselectively block both isoforms, producing analgesia as well as potential adverse effects including coagulopathy, gastric ulceration and nephropathy. The hope that selective COX-2 inhibitors would produce analgesia without unwanted effects has not been supported by clinical data, and several of these compounds have been removed from use due to increased

incidence of myocardial infarcts and cerebrovascular accidents.

Geriatric patients are at a higher risk of complications from NSAIDS including: renal failure, gastropathy, and cardiovascular disease.[4] Gastroprotective agents, such as proton pump inhibitors (PPI), may help reduce some of these risks for the elderly,[11] however the other risk factors remain unmodified. Renal function, which normally declines after 30 years of age, is potentially decreased further with the use of NSAIDS, increasing the risk of renal impairment in the elderly.[7] Prostaglandins needed to maintain glomerular filtration rate and renal blood flow are inhibited by NSAIDS leading to renal dysfunction.[7]

Other Pharmacologic Agents

Successful treatment of pain while limiting side effects often depends upon a multimodal approach. In addition to traditional therapies outlined above, there are several others that deserve mention. When pain syndromes become chronic, there is often an element of depression. Conversely, preexisting depression can greatly increase the perception of pain. Antidepressants, therefore, can be very useful in decreasing pain. Tricyclic antidepressants (TCA) and selective serotonin reuptake inhibitors (SSRI) are often prescribed. One large retrospective study in the elderly found amitriptyline and dosulepin (both TCA's) to have the lowest rates of serious side effects studied such as mortality, stroke, falls, seizure and hyponatremia.[13] However, another TCA, trazodone, was found to have some of the highest rates of complication, as were drugs from other classes such as venlafaxine and mirtazapine.[13] For all drugs studied, complications tended to occur in the first 28 days of therapy and the first 28 days following discontinuation.[13]

In the case of neuropathic pain, TCA's are useful as well as gabapentin and pregabalin. The choice between the two is usually made based on tolerability rather than efficacy.[14] If the pain is localized, topical lidocaine and capsaicin may also be of benefit. Serotonin-noradrenaline reuptake inhibitors such as duloxetine and venlafaxine are considered second line agents.[14]

Non-Pharmacological Treatment Options

Considering the prevalence and importance of pharmacological adverse effects in the elderly, practitioners should always consider the myriad other treatment modalities available. Although not a comprehensive list, some of the more commonly used are physical therapy, osteopathic manipulation, massage therapy, TENS units, acupuncture, biofeedback, cognitive behavioral therapy and psychotherapy. All have been used safely in the geriatric population and are effective ways to both decrease pain and improve quality of life. The success of these is dependent on both the etiology of pain as well as the individual patient's own capabilities.

Conclusion

Although pain becomes increasingly prevalent with age, it is not a normal part of the aging process. Pain can and does introduce a serious compromise to the quality of life of geriatric patients and in many cases, limits independence or ends it altogether. There are important barriers to overcome with regard to safe and effective treatment of pain such as proper assessment, multiple comorbid conditions, altered physiology and polypharmacy. Practitioners can help to achieve improved pain control through an understanding of these challenges, appropriate use of treatment modalities and using a multidisciplinary approach to treatment.

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Disclosure

None reported.

MM

Improving Care Access for New Patients in an Outpatient Gastroenterology Clinic: A Novel Approach

by Michelle L. Matteson-Kome, PhD, Kristi T. Lopez, MD, Ashley D. Sliger, BS, Melisa J. Mathews & Matthew L. Bechtold, MD

New patient access to subspecialty clinics can be improved with simple initiatives, staff education, and improved teamwork.



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Abstract

Background

We performed a quality initiative to improve our gastroenterology clinic access.

Methods

A prospective quality improvement initiative was implemented in 12/2012.

Results

From 10/2011 – 11/2012, 35.1% new patients were seen ≤ 10 days. After initiation of the quality improvement initiatives from 12/2012 – 1/2014, 75.2% new patients were seen ≤ 10 days ($p<0.01$).

Conclusion

New patient access to subspecialty clinics can be improved with simple initiatives, staff education, and improved teamwork.

Introduction

Access to subspecialty clinics is an important health care issue for patient care, referring physicians, downstream revenue, and practice efficiency. With long waiting lists, high no-show rates, and increased patient demand for gastroenterology (GI) services, access to GI specialty clinics is causing clinical and financial concern for all GI practices. Increased clinic wait times can cause increased nursing time to triage patients (decreased clinic efficiency), increased urgent care and emergency room visits, and increased negative health outcomes.[1] These increased wait times do not satisfy the Institute of Medicine's call for timely access and patient-centered care.[2]

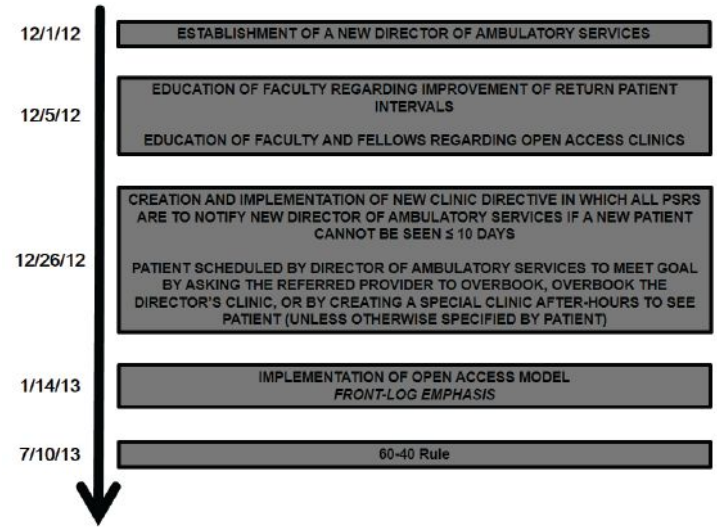
Advanced access scheduling is a system in which patients are able to see who they want, when they want, and is a more patient-centered appointment method.[1, 3] Advantages of advanced access scheduling are decreased no-show rates and lower health care costs, while improving continuity of care, patient satisfaction, and productivity of health care providers (operational efficiency).[1, 3-7]

Challenges for practices adopting advanced access are many. Several barriers to advanced access are as

follows: physician and clinic administrator's buy-in and level of participation, physician leaves/vacations, and patient supply and demand issues.[2] Also, continuity of care with a specific provider was difficult to maintain with the advanced access system.[8] Advanced access research is limited and studies lack detailed evaluations of data, such as utilizing appointment availability only without checking no-show rates or patient and staff satisfaction scores.[2]

Over the past two years, our institution, like many others, have struggled with supplying optimal access to new patients while trying to address high no-show rates. Therefore, a quality initiative was undertaken by the Division of Gastroenterology at the University of Missouri (MU-GI) to meet a goal of > 70% of new patients to be scheduled ≤ 10 days.

Figure 1
Timeline and details of quality initiative performed in the GI clinic.



Methods

Setting

The quality improvement study was performed at the University of Missouri in the Division of Gastroenterology. The project was approved by our Institutional Review Board (IRB). The GI division is an academic, tertiary-care facility which services the entire state of Missouri. The GI division has 10 attending physicians, 12 fellows, and one nurse practitioner with 8,215 patient visits in 2013.

Implementation

A prospective quality improvement study was conducted from December 2012 to January 2014. All new patients referred to our outpatient GI clinics were monitored and recorded. Data before December 2012 was retrospectively evaluated, dating back to October 2011. A quality initiative was implemented by a new Director of Ambulatory Services (beginning December 2012).

In December 2012, a supply-demand analysis was performed. On December 5, an educational session to faculty and fellows regarding prolonged access times and adoption of an open or advanced access clinic model with a front-log emphasis were performed. On December 26, a policy was created and implemented with all Patient Service Representatives (PSRs) to notify Director of Ambulatory Services if any new patient referred to MU GI cannot be scheduled ≤ 10 days. If a new patient cannot be seen ≤ 10 days, one of three options was initiated: referred providers to over-book their clinic, Director of Ambulatory Services to overbook his clinic, or the Director created a special clinic outside of normal clinic time to see the patient. In January 2013, an advanced access model was adopted and initiated at MU GI. In July of 2013, we implemented a 60/40 rule – 60% return and 40% new patients over each clinic schedule. Figure 1 describes the timeline and details of the quality initiatives.

Statistical Analysis

Descriptive statistics were utilized in evaluating the populations. Fisher's exact test was used to compare recent groups with baseline.

Results

From October 2011 to November 2012, a total of 2,478 new patients were referred to MU GI. Of those 2,478 new patients across multiple clinics, 871 were seen ≤ 10 days (35.1%) with the best month being 47.7% in August 2012. A supply versus demand analysis

Figure 2
Supply versus demand analysis performed in December 2012.

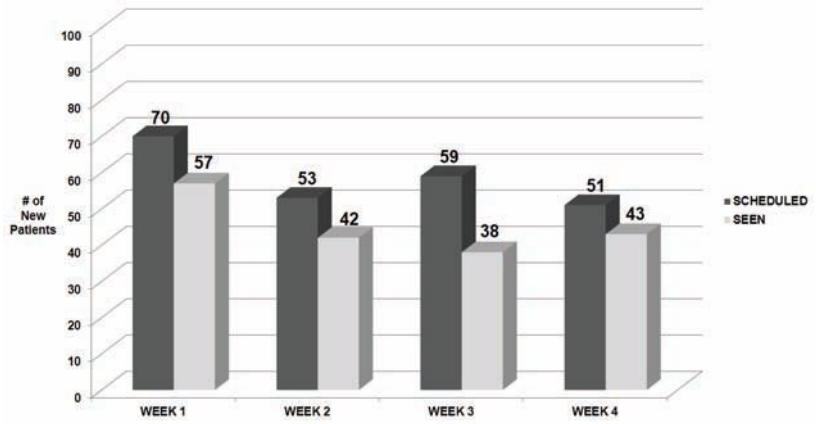
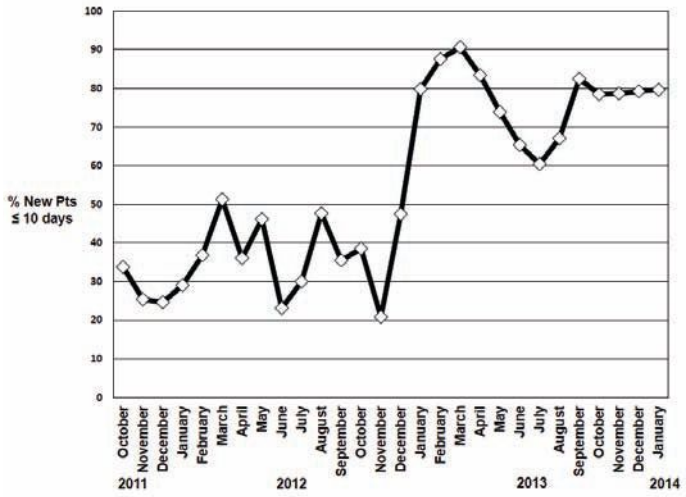


Figure 3
New patients seen ≤ 10 day in the GI clinic from October 2011 to January 2014.



was performed in December 2012 showing 233 new patients scheduled with 180 being seen (77%). (See Figure 2.) This analysis demonstrated that the clinics were able to perform at >70% of new patients seen at any time based upon current infrastructure (number of providers, number of clinics, etc). Since December 2012, after initiation of the multiple quality improvement initiatives from December 2012 to January 2014, 1,903 of 2,530 (75.2%) new patients were seen ≤ 10 days, which was statistically significant increase as compared to October 2011 to November 2012 ($p<0.01$). (See Figure 3.) The best month under the new system was 90.6% in March 2013. A statistically significant increase was noted in new patients seen ≤ 10 days per month from October 2011 to November 2012 as compared to December 2012 to January 2014 (62.2 ± 25.1 versus 135.9 ± 27.8 new patients, $p<0.01$). From June 2013 to August 2013, clinic access for new patients ≤ 10 days dropped below 70%, likely due to physicians vacations, sick-leave, and increased number of return patients being seen (due to increased new patients over the past 6 months). In response, the system was altered in every clinic in mid-July 2013 to be 60% return patients and 40% new patients. Overbooking of returns was allowed only in return patient slots. After this new quality improvement initiative was implemented from September 2013 to January 2014, 733 of 920 (79.7%) new patients were seen ≤ 10 days with no month falling below 78.4%.

Discussion

New patient access is an important issue for all clinical settings. Open access, also known as advanced access, scheduling has been shown to decrease wait times, urgent care/walk-in clinic utilization, cancellations/no-shows while creating and improving patient satisfaction, physician morale and market growth.[5] However, according to Solberg et al., the major issue with organizational change is the tension among physicians related to their autonomy.[9] Secondly, balancing the need for flexibility and need for clarity creates pressure for the entire office. Primary care and various specialties have attempted to rectify patient access issues by utilizing different scheduling procedures with varying success.

Previous attempts to improve patient access have been mixed and efforts not easily sustained. In 2004, Schall et al. implemented changes consisting of reducing the number of appointment types, extending the return appointment times, and transferring patients back to their primary-care provider allowed for increased access

to their clinic.[10] Parente et al. in 2005 found improved operational efficiency and PCP access, while decreasing wait times with their VA clinics.[3] Patient satisfaction did not increase. In 2009, Snow et al. blocked 10% of the appointments for five weeks to have 50% of the schedule reserved for new patients.[11] These appointments were then opened the week prior to the clinic date to have the necessary space for new patient demand. In 2010, Cameron et al. found within their academic primary-care center, open access scheduling improved patient access and no-show rates without affecting patient volumes.[12]

In our quality initiative, our access for new patients seen ≤ 10 days was significantly increased by a few minor system changes. With the adoption of the open or advanced access model with a front-log emphasis and enhanced team-work among physicians, nurses, and PSRs, we were able to improve from a dismal 35.1% to 79.7% over the span of one year. The quantity of new patients seen in ≤ 10 days per month doubled. A unique aspect to the open or advanced access model is the concept of a front-log emphasis. When initiating this system, a back-log of patients will be present. Instead of seeing all the back-log of new patients over the span of six to twelve months, we chose the front-log approach in which all new patients requiring appointments were fit into schedules by schedule openings due to cancellation or overbooking. We believe this approach led to a more rapid compliance with our goal than the back-log emphasis. Based upon all these changes, this quality improvement model may be replicated in other clinics, especially those struggling to see new patients in a timely manner.

A major strength of our study is we accomplished the organizational changes through teamwork. From the PSRs to physicians (fellows and attendings), all members contributed and adopted the new scheduling process. Secondly, access was improved with simple initiatives and staff education. Third, the key to our organizational change success was having a physician champion to facilitate the initiatives and maintain accountability. Through teamwork, we were able to increase new patient access consistently above 70%.

A few weaknesses in our QI study are noted. Our GI program is an academic tertiary-care center with only one private for-profit hospital with GI services in the same city. Therefore, this may not be applicable to all subspecialty clinics in every system. Secondly, patient or physician satisfaction data was not obtained. Thirdly, new patient appointments were further limited by provider/physician vacations and increased number of returns, which are noted by the increase in wait times during July and August. This is the reason the 60/40 rule was initiated. Finally, some GI subspecialty providers simply have more patient demand than they can manage. Our pancreatobiliary specialist and hepatologists initially had longer wait times than general gastroenterologists; however, over time, these sub-specialties met the 10-day goal.

Conclusion

New patient access to subspecialty clinics can be improved with simple initiatives, staff education, and improved teamwork. This successful model may be used to meet the current and future new patient demand in GI and other subspecialty clinics.

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Disclosure

None reported. **MM**

Psychological Aspects of Dialysis: A Case-Based Discussion

by Walter F. Ricci, MD, Harriet S. Langley, MD & Kemal Sagduyu, MD

The patient brings to the physician the opportunity to use his knowledge and skills and to recognize his humanity.



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Abstract

End-stage renal disease is a life-threatening condition that requires the assessment and contribution of a multi-faceted treatment plan. The management of patients with kidney failure is at times very challenging and requires sudden adaptation to treat this devastating illness. The role of the professionals and the dialysis unit itself will be of invaluable help in assisting the adaptation to the disease that has impacted the life of the individual in so many spheres.

Introduction

End-stage renal disease requires the assessment and contribution of a multi-faceted treatment plan which includes the thrice weekly dialysis treatments and medical requirements, as well as a complete and continuous assessment of all the factors that may impinge upon the patient and his human dimensions. These include the biological, psychological, social, and spiritual issues that affect every person, relative to his or her own particular life situation.

Problem lays in the difficulty of forming an approach by the physician in charge, using the flexibility acquired to constantly inquire and display the necessary curiosity about all the factors that may be weighing on the treatment. This enables him or her to understand the nature of the ongoing dynamics that both patient and all the involved caregivers must understand and empathetically and compassionately deal with, to best manage and survive the illness.

Case Report

Mr. Lee is a 63-year old white male widower, and is a successful attorney and president of his firm. He has developed end-stage renal disease secondary to a severe ischemic cardio-myopathy. He has been very cooperative and compliant with his medical regimen. He has four hour treatment sessions, three days weekly, he never misses one or signs off early.

Despite his compliance, he has needed episodic brief stay admissions to the hospital for decompensated congestive heart failure. This occurs despite the fact that he adheres to his dietary and fluid restrictions, and takes his medication appropriately.

Lately, although he has maintained remarkable stamina and energy, it has become apparent to his nephrologist that he is exhibiting an increased sense of futility and quiet despair, as well as certain undertones of hopelessness. When this observation is addressed by his physician, Mr. Lee tries to minimize the issues involved, but soon his initial denial dissolves in tears of frustration and anguish. Further exploration reveals that his conflicts have become focused upon his relationship with his eldest daughter.

Mr. Lee's eldest daughter is an attorney like her father, and works closely with him in the same firm. He has been her mentor, and has filled the void left by the sudden death of her mother five years earlier. Now Mr. Lee feels that he cannot fulfill or maintain this role because of his poor health, and even more importantly, he believes that he has become a source of worry to his beloved daughter.

Recently, during a visit with her father in the hospital, she displayed such intense distress and anxiety that Mr. Lee felt he had become a major handicap in his daughter's life. The nephrologist recognizes that Mr. Lee is very depressed and feels guilty about not only not helping his daughter, but being the major source of her pain. He is experiencing moments of great vulnerability that are apparent to the nephrologist to the point that Mr. Lee is strongly considering discontinuing his dialysis treatments. He believes that after the initial pain and loss his daughter will feel, her life will be restored to a more peaceful existence. The attending nephrologist consulted with a psychiatrist colleague, and this resulted in a three-way dialogue between the patient, his daughter, and the nephrologist.

This dialogue helped Mr. Lee's daughter recognize that the anxiety and anguish that her father's health was causing was increased because of the sense of responsibility and duty he carried on his shoulders about her. She recognized sadly that her worry about her father was real worry about herself, and her fear that like her mother before him, he would die and leave her to suffer a great loss. She grew to understand that it was her time to develop the ability to deal more selflessly with her father and assume more responsibility.

Mr. Lee and his daughter accepted being under the care of the psychiatrist with which his physician had collaborated. This helped them both to understand each other's pain and distress and cope with each other's sense of loss. This lead to a sustained improvement and sense of peace and wellbeing in Mr. Lee, and together with the talk therapy, and the addition of sertraline, Mr. Lee was able to regain his balance and subsequently a new and more direct, open manner of communication developed between him and his daughter.

This is a situation where clearly the physician's knowledge of this patient, coupled with the patient's trust in his physician, turned around what could have been a disastrous decision into an occasion that, instead, brought those involved into a deeper, closer, more loving and trusting relationship, one that stood ready to deal with life's future events. Mr. Lee gained the insight that real strength resides in dealing with issues rather than avoiding and surrendering to them.

The Patient

The variety of coping devices that individuals acquire will be of paramount importance in dictating the course of the illness and the compliance, adherence, and cooperation that will be required with a successful therapeutic alliance, according to Brennan.[1]

An important factor in these coping devices is the degree of resiliency. By resiliency, we mean the ability of each individual to "stumble but not fall." Resiliency is related to a concept of self-righting. Patients with disabilities have the ability to acquire or develop positive experiences in their lives, despite hardships they may have to endure. The human experience, according to Abraham Maslow,[2] is presented as having the resources of self-organizing, self-directing, and adaptation. The positive capacity allows the patients, with the help of the professional staff, after the initial disorganization brought about by the illness, to go from helplessness and depression to one of more resourcefulness and hopefulness.

The recognition of the limitations imposed by our forced dependency, by decreasing our autonomy, creates a lowering of our self esteem and self sufficiency which clinically can be translated to a state of chronic shame. Shame is a word which in itself has a shaming connotation. This appears as a response to our limitations of agency and autonomy. A caveat is that shaming called by its own name is shaming. We use shame as one of the affects described by Silvan Tomkins.[3] It is the main modulator of interpersonal distance and connection with each other. It is important when discussing with the patient to use other words unless the patient is insightful about the concept. For example, it is more calming to say, "this is a difficult moment" or "this places abnormal stress on a person."



End-stage renal disease requires the assessment and contribution of a multi-faceted treatment plan which includes the thrice weekly dialysis treatments and medical requirements, as well as a complete and continuous assessment of all the factors that may impinge upon the patient and his human dimensions.

Spectrum of Narcissism

The presence of narcissism as an investment in interest and concern on the self is a normal component of our personality. It is part of our survival. Although used at times pejoratively as a synonym for excessive preoccupation with the self, it was considered in psychoanalysis as part of the normal developmental stage in children.

The presence of this trait narcissism becomes dysfunctional when it impairs the social and interpersonal relationships and denies the validation and importance of others and their subjectivity with their own center of initiative. The narcissistic individual is immersed in a sense of uniqueness and grandiosity and has very little ability to recognize the existence of "other" minds. The "other" minds are mostly related as a means to increase the self esteem of the individual who needs continuous confirmation of his needs for perfection and power. The narcissistic individual has certain characteristics that are valuable to recognize.

Again, whether in the moment of imbalance as a chronic trait, all have in common three key elements:

1. Expectation of the perfect response by the "other;"
2. Expectation of complete control of the subjectivity of the "other;" and
3. Denial of the right of the other person to a different subjectivity.

When the narcissist does not receive the expected response from "the other," narcissistic disequilibrium with shame develops, whether acknowledged or not. This shame is usually defended vigorously by anger, indifference, obliviousness, contempt, or devaluation of the "other." The narcissistic individual needs validation of his special status and needs this with the intensity of an addict and the presence of a captive audience. This audience must reflect back the self perceived importance, entitlement, and superior status which are rightfully his own in his eyes. A chronic illness, because of the decrease in functionality and autonomy, creates the

conditions for those so predisposed, to an increased need for medical attention. This is assessed clinically by the brittleness, irritability, and lack of resiliency in some of these chronic renal patients which can escalate to psychological or psychiatric episodes. The need for dialysis in these patients could become a sort of stigma or it may justify in their eyes their increased right to have their needs satisfied automatically.

Because of these issues, the management of patients with kidney failure is at times very challenging and requires sudden adaptation to treat this devastating illness. The more precarious the coping devices of the patients and their families, the more severe will be the impact and the course of treatment. Here the role of the professionals and the dialysis unit itself will be of invaluable help in assisting the adaptation to the disease that has impacted the life of the individual in so many spheres. These spheres include: income, mobility, employment, sexual function, family relations, community standing, and multiple medical complications.

Interaction Between Patient and Dialysis Personnel

The interaction between the patient and the dialysis staff deserve our multi-faceted full attention; from the physical characteristics of the surroundings, to the personal traits of the care givers, and the overall attitude of helpful respect and encouragement. The personal fit between the patient and his doctors is a key element in the difficult moments of this disease. The doctor is needed as much for his technical knowledge as for his humility and compassionate empathy. The professionals will find and seek validation of their own work in the recognition that as healers in such moments of anguish, they will have the opportunity to display compassion and knowledge, which will mutually validate the humanity of this endeavor. The professional in charge of directing the care and treatment of the dialysis patient should try to create a therapeutic alliance based on the mutual respect ad recognition of the humanness of the persons involved. These factors will include:

1. The patient's perception of the problem,
2. The personality of the patient and his friends and loved ones;
3. The context and life events occurring within the patient at the time of the health encounter;
4. The nephrologist's wisdom and knowledge of the field;
5. The personality of the physician;
6. The context and life events, professional and personal, happening to the physician at the time of interaction; and
7. The humble and realistic promise by the doctor of what can be safely delivered.

The Physician-Patient Relationship

This relationship should be considered within the context of both as subjects. The physician recognizes the "other" as a subject (with a subjectivity of his own) and the patient recognizes the physician (although perhaps more slowly) as a subject as well. When one has been related to as a subject, there is a feeling of being "felt" by the "other," according to Siegel.[4] There may be unexpected gaps or ruptures in these feelings, but there would always be a genuine desire to repair the disruption and recover the mutuality of the validation. Many studies show that physicians who have been perceived as authoritarian or contemptuous in their encounters with their patients, can precipitate severe crisis in the treatment, in some cases, with patients stopping their dialysis and preferring to die as an act of recovering their autonomy and agency that have been lost, even at the price of losing their lives. According to Gladwell.[5] Perceiving each other as sentient subjects is a precondition for cooperation and development of the therapeutic alliance. The asymmetry in the relationship exists in the technical and professional realm. The physician possesses something that the patient needs, his skill, knowledge, and caring. The patient brings to the physician the opportunity to use his knowledge and skills and to recognize his humanity. It is not possible for this human condition to be slanted or diminished without objectification of the outcome with shame as its consequence.

Therapeutic Implications

Aaron Lazarre's[6] ideas in his Chapter, "Shame, Humiliation, and Stigma," guide us in the medical interview. Every member of the care team has to be aware of other aspects not directly involved in the treatment per se, and their tremendous influence on the treatment and its acceptance. Patients usually feel frightened, anonymous, and dehumanized with the fear that their symptoms could be taken as complaints and that they do not have the right to communicate their opinions to the professionals directing their medical care. For that reason, the physicians need to work with

the administrators of the clinics to prepare a nurturing milieu where the patients feel welcome and safe and respected as if they were long time members of a club.

Waiting For Care

It is important that the patient is seen and treated within a reasonable time of the expected appointments. Delays and interruptions give the patient the perception that their lives, their time, and their problems are of no importance to the medical staff. Humility and apology and correction of the inconvenience are the responsibility of the staff and should be acknowledged when there is a problem, whether or not it is due to unavoidable causes. This will reinforce to the patient that he or she is of the utmost importance.

Addressing the Patient

During the initial visits, the patient should be referred to by his complete title and name. If a degree of informality occurs or is considered, it should be asked respectfully by the professional if this satisfactory to the patient; otherwise there is the potential for disrespect toward the patient without due regard for his preferences and feelings. In other words, it should be a respectful negotiation and dialogue, as should any future exchange that involves the human vulnerability of the patient.

Supporting the Patient's Sense of Identity

Being ill has already taken the patient far away from being the person they were before the chronic illness. Becoming the patient in this type of chronic dialysis setting is depersonalizing. There are rules that forbid certain personal articles of clothing or jewelry and can have a devastating effect on the patient's sense of identity. Patients try to counteract this loss of social and personal identity by bringing personal items or photographs to emphasize their non-patient roles. Privacy needs also require the utmost respect and attention and this delicate situation can best be dealt with by directly engaging the patient in a discussion about his or her wishes and needs.

The Attention to Privacy

Here, beyond Health Insurance Portability and Accountability Act (HIPPA),[7] we have to recognize the shame that will always occur when something that one wished to be kept private is exposed. We cannot assume that something we see as a public medical event is not seen as such by the patient. Discussions concerning individual's illnesses and personal medical information, or discussions about private family issues or monetary issues including insurance, or remarks about spiritual matters that should be dealt with in utmost privacy and kept private. This is challenging, since most of the dialysis procedures are done in open spaces and as such there is very limited natural privacy. There should be a policy that such matters are discussed before or after the treatments in a private office setting. This, too, is a most delicate issue, since privacy requirements can obstruct the often soothing friendly and familiar discussions and exchanges that can so humanize a medical setting.

Maintaining the Therapeutic Alliance

Professionals should be very aware of the communication and connection that occurs with patients. Each patient has his own perception of the problems and the nature and goals of the treatment. It is important to detect changes in style between the patient and staff, empathetically and respectfully, and ask for clarification if there has been any conflictive dialogue. Such an inquiry returns a message to the patient that what they say and express matters. Should harmoniousness be ruptured, it is imperative that an immediate attempt be made to repair the damage. Only with genuine respect, empathy, sensitivity, and availability, and a desire and commitment on both sides to promptly address concerns, can the therapeutic alliance be strengthened and maintained.

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Disclosure

None reported. **MM**

2014 Missouri Medicine Index

A

Advertisers

American Association of Medical Review Officers....173
Centers for Medicaid and Medicare....190, 297
Doctors Company....88, 165, 396, 461
MSM Foundation.. CV2 Jan/Feb, Mar/Apr, May/June, July/Aug, Sept/Oct, Nov/Dec
MMPAC....361, S/CV3, 460
Moneta Group....319, 391, 491
MSMA Insurance Agency.....CV4 Jan/Feb, Mar/Apr, May/June, July/Aug, Sept/Oct, Nov/Dec
Navy Reserve....169
PNC Bank....111, 452
PPIA....189, 481
ProAssurance....184, 365, 471
PSIC....10, 192, 291, 371, 466
Socket....113, 296
St. John's/Mercy....28, 108, 187, 2933, 364, 484
University of Iowa....475
University of Missouri....30
University of Missouri-Kansas City School of Medicine....390
Wilshire Pennington.....CV3 Jan/Feb, Mar/Apr, May/June, July/Aug, Sept/Oct, Nov/Dec

Advocacy

Big Push for Tort Reform This Legislative Session by Jeff Howell....458
Physician of the Day....460
White Coat Rally Day 2015....460

Alliance

Alliance Presidential Biography by Kathy Weigand....247
Holiday Sharing Card....484
MSMA Alliance Officer Directory....S/39
Pills Are Not a Party/Smoking Is Not for Me....29

American Medical Association

Missouri Delegation Continues in Leadership Roles at AMA by Charles Van Way, III....312
AMA Tackles Maintenance of Certification & Credentialing by Ted Groshong....464

Annual Convention

Attendance....276
Biography MSMA President by Jeffrey G. Copeland....246
Council Minutes Summary....260
Credentials & Appointments....259
Delegate Handbook Reports....265
Elections....275
50-Year Physician Pin....254
Guest Speakers....21
Preliminary Program....20
Presidential Address by James Wolfe....248
Presidential Inaugural Address by Jeffrey G. Copeland....250
Resolutions/Actions....255
Service Awards....257
Sponsors and Exhibitors....259

As I See It

ObamaCare 2016: Happy Yet? by Bradley S. Allen....6
Bare Bones Medical Care by Max Heeb....138
Doctors Extending Their Education: Why an MBA? Is It a Degree of Success? by Adrian J. Delaney, III, Bridget McCandless & Jeffrey B. Kramer....170
Planning the Path to Retirement by Lenard L. Politte....369
How One Physician Became the "Accidental Activist" by Ed Kraemer....467
The Intentional Activist by John B. Holds....470
The Art of Medicine by George M. Bohigian....472

Authors

Carla Allan....199
Bradley S. Allen....6
Edwin L. Anderson....344
Stephanie Andrews....202
Timothy R. Apodaca....212
M. Javed Ashraf....73
James R. Batterson....202
Paramdeep S. Baweja....73
Zachary W. Bear....352
Matthew L. Bechtold....512
Anthony M. Belenchia....49
Robert B. Belshe....321
Denise Bickel....174
J. Andrew Billings....120
Benjamin Black....207
Christa B. Blecher....439
George M. Bohigian....472
Robert Borsheski....508
Elisabeth Brander....424
Nancy Evans Bush....486
Roger K. Cady....292
Cynthia R. Call....195
Lisa Campbell....199
Arthur L. Caplan....474
Christopher R. Carpenter....399
Jean Carstensen....222
Brian S. Carter....384
Melissa I. Carter....59
Ravikumar Chockalingam....148
Sophia M. Chung....294
Jordan Cicoria....304
Tony Cicoria....304
Jeffrey G. Copeland....246, 250, 309, 366, 462
Joseph A. Craft, III....362
Kevin W. Craig....298
John S. Daniels....80
Amanda D. Deacy....217
Adrian J. Delaney, III....170
Jim Denning....162
J. Kent Dexter....292
Emily Doucette....139
Sue Duval....89
Joel C. Eissenberg....114, 428
Robert J. Engeszer....404
Susan A. Fowler....416
Kenneth E. Freedland....148
Seth Freeman....139
Brandi R. French....289
Sharon E. Frey....332
Kevin L. Fritsche....41
Sara Gable....44
Arthur Gale....8, 109, 476
Ross F. Garberich....89
Jeremy R. Garrett....384
Sarah L. George....337, 343
Jonathan A. Green....143
Bruce Greyson....486
Vamsi P. Guntur....238
Karen E. Gutzman....408
John C. Hagan, III....4, 99, 280, 283, 360, 456
Leslie W. Hall....166
Angela C. Hardi....416
Christopher Hardin....39
Kevin M. Harris....89
Jean Renee Hausheer....180

2014 Missouri Medicine Index

by Max Heeb 138
Pamela S. Hinton 59
Daniel F. Hoft 320, 326
John B. Holds 470
Kristi L. Holmes.. 408
Pamela J. Honeycutt 174
Jeff Howell 458
Jason Husgen 478
Thomas G. Johans 32
Rebecca J. Johnson 217
Quinn L. Johnson 508
Betsy Kelly 413
Diane Kennedy 212
Michele G. Kilo 191
Christy Kleinsorge 202
Jennifer F. Knudtson 434
Ed Kraemer 467
Jeffrey B. Kramer 170
Stacia Merkel Kraus 89
Harriet S. Langley 516
John D. Lantos 384
Carl J. Lavie 95
Heather J. Leidy 54
J.B. LePichon 202
John R. Lesser 89
Erik Lindbloom 139
Jennifer S. Linebarger, ... 381, 384
Victoria C. Little 195
Stephen Logsdon 398
Jeffrey Long 372
Kristi T. Lopez 51
Patrick J. Lustman 148
Keith Mann 316
Catherine Madden 207
Michele H. Maddux 217
Amgad G. Masoud 444
Melisa J. Mathews 51
Michelle L. Matteson-Kome 51
Bridget McCandless 170
Peter A. McCullough 95
Peter J. McDonnell 164
Carl V. Migliazzo 283
Anthony A Mikulec 352
Melissa K. Miller 212
Susan M. Miller 386
Mark Mueller 139
Patrick Murphy 222
Margo Myers 65
Cy B. Nadler 195
Sarah S. Nyp 195
Frederick T. O'Donnell 231
Stephen N. Oesterle 89
James H. O'Keefe 89
Debra Parker Oliver 298
Melvin J. Oliver 492
Pamela M. Otto 439
Vassilis N. Panagopoulos 148
Young-Min Park 65
Gretchen Peichel 89
A. Rolando Peralta 352
Catherine A. Peterson 49
Blaine B. Pitts 384
Lenard L. Politte 369
Donald A. Potts. 80
Victoria J. Vieira-Potter 65
Sandy Price 202
Ryan K. Rader 143, 349, 447
Dean Radin 24
John M. Ray 148
Walter F. Ricci 516
Martha Riley 424
Charles C. Roberts 193
William O. Roberts 89
Randal D. Robinson 434
Howard Rosen 104
Kathleen R. Rosen 231
Mitchell S. Rosenthal 102
Kemal Sagduyu 516
Pratik B. Sandesara 73
Cathy C. Sarli 399, 404
effrey F. Scherrer 148
Karen D. Schilli 143, 349, 447
Paul A. Schoening 397
Jennifer Verrill Schurman 217
Jonathan G. Schwartz 89
Robert S. Schwartz 89
Katherine Semenkovich 148
Marc K. Siegel 112
Elizabeth Simpson 222
Niranjan N. Singh 289
Philip Skroska 419
Ashley D. Sliger 51
William S. Sly 114
Sherea M. Stricklin 349, 447
Shayla Sullivant 202
Dragan M. Svrakic 148
Nasreen Talib 316
Paul E. Tatum, III 298
Harvey Tettlebaum 120
Aneesh K. Tosh 44
Kelly Trowbridge 212
Sarah L. Tsai 212
Pim van Lommel 126
Benjamin J. Van Treeck 444
Charles Van Way, III 160, 312
Marcy L. Vana. 408
Karla T. Washington 298
Matt Wassom 217
David Westbrook 193
Kathy Weigand 247
Kirsten Weltmer 316
Kimela West 10
Kelly K. Wickstrom 89
Amy Williams 139
Debra Willsie 207
James B. Wolfe 22, 132, 248
Lauren H. Yaeger 413

D

Dean's Report

Providing Patient-Centered Care, Education & Research to Benefit Missouri
by Leslie W. Hall 166

Directories

Alphabetical Roster of Members S/42
Membership Roster of Primary Specialties S/100
CME Accredited Organizations S/38
Component Society Codes S/40
Component Society Directory S/29
District and Component Society Map S/CV2
Medical Specialty Organizations S/33

E

Editorials

The Blue Plate Special by John C. Hagan, III....4
Coronary Artery Plaque and Cardiotoxicity as a Result of Extreme Endurance Exercise by Peter A. McCullough, MPH & Carl J. Lavie....95
Pheidippides' Final Words: "My Feet Are Killing Me!" by John C. Hagan, III....99
Secondary Gain, Gone with the Wind & the SGR by Charles Van Way, III....160
A Eureka Moment? Beta Blocker Eye Drops For Acute Migraines by John C. Hagan, III....280
Beta Blocker Eye Drops For Treatment of Acute Migraine by Carl V. Migliazzo & John C. Hagan, III....283
Beta Blocking Eye Drops in Acute Migraine: A Novel Use of an Old Drug by Brandi R. French & Niranjan N. Singh....289
Ophthalmic Beta Blockers: Treatment for Acute Migraine? by J. Kent Dexter & Roger K. Cady....292
Can Topical Beta Blockers be Successful for Acute Migraine Management? by Sophia M. Chung....294
Short & Sweet: Make Your Mark on November 2014 Election by John C. Hagan, III....360
In the Age of ACOs, the Systems of Measuring Health-Care Quality Remain in Their Infancy by Joseph A. Craft, III....362
Physician Advocacy Begins With YOU! by John C. Hagan, III....456

F

Financial Statements

Missouri Physicians Health Foundation....156
Missouri State Medical Association....155
Missouri State Medical Foundation....155

M

Medical-Legal

Patient Medical Information At Risk From Stolen Computers by Kimela West....10
Five HIPAA Violations by DocbookMD....13
Product Liability Suits Involving Drug or Device Manufacturers and Physicians: The Learned Intermediary Doctrine and the Physician's Duty to Warn by Jason Husgen....478

Missouri Medicine Departments

1 Picture = 1,000 Words....58, 161, 318
Book Review....29, 131, 380
Correspondence....14, 134, 392, 482
Errata....19, 135
Index for Missouri Medicine....524
In Memoriam....484
In the News....182, 136, 394, 482
Style Sheet....S/9
Statement of Ownership, Management and Circulation....368
Physician Candidates for 2014 Election....357

Missouri Physicians Health Program

Missouri Physicians Health Program Contributor Report....31

Missouri State Medical Association

Bylaws....S/11
Committees and Commissions....S/25
Constitution....S/10
Contact Guide....3, 87, 158, 279, S/3, 359, 455
Editorial Board....2, 86, 157, 278, S/2, 358, 454
Guide to Membership Benefits....S/4
Membership Grid....8
Officers & Leadership....S/26
Policy Manual....S/19

P

Perspective

The Electronic Medical Records Fiasco by Arthur Gale....8
Acupuncture: A Western Physician's Experience by Thomas G. Johans....32
Let's Work To Keep Missouri From Going To Pot! Let's Not Kid Ourselves About Marijuana by Mitchell S. Rosenthal....102
Is Obesity A Disease or A Behavior Abnormality? Did the AMA Get It Right? by Howard Rosen....104
The Medicare Advantage Debacle by Arthur Gale....109
The Death of the Bedside Manner: ObamaCare is Speeding the Decline in the Quality of Medical Practice by Marc K. Siegel....112
The Nobel Path of Cellular Proteins by Joel C. Eissenberg & William S. Sly....114
Kansas Legislature Passes Health Care Cost Transparency Bill: Real Time Explanation of Benefits by Jim Denning....162
The Skinny on Obesity by Peter J. McDonnell....164
Retail-Based Clinics & the Patient-Centered Medical Home by Kirsten Weltmer, Nasreen Talib & Keith Mann....316
The Role of Eugenics in Research Misconduct by Susan M. Miller....386
Not Enough Primary-Care Doctors? Try Missouri's Prescription by Arthur L. Caplan....474
Another Failed Government Program: Pay For Performance by Arthur Gale....476

President's Forum

What Do Physicians & Pilots Have in Common? by James B. Wolfe....22
Medicine & "Connections"by James B. Wolfe....132
Electronic Burden: Where is the Technology Helping Us Care for Our Patients? by Jeffrey G. Copeland....309
Philology, or What's the Good Word? by Jeffrey G. Copeland....366
MSMA Advocates Both For and To Our Physicians by Jeffrey G. Copeland....462

S

Scientific Articles by Issue Release Date & Theme

Nutrition and Exercise Physiology
by University of Missouri School of Medicine
College of Human Environmental Sciences
College of Agriculture Food and Natural Resources

A 'Fitting' Message: Exercise More, Eat Lessby Christopher Hardin....39
Linoleic Acid, Vegetable Oils & Inflammationby Kevin L. Fritsche....41
Children, Youth, and Parents: Screening for Obesity Risk With the Spectrum of Physical Activityby Sara Gable & Aneesh K. Tosh....44
Vitamin D Deficiency & Childhood Obesity: A Tale of Two Epidemics by Catherine A. Peterson & Anthony M. Belenchia....49
Increased Dietary Protein as a Dietary Strategy to Prevent and/or Treat Obesity by Heather J. Leidy....54
Physical Activity and Bone Health by Melissa I. Carter & Pamela S. Hinton....59
Adipose Tissue Inflammation and Metabolic Dysfunction: Role of Exercise by Young-Min Park, Margo Myers & Victoria J. Vieira-Potter....65

Pediatric Developmental & Behavioral Health
Children's Mercy Hospital
Division of Developmental & Behavioral Sciences

Developmental & Behavioral Health Care Integration Between Pediatricians & Pediatric Behavioral Health Specialists by Michele G. Kilo....191
On Collaboration by Charles C. Roberts & David Westbrook....193
Driven By Evidence: Diagnosis and Treatment for Children with Autism Spectrum Disorders by Sarah S. Nyp, Cy B. Nadler, Cynthia R. Call Victoria C. Little....195
The ADHD Clinic: A Collaborative Model of Care by Lisa Campbell & Carla Allan....199
A Refresher on Tourette Syndrome by James R. Batterson, Shayla Sullivant, J.B. Le Pichon, Christy Kleinsorge, Sandy Price & Stephanie Andrews....202

2014 Missouri Medicine Index

Treating Our Youngest Patients: Psychotropic Medications in Early Childhood by Catherine Madden, Benjamin Black & Debra Willsie 207
Implementing Motivational Interviewing in a Pediatric Hospital by Timothy R. Apodaca, Sarah L. Tsai, Melissa K. Miller, Michele H. Maddux, Diane Kennedy & Kelly Trowbridge.. 212
No Guts, No Glory: Models of Integrated Care within a GI Subspecialty Practice by Amanda D. Deacy, Michele H. Maddux, Matt Wassom, Rebecca J. Johnson & Jennifer Verrill Schurman 217
Neonatal Circumcision: New Recommendations & Implications for Practice by Elizabeth Simpson, Jean Carstensen & Patrick Murphy....222

Saint Louis University Center for Vaccine Development

Research Continues on New Vaccines and Biologics at the Saint Louis University Center for Vaccine Development by Daniel F. Hoft 320
Progress Toward the Development of Universal Influenza Vaccines by Daniel F. Hoft & Robert B. Belshe....321
Development of Vaccines to Control the Worldwide Tuberculosis Pandemic by Daniel F. Hoft 326
New Smallpox Vaccines for an Ancient Scourge by Sharon E. Frey....332
Prospects for a Dengue Vaccine: Progress and Pitfalls by Sarah L. George 337
Chikungunya Update by Sarah L. George 343
Recommended Solutions to the Barriers to Immunization in Children and Adults by Edwin L. Anderson....344

Bernard Becker Medical Library
Washington University School of Medicine

The Changing Nature of Academic Health Sciences Libraries by Paul A. Schoening....397
In Memoriam – Bernard Becker (1920-2013) by Stephen Logsdon 398
Measuring Academic Productivity and Changing Definitions of Scientific Impact by Cathy C. Sarli & Christopher R. Carpenter....399
Libraries and Open Access Support: New Roles in the Digital Publishing Era by Robert J. Engeszer & Cathy C. Sarli 404
Libraries and Genomics: Providing Support to Health Care Providers and Consumers by Karen E. Gutzman Marcy L. Vana & Kristi L. Holmes... 408
Evidence-Based Medicine: Medical Librarians Providing Evidence at the Point of Care by Lauren H. Yaeger & Betsy Kelly....413
Evidence-Based Medicine and Systematic Review Services at Becker Medical Library by Angela C. Hardi & Susan A. Fowler....416
The William Beaumont Papers: A Life in Letters by Philip Skroska....419
More than Just Medicine: Hidden Depths in the Becker Library's Rare Book Collections by Elisabeth Brander & Martha Riley....424

Mini-Series

The Bite of the Loxosceles Reclusa

Viscerocutaneous Loxoscelism in an Adult with Acute Generalized Exanthematous Pustulosis by Mark Mueller, Emily Doucette, Seth Freeman, Amy Williams & Erik Lindbloom 139
Obtundation and Myocardial Infarction in a Case of Systemic Loxoscelism by Karen D. Schilli, Ryan K. Rader, Katie S. Payne, Jonathan A. Green & William V. Stoecker.... 143

Clues by Hands

Clues from Hands / Part I
Personal Details about Patients Revealed by Hand Examination by Sherea M. Stricklin, Katie S. Payne, Ryan K. Rader, Karen D. Schilli & William V. Stoecker 349
Clues from Hands / Part 2
Personal Details about Patients Revealed by Hand Examination by Karen Danielle Schilli, Sherea Monica Stricklin, Katie Sue Payne, Ryan Kent Rader & William V. Stoecker 447

Hearts Breaking Over Marathon Running

Increased Coronary Artery Plaque Volume Among Male Marathon Runners by Robert S. Schwartz, Stacia Merkel Kraus, Jonathan G. Schwartz, Kelly K. Wickstrom, Gretchen Peichel, Ross F. Garberich, John R. Lesser, Stephen N. Oesterle, Thomas Knickelbine, Kevin M. Harris, Sue Duval, William O. Roberts & James H. O'Keefe 89

Death & Near Death Experiences

Dutch Prospective Research on Near-Death Experiences During Cardiac Arrest by Pim van Lommel 126
Out of One's Mind or Beyond the Brain? The Challenge of Interpreting Near-Death Experiences by Dean Radin....24
The Culture Change of Life & Death: Will Health Reform, Demographics & the Economy Bring It About? by Harvey Tettlebaum & J. Andrew Billings 120
Palliative Care Begins At Home by Pamela J. Honeycutt & Denise Bickel....174
My Unimaginable Journey: A Physician's Near-Death Experience by Jean Renee Hausheer 180
Evolution of the Care of the Dying Patient by Paul E. Tatum, III, Kevin W. Craig, Karla T. Washington & Debra Parker Oliver....298
My Near-Death Experience: A Telephone Call From God by Tony Cicoria & Jordan Cicoria....304
Near-Death Experiences: Evidence for Their Reality by Jeffrey Long....372
When the Beginning and the End Are Close by Jennifer S. Linebarger....381
Our Answer to Belgium: Palliative Care for Children is Preferable to Euthanasia by Brian S. Carter, Blaine B. Pitts, Jennifer S. Linebarger, Jeremy R. Garrett & John D. Lantos 384
Distressing Near-Death Experiences: The Basics by Nancy Evans Bush & Bruce Greyson 486

Pain Management

Pediatric Pain Management: A Review by Frederick T. O'Donnell & Kathleen R. Rosen....231
Pain Management in the Geriatric Population by Robert Borsheski & Quinn L. Johnson....508

Preventive Cardiology

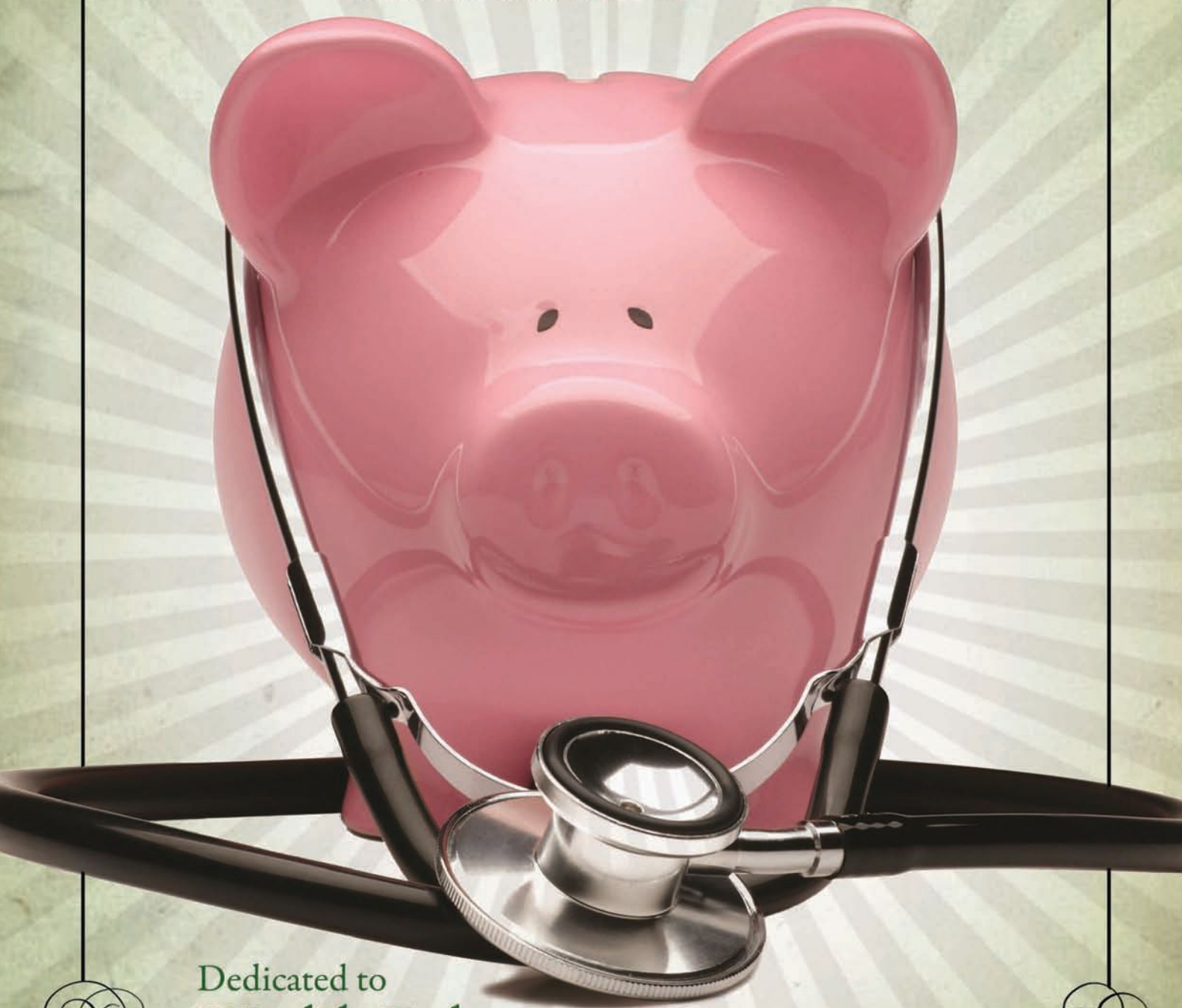
Asymptomatic Coronary Artery Disease in Type II Diabetes by Paramdeep S. Baweja, Pratik B. Sandesara & M. Javed Ashraf 73
Nicotine Addiction Treatment: A Review by Donald A. Potts & John S. Daniels...80

Additional Scientific

Prescription Opioid Analgesics Increase Risk of Major Depression: New Evidence, Plausible Neurobiological Mechanisms and Management to Achieve Depression Prophylaxis by Katherine Semenkovich, BA, Ravikumar Chockalingam, Jeffrey F. Scherrer, Vassilis N. Panagopoulos, Patrick J. Lustman, John M. Ray, MA, Kenneth E. Freedland & Dragan M. Svrakic....148
Safety and Efficacy of Electronic Cigarettes: A Review by A. Rolando Peralta & Vamsi P. Guntur 238
Intratympanic Steroid Therapy for Treatment of Idiopathic Sudden Sensorineural Hearing Loss by Zachary W. Bear & Anthony A Mikulec....352
Epigenetics: Modifying the Genetic Blueprint by Joel C. Eissenberg....428
Fertility Preservation in Patients Receiving Chemotherapy or Radiotherapy by Randal D. Robinson & Jennifer F. Knudtson 434
Controversies Surrounding Screening Mammography by Pamela M. Otto & Christa B. Blecher 439
Hypothyroid Cardiomyopathy Complicated by a Left Ventricular Laminar Thrombus by Benjamin J. Van Treeck & Amgad G. Masoud 444
Why We Need GMO Crops in Agriculture by Melvin J. Oliver....492
Improving Care Access for New Patients in an Outpatient Gastroenterology Clinic: A Novel Approach by Michelle L. Matteson-Kome, Kristi T. Lopez, Ashley D. Sliger, Melisa J. Mathews & Matthew L. Bechtold 512
Psychological Aspects of Dialysis: A Case-Based Discussion by Walter F. Ricci, Harriet S. Langley & Kemal Sagduyu 516

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